

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3, 15827Blankenfelde-Mahlow, Germany Tel: +49 33 70 83 55 030 Email: <u>amug@atlas-medical.com</u>

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK Tel: +44 1223 858 910 Fax: +44 1223 858 524 Email: <u>info@atlas-site.co.uk</u>

Middle East Site: Sahab Free Zone Area P. O. Box 204, Amman 11512, Jordan. Tel.: +962 6 4026468 Fax: +962 6 4022588 Email: info@atlas-medical.com

Agent: San Medico Republic of Moldova, city Chisina +37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

- 1. This appointment is valid for 3 year from the above mentioned date.
- 2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer General Manager Haya Amawi

Atlas Medical Quality Diagnostic Products

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Germany. Tel: +49 33 70 83 55 030 Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK. Tel: +44 1223 858 910 Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan



Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3 Blankenfelde-Mahlow, Germany. Tel: +49 - 33708 – 3550 30 Email: <u>info@atlas-medical.com</u>

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan. Tel.: +962 6 4026468 Fax: +962 6 4022588 Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED: Certificate N⁰.: 36655 rev 1 Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016, EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And Intended for In-Vitro Professional use only.

Manufacturer Atlas Medical Ludwig-Erhard-Ring 3 Blankenfelde-Mahlow, Germany.

	Medical
Atlas	Nostic Products

Atlas	Issue date	Date of review	Quality Management approval	MRXDO10F.10
Medical	March.2021	09.03.2021	1	08.02.2011



CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).8.00.00.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex(A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control)Without card, stirring sticks.

8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical Quality Diagnostic Products



GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow GERMANY

pour les activités for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales complies with the requirements of the international standards

ISO 13485: 2016

Début de validité / Effective date October 9th, 2023 (included) Valable jusqu'au / Expiry date : October 8th, 2026 (included) Etabli le / Issued on : October 9th, 2023



ő

GMED N° 36655–2 Ce certificat est délivré selon les règles de certification

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459 Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr





Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version :

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for selftesting, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow GERMANY

French version: **Siège social, responsable de la mise sur le marché** *English version: Headquarter, legal manufacturer*

Sahab Industrial Zone Area King Abdullah II Industrial City Amman 11512 JORDAN

French version: **Conception, fabrication et contrôle final** *English version: Design, manufacture and final control*



On behalf of the President Béatrice LYS Technical Director



STREPTOCOCCAL GROUPING SLIDE

TEST

IVD For *In-Vitro* diagnostic and professional use only

₽^{8℃} Store at 2° to 8° C

CE

INTENDED USE:

2'C

ATLAS Streptococcus Latex Kit is used for qualitative detection and identification of the Lancefield group of Streptococci. Reagents are provided for groups A, B, C, D, F and G.

INTRODUCTION

ATLAS Streptococcal test uses an enzyme extraction procedure to release Carbohydrate antigen from Streptococcal cell walls. The antigens are detected using specific antibodies to groups A, B, C, D, F and G Lancefield. These antibodies are coated on latex particles. When the antigen extract is mixed with the latex reagent, agglutination will occur. The agglutination appears as a visible clumping and can be seen macroscopically.

PRINCIPLE

Some well isolated colonies are mixed with chemical extraction reagents to liberate the group antigen. This antigen is spread on different circles of the testing glass slide.

Then latex sensitized with antibodies specific for each group, is added. If the correspondent antigen is present in the sample, the antigen-antibody reaction will cause a visible agglutination (clumping). If a sample shows negative reaction with latex of groups A, B, C, F, and G, select other colonies morphologically similar to the proceeding and threat them with the reagent for enzymatic extraction. Test the obtained antigen with latex for group D. A polyvalent extract of streptococci of the abovementioned groups is supplied as a control for the reliability of the latex reagents.

MATERIALS

MATERIALS PROVIDED

- Extracting Reagent 2: Acetic acid solution, ready to use.
- Extracting Reagent 3: Ammonium carbonate solution, ready to use. Contains sodium azide 0.9 g/L as preservative.
- Extracting Reagent E: lyophilized lisozyme in Tris buffer pH 8.2 + 0.2. Contains non-reactive stabilizer and sodium azide 0.9 g/L as preservative. Before use, dissolve with 2.0 mL of sterile distilled water.
- Latex A: sensitized with antibodies (from rabbit) to streptococci of group A. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- Latex B: sensitized with antibodies (from rabbit) to

streptococci of group B. Ready to use. Contains sodium azide 0.9 g/L as preservative.

- Latex C: sensitized with antibodies (from rabbit) to streptococci of group C. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- Latex D: sensitized with antibodies (from rabbit) to streptococci of group D. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- Latex F: sensitized with antibodies (from rabbit) to streptococci of group F. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- Latex G: sensitized with antibodies (from rabbit) to streptococci of group G. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- Positive Control: Lyophilized. Streptococci antigens of groups A, B, C, D, F and G in physiological saline. Contains non-reactive stabilizer and sodium azide 0.9 g/L as preservative. Before use, dissolve with 1.0 mL of sterile distilled water.
- Test slide.
- Stirring Sticks.
- Package Insert.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Water bath.
- Test tube.
- Pipettes.
- Sterile loop.

PACKAGING CONTENT

REF 8.00.13.0.0300 (5x1.5 mL Latex (A, B, C, G, F) ,1x3.0 mL Latex (D), 1x1.0 mL Positive Control, 1x 1.5 mL Extraction Reagent 1 , 1x1.5 mL Extraction Reagent 2 , 2x2.5 mL Extraction Reagent 3, 1x2 mL Extraction Reagent E, Glass Slide, plastic stirring sticks).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 8°C avoiding direct light.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

PRECAUTIONS

- 1. The reagents are intended *for in vitro diagnostic and professional* use only.
- 2. Do not pipette by mouth.
- 3. Always ensure an acceptable performance of the kit by performing the test on the Positive controls before using the kit.

- 4. Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
- 5. Test materials and samples should be discarded properly in a biohazard container.
- 6. Wash hands and the test table top with water and soap once the testing is done.
- 7. Test specimens may contain pathogenic organisms and must be handled with appropriate precautions.
- 8. When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions in these Instructions for Use, the reagents supplied are not considered to present a hazard to health.
- 9. Do not use the kit if the kit label is not available or damaged.
- 10. Don't use the kit if damaged or the vials are leaking and discard the contents immediately.
- 11. The test should be performed at room temperature in a well let area with very good visibility.
- 12. Do not use the reagent if it contains particles as this may indicate reagent deterioration or contamination.
- 13. The Latex Suspensions and Positive Control contain 0.9g/l sodium azide. Azides can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small; nevertheless when disposing of azide-containing materials they should be flushed away with large volumes of water.
- 14. In accordance with the principles of Good Laboratory Practice it is strongly recommended that extracts at any stage of testing should be treated as potentially infectious and handled with all necessary precautions.
- 15. Extraction Reagents 2 and 3 contain a weak acid and a mild irritant respectively. Avoid direct contact by wearing suitable protective equipment. If the material comes into contact with the skin, mucous membranes or eyes immediately wash the area by rinsing with plenty of water.

REAGENT PREPARITION

Latex reagents and extracting reagents 1, 2, and 3 and are ready to use. Bring the reagents to room temperature before use, shake the latex reagents gently to obtain a homogenous suspension of particles. After opening, the reagents are stable until the expiry date if kept as indicated in "STORAGE CONDITIONS". Extracting Reagent E and Positive control are lyophilized and must be re-suspended in sterile distilled water before use. If stored at 2-8 ° C and preserved from contamination, reagents are stable for 3 months.

SPECIMEN AND SAMPLE PREPARATION

For a correct identification it is important that the colonies (which must be well isolated on blood agar) are picked up fresh.

Before serological analysis, it is advisable to observe the hemolytic activity and set up a slide with Gram stain to ensure the purity of the strain to be tested.

PROCEDURES

Allow all reagents and samples to reach room temperature (18-30°C) before use.

- A. Technique with Chemical Extraction
- 1. Transfer **30 μL (one drop) of Extracting Reagent 1** into a labelled test tube.
- Pick up 5-6 colonies with a stirring stick, being careful not to pick up part of the culture medium. Add colonies into the test tube and mix to obtain a homogeneous suspension.
- 3. Transfer 30 µL (one drop) of Extracting Reagent 2.
- Let stand for at least 5 minutes at room temperature. Do not exceed 10 minutes. A prolonged extraction time decreases the sensitivity of the test.
- 5. Transfer **60 μL (two drops) of Extracting Reagent 3** and mix. Use within 15 minutes.
- 6. Re-suspend the latex reagent to be used (i.e. A, B, C, F, and/or G) by shaking the vial.
- 7. Holding the dropper vertically, add 1 free-falling drop of latex in one circle of the glass slide. Repeat this operation for each latex to be used.
- 8. Transfer 15 µL of antigenic extract in each circle.
- 9. Using a clean stirring stick, mix and spread the reaction mixture carefully. Discard the used stirring stick.
- Tilt and rotate the glass slide. After one minute, observe each circle for evidence of agglutination (clumping). Later agglutinations should be considered as nonspecific.
 NOTE: If all results are negative, proceed with the technique for identification of Group D Streptococci.

B. Direct Technique

(This procedure is able to identify about 70% of Group D strains).

- 1. Transfer **30 μL (a drop) of Extracting Reagent 3** in a circle of the slide.
- 2. Pick up 2-3 colonies with a clean stirring stick, being careful not to pick up part of the culture medium, and carefully mix them in the same circle of the slide.
- 3. Add a drop of Latex D.
- Tilt the slide for 1 minute. At the end observe each circle for the presence or absence of agglutination. Later agglutinations should be considered as nonspecific.
 NOTE: If negative results are obtained continues with enzymatic extraction technique.

C. Technique with Enzymatic Extraction

(This procedure is able to identify more than 95% of group D strains)

 Distribute, after reconstitution, 60 μL (two drops) of Extracting Reagent E into a labelled test tube.

- 2. Pick up 2-3 colonies with a clean stirring stick, being careful not to pick up part of the culture medium. Insert colonies into the test tube and mix to obtain a homogeneous suspension.
- 3. Incubate at 37° C for 10 minutes.
- Holding the dropper vertically, add 1 free-falling drop of Latex D in one circle of the glass slide.
- 5. Add **15 µL of antigenic extract** in one circle.
- 6. Using a clean stirring stick, mix and spread the reaction mixture carefully. Discard the used stirring stick.
- Tilt and rotate the glass slide. After one minute, observe each circle for evidence of agglutination (clumping). Later agglutinations should be considered as nonspecific.

Quality Control

Use the positive control and saline as if they were extracted from a sample. The absence of reactions (respectively positive or negative) is index of alteration of the reagents and / or controls .

READING THE RESULT

A. Technique with Chemical Extraction

Positive: If Agglutination appears in the test circle with latex A, B, C, F or G respectively.

Negative: Fine particles appear in the test circle with latex A, B, C, F or G respectively with **no agglutination or clumping**.

B. Direct Technique

Positive: If Agglutination appears in the test circle with latex D. **Negative: Fine particles** appear in the test circle with latex D with **no agglutination or clumping**.

C. Technique with Enzymatic Extraction

Positive: If Agglutination appears in the test circle with latex D. **Negative: Fine particles** appear in the test circle with latex D with **no agglutination or clumping**.

NOTE: An insufficient amount of bacterial culture used can cause false negative results.

PERFORMANCE CHARACTERISTICS

Sensitivity

The identification with chemical extraction technique of groups A, B, C, F and G streptococci, performed both on lyophilized collection strains and on clinical isolations, has showed a sensitivity of 98%.

The identification of group D with direct technique has showed a sensitivity of 74.3%.

The identification of group D with enzymatic extraction has showed a sensitivity of 92%.

REFERENCES

 Arcuri F., Molina A.M., Calegari L., Fontana G (1963). Anticorpi antistreptococcici nei sieri umani. Applicazione della reazione di agglutinazione al latex per la dimostrazione degli anticorpi anti.M. L'Igiene moderna. 56, 147.

- 2. Fanini A., Vignola D., Strapparava E.
- Lancefield R.C.(1928). The Antigenic Complex of Streptococcus haemolyticus: I.Demonstration of a typespecific substance in extracts of Streptococcus Haemolyticus. J Exp Med • 47, 91-103.
- 4. Molina A.M., Saletti M.
- 5. Pianigiani A. (1965).
- 6. Pianigiani A., Pianigiani M.
- Romanzi C.A. (1966). Biology of Streptococcus pyogenes and immunological response to streptococcic antigens in rheumatic disease. Giorn Mal Infett Parass, 18, 375-411,.
- Rossolini A., Lecchini L., Forte D., Benedetti P.A. (1963) Antibody M in children affected by streptococcal infections. Riv Clin Ped, 72, 268-291.
- Facklam R.F., Martin D.R., Lovgren M., Johnson D.R., Efstratiou A., Thompson T.A., Gowan S., Kriz P., Tyrrell G.J. Kaplan E. and Beall B. (2002) Extension of the Lancefield classification for group A streptococci by addition of 22 new M protein gene sequence types from clinical isolates: emm 103 to emm 124. Clin. Infect Dis. 34(1):28-38.

ATLAS Medical GmbH Ludwig-Erhard Ring 3, 15827 Blankenfelde-Mahlow, Germany Tel: +49 - 33708 – 3550 30 Email: <u>Info@atlas-medical.com</u> Website: www.atlas-medical.com

PPI1415A01

Rev G (18.10.2023)

REF	Catalogue Number	ľ	Temperature limit
IVD	In Vitro diagnostic medical device	\wedge	Caution
¥	Contains sufficient for <n> tests and Relative size</n>	<u>[]</u>	Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
I	Fragile, handle with care		Use-by date
	Manufacturer fax number	(Do not use if package is damaged
3	Manufacturer telephone number	3	Date of Manufacture
*	Keep away from sunlight	ſ	Keep dry
CONTROL +	Positive control	Control -	Negative control





HiMedia Laboratories Pvt. Ltd.

Date: 07th March 2024.

TO WHOMSOEVER IT MAY CONCERN

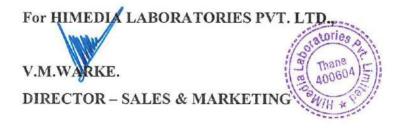
We hereby certify that,

Sanmedico SRL Str. Corobceanu 7A, Apt.9, MD-2012, CITY CHISINAU Republic of Moldova, Tel:-00-373-231 31515 / 00-373-222 60595 Fax:-00-373-22 62 30 32 E-mail: <u>sanmedico.office@gmail.com</u>

have been appointed by us as our Authorized Distributor for selling our Products in MOLDOVA

This certificate is valid upto 06th March 2026.

This Authorization Letter shall stand effective from the date of signing and can be terminated by either party with two months advance notice.









Page 1 of 130

DECLARATION OF CONFORMITY MICROBIOLOGY PRODUCTS

1) <u>Manufacturer</u> (Name, department): HiMedia Laboratories Pvt. Ltd.

Address: Plot No. C-40, Road No. 21/Y, MIDC, Wagle Industrial Area, Thane(West)-400604, Maharashtra, India

and

2) European authorized representative: CEpartner4U BV,

Address: EsboornLaan 13, 3951DB Maarn, The NetherLands; (on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) (groupnames /.):

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants,Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J.Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips, HiComb™ MIC Strip, Modified & Ezy MIC Strips, HiMIC™ Plate Kit	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs	NL-CA002-2013-26445	5

type and model numbers: see appendix

The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking: In vitro Diagnostic Medical Device Directive, Annex III

Mumbai, India; 2022-03-01

Dr. G.M.Warke, Managing Director

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)

4)



Appendix

List of devices:

Date: 2022-03-01

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Dehydrated Culture Media				
DCM	M1739	A7 Agar Base (Shepard's Differential Agar Base)	Low risk	20/12/2012
DCM	MCD884	Aeromonas Isolation HiCynth™ Medium Base	Low risk	12/08/2015
DCM	MV884	Aeromonas Isolation HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M884	Aeromonas Isolation Medium Base	Low risk	20/12/2012
DCM	M1284	Aeromonas Starch DNA Agar Base	Low risk	20/12/2012
DCM	M016B	Agar Medium L (Brilliant Green, Phenol Red, Lactose Monohydrate, Sucrose Agar)	Low risk	20/12/2012
DCM	ME016	Agar Medium L (Brilliant Green, Phenol Red, Lactose Monohydrate, Sucrose Agar)	Low risk	20/12/2012
DCM	MCD618	Alkaline HiCynth™ Peptone Water	Low risk	12/08/2015
DCM	MV618	Alkaline HiVeg™ Peptone Water	Low risk	20/12/2012
DCM	M618	Alkaline Peptone Water	Low risk	20/12/2012
DCM	M1887	Alkaline Saline Peptone Water (ASPW)	Low risk	10/11/2020
DCM	M651	Amies Transport Medium w/ Charcoal	Low risk	20/12/2012
DCM	M684A	Amies Transport Medium, Liquid w/o charcoal	Low risk	25/08/2016
DCM	M228	Anaerobic Agar	Low risk	20/12/2012
DCM	M491	Anaerobic Agar (Brewer)	Low risk	20/12/2012
DCM	M230	Anaerobic Agar w/o Dextrose	Low risk	20/12/2012
DCM	M229	Anaerobic Agar w/o Dextrose and Eh Indicator	Low risk	20/12/2012
DCM	M1635	Anaerobic Basal Agar	Low risk	20/12/2012
DCM	M1636	Anaerobic Basal Broth	Low risk	20/12/2012
DCM	M1345	Anaerobic Blood Agar Base	Low risk	20/12/2012
DCM	M975A	Anaerobic Blood Agar Base	Low risk	20/12/2012
DCM	M1034	Anaerobic CNA Agar Base	Low risk	20/12/2012
DCM	MV228	Anaerobic HiVeg™ Agar	Low risk	20/12/2012
DCM	MV491	Anaerobic HiVeg™ Agar (Brewer)	Low risk	20/12/2012
DCM	MV230	Anaerobic HiVeg™ Agar w/o Dextrose	Low risk	20/12/2012
DCM	MV229	Anaerobic HiVeg™ Agar w/o Dextrose and Eh Indicator	Low risk	20/12/2012
DCM	MV909	Andrade Peptone Water w/ HiVeg™ Extract No. 1	Low risk	20/12/2012
DCM	M909	Andrade Peptone Water w/ HM Extract	Low risk	20/12/2012
DCM	M1485	Antibiotic Sulphonamide Sensitivity Test Agar (ASS Agar)	Low risk	20/12/2012
DCM	M1576	Arabinose Agar Base	Low risk	30/10/2018
DCM	M1637	Arcobacter Broth Base	Low risk	10/11/2020
DCM	M1894	Arcobacter Selective Broth Base	Low risk	10/11/2020

IM		

Document ref.: DoC 2022 vs. 15

Page 3 of 130

DCM	M672	Asparagine Broth (Coccidioidin and Histoplasmin Broth)	Low risk	20/12/2013
DCM	M158	Azide Blood Agar Base	Low risk	20/12/2013
DCM	MV158	Azide Blood Agar Base, HiVeg™	Low risk	20/12/2013
DCM	M1271	Azide Dextrose Broth w/ BCP	Low risk	10/11/2020
DCM	M220	B.A.G.G. Broth Base (Buffered Azide Glucose Glycerol Broth Base)	Low risk	20/12/2013
DCM	MV220	B.A.G.G. HiVeg™ Broth Base (Buffered Azide Glucose Glycerol HiVeg™ Broth Base)	Low risk	20/12/201
DCM	M106	B.C.G Dextrose Agar (Snyder Test Agar)	Low risk	20/12/2013
DCM	MV106	B.C.G Dextrose HiVeg™ Agar (Snyder Test HiVeg™ Agar)	Low risk	20/12/201
DCM	MCD462	B.Q.Vaccine HiCynth™ Medium (Thioglycollate HiCynth™ Broth)	Low risk	28/04/201
DCM	MV462	B.Q.Vaccine HiVeg [™] Medium (Thioglycollate Broth w/ HiVeg [™] Extract No. 2)	Low risk	20/12/201
DCM	M462	B.Q.Vaccine Medium (Thioglycollate Broth w/ HL Extract)	Low risk	20/12/201
DCM	M861	B.T.B. Lactose Agar	Low risk	20/12/201
DCM	MCD861	B.T.B. Lactose HiCynth™ Agar	Low risk	28/04/201
DCM	MCD1081	B.T.B. Lactose HiCynth™ Agar, Modified	Low risk	28/04/201
DCM	MV861	B.T.B. Lactose HiVeg™ Agar	Low risk	20/12/201
DCM	MV833	Bacillus Cereus HiVeg™ Agar Base	Low risk	22/04/201
DCM	M833	Bacillus Cereus Agar Base	Low risk	22/04/201
DCM	M805	Bacteroides Bile Esculin Agar Base (BBE)	Low risk	20/12/201
DCM	MV805	Bacteroides HiVeg™ Agar Base (BBE)	Low risk	20/12/201
DCM	M043	Baird Parker Agar Base	Low risk	20/12/201
DCM	M2093	Baird Parker Agar Base w/o Egg Yolk Emulsion	Low risk	22/04/201
DCM	MCD043	Baird Parker HiCynth™ Agar Base	Low risk	12/08/201
DCM	MV043	Baird Parker HiVeg™ Agar Base	Low risk	20/12/201
DCM	M1091	Baird Staphylococcus Enrichment Broth Base	Low risk	10/11/202
DCM	M694	Bennet's Agar	Low risk	20/12/201
DCM	M1683	Bennet's Broth	Low risk	20/12/201
DCM	MV694	Bennet's HiVeg™ Agar	Low risk	20/12/201
DCM	M1888	BETA-SSA Agar (Group A Streptococci Selective Agar)	Low risk	20/12/201
DCM	M211	BHI Agar (Special Infusion Agar)	Low risk	20/12/201
DCM	M211A	BHI Agar w/ 1% Agar	Low risk	20/12/201
DCM	MV211A	BHI Agar w/ 1% Agar, HiVeg™	Low risk	20/12/201
DCM	M1069	BHI Agar w/ 3.0% Agar	Low risk	20/12/201
DCM	MV211	BHI Agar, HiVeg™ (Special Infusion Agar, HiVeg™)	Low risk	20/12/201
DCM	M1611	BHI Agar, Modified	Low risk	20/12/201
DCM	M210	BHI Broth	Low risk	20/12/201
DCM	M210I	BHI Broth	Low risk	20/12/201
DCM	M209	BHI CC Agar	Low risk	20/12/201
DCM	MV209	BHI CC Agar, HiVeg™	Low risk	20/12/201
DCM	MCD211	BHI HiCynth™ Agar (Special Insusion HiCynth™ Agar)	Low risk	12/08/201

ГТТ	М		

Document ref.: DoC 2022 vs. 15

Page 4 of 130

DCM	MCD210	BHI HiCynth™ Broth	Low risk	12/08/2015
DCM	M1036	BHI w/ 0.1% Agar	Low risk	20/12/2012
DCM	M1037	BHI w/ 6.5% NaCl	Low risk	20/12/2012
DCM	MV1037	BHI w/ 6.5% NaCl, HiVeg™	Low risk	20/12/2012
DCM	M212	BHI w/ PABA	Low risk	20/12/2012
DCM	M213	BHI w/ PABA and Agar	Low risk	20/12/2012
DCM	MV213	BHI w/ PABA and Agar, HiVeg™	Low risk	20/12/2012
DCM	MV212	BHI w/ PABA, HiVeg™	Low risk	20/12/2012
DCM	MV1036	BHI with 0.1% Agar, HiVeg™	Low risk	20/12/2012
DCM	MV210	BHI, HiVeg™	Low risk	20/12/2012
DCM	M217	Bi.G.G.Y. Agar (Nickerson Medium)	Low risk	20/12/2012
DCM	MCD217	Bi.G.G.Y. HiCynth™ Agar (Nickerson HiCynth™ Agar)	Low risk	25/08/2016
DCM	M1396	Bifidobacterium Agar	Low risk	10/11/2020
DCM	M1960R	Bifidobacterium Agar (HiCrome™)	Low risk	25/08/2016
DCM	M1396R	Bifidobacterium Agar (Modified, Selective Medium, Kit)	Low risk	04/07/2018
DCM	M1858	Bifidobacterium Agar, Modified	Low risk	20/12/2012
DCM	M1395	Bifidobacterium Broth	Low risk	10/11/2020
DCM	M071	Bile Broth Base	Low risk	20/12/2013
DCM	MV071	Bile Broth Base, HiVeg™	Low risk	20/12/201
DCM	M972A	Bile Esculin Agar, Modified	Low risk	22/04/201
DCM	M493	Bile Esculin Azide Agar	Low risk	10/11/2020
DCM	MV493	Bile Esculin Azide HiVeg™ Agar	Low risk	10/11/2020
DCM	MCD493	Bile Esculin Azide HiCynth™ Agar	Low risk	10/11/202
DCM	M481	Bile Peptone Transport Medium	Low risk	20/12/201
DCM	M739	Bile Salt Agar	Low risk	20/12/201
DCM	MCD027	Bismuth Sulphite HiCynth™ Agar	Low risk	12/08/201
DCM	M027	Bismuth Sulphite Agar	Low risk	20/12/201
DCM	M027L	Bismuth Sulphite Agar	Low risk	04/07/201
DCM	MU027	Bismuth Sulphite Agar Medium	Low risk	20/12/201
DCM	M1004	Bismuth Sulphite Agar, Modified	Low risk	20/12/201
DCM	MV027	Bismuth Sulphite HiVeg™ Agar	Low risk	20/12/201
DCM	MV1004	Bismuth Sulphite HiVeg™ Agar, Modified	Low risk	20/12/201
DCM	M073	Blood Agar Base (Infusion Agar)	Low risk	20/12/201
DCM	M834	Blood Agar Base No. 2	Low risk	20/12/201
DCM	M834A	Blood Agar Base No. 2 w/ 1.2% Agar	Low risk	20/12/201
DCM	MV834A	Blood Agar Base No. 2 w/ 1.2% Agar, HiVeg™	Low risk	20/12/201
DCM	MV834	Blood Agar Base No. 2, HiVeg™	Low risk	20/12/201
DCM	M834Z	Blood Agar Base No.2	Low risk	28/04/201
DCM	M089	Blood Agar Base w/ Low pH	Low risk	20/12/201
DCM	MV089	Blood Agar Base w/ Low pH, HiVeg™	Low risk	20/12/2013

HH	

Document ref.: DoC 2022 vs. 15

Page 5 of 130

DCM	M1904	Blood Agar Base w/ Nalidixic Acid	Low risk	20/12/2012
DCM	MV073	Blood Agar Base, HiVeg™ (Infusion Agar, HiVeg™)	Low risk	20/12/2012
DCM	M1989	Blood Agar Base, Modified	Low risk	20/12/2012
DCM	M1318	Blood Free Campylobacter Broth Base	Low risk	20/12/2012
DCM	MCD073	Blood HiCynth™ Agar Base (Infusion HiCynth™ Agar Base)	Low risk	25/08/2016
DCM	MCD834	Blood HiCynth™ Agar Base No.2	Low risk	25/08/2016
DCM	MCD089	Blood HiCynth™ Agar Base w/ Low pH	Low risk	25/08/2016
DCM	M175	Bordet Gengou Agar Base	Low risk	20/12/2012
DCM	M175A	Bordet Gengou Agar Base w/ 1.6% Agar	Low risk	20/12/2012
DCM	M175SB	Bordet Gengou Agar Base, Modified	Low risk	16/12/2017
DCM	M2012	Bordet Gengou Broth	Low risk	25/08/2016
DCM	MV175	Bordet Gengou HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV175A	Bordet Gengou HiVeg™ Agar Base w/ 1.6% Agar	Low risk	20/12/2012
DCM	M1020	BPL Agar	Low risk	20/12/2012
DCM	MV1020	BPL HiVeg™ Agar	Low risk	20/12/2012
DCM	M016A	Brilliant Green Agar Base w/ 1.2% Agar	Low risk	20/12/2012
DCM	M971	Brilliant Green Agar Base w/ Phosphates	Low risk	20/12/2012
DCM	M016	Brilliant Green Agar Base, Modified	Low risk	20/12/2012
DCM	MCD016	Brilliant Green Agar HiCynth™ Base, Modified	Low risk	12/08/2015
DCM	MU016	Brilliant Green Agar Medium	Low risk	20/12/2012
DCM	MM016	Brilliant Green Agar Medium 16	Low risk	20/12/2012
DCM	MV016A	Brilliant Green HiVeg™ Agar Base w/ 1.2% Agar	Low risk	20/12/2012
DCM	MV971	Brilliant Green HiVeg™ Agar Base w/ Phosphates	Low risk	20/12/2012
DCM	MV016	Brilliant Green HiVeg™ Agar Base, Modified	Low risk	20/12/2012
DCM	M016B	Brilliant Green, Phenol Red, Lactose Monohydrate, Sucrose Agar (Agar Medium L)	Low risk	20/12/2012
DCM	ME016	Brilliant Green, Phenol Red, Lactose Monohydrate, Sucrose Agar (Agar Medium L)	Low risk	20/12/2012
DCM	M1822	Bromo Thymol Lactose Blue Agar	Low risk	16/12/2017
DCM	M074	Brucella Agar Base	Low risk	20/12/2012
DCM	M1638	Brucella Agar Base w/ 1.0% Dextrose	Low risk	20/12/2012
DCM	M1039	Brucella Agar Base w/ Hemin and Vitamin K	Low risk	20/12/2012
DCM	M074A	Brucella Agar Base, Modified	Low risk	20/12/2012
DCM	M5392	Brucella Broth Base	Low risk	30/10/2018
DCM	M348	Brucella Broth Base	Low risk	20/12/2012
DCM	MV074	Brucella HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV074A	Brucella HiVeg™ Agar Base, Modified	Low risk	20/12/2012
DCM	MV348	Brucella HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M822	Brucella Selective Medium Base	Low risk	20/12/2012
DCM	M1890	BSIBG Agar (Aeromonas Selective Agar)	Low risk	10/11/2020
DCM	M1668	BSK - H Medium Base	Low risk	20/12/2012

IM		

Document ref.: DoC 2022 vs. 15

Page 6 of 130

DCM	M1668B	BSK - H Medium Base w/o BSA	Low risk	28/04/2017
DCM	M813	Buffered Charcoal Yeast Extract Agar Base	Low risk	20/12/2012
DCM	M813I	Buffered Charcoal Yeast Extract Agar Medium (BCYE Medium)	Low risk	20/12/2012
DCM	MCD813	Buffered Charcoal Yeast Extract HiCynth™ Medium	Low risk	25/08/2016
DCM	M204	Buffered Glycerol Saline Base	Low risk	20/12/2012
DCM	MCD1275	Buffered HiCynth [™] Peptone Water w/ NaCl	Low risk	12/08/2015
DCM	MV614	Buffered HiVeg™ Peptone Water	Low risk	22/04/2019
DCM	MV1275	Buffered HiVeg™ Peptone Water w/NaCL	Low risk	20/12/2012
DCM	M614	Buffered Peptone Water	Low risk	22/04/2019
DCM	M1275	Buffered Peptone Water w/ NaCl	Low risk	20/12/2012
DCM	M1851	Buffered Peptone Water w/ Pyruvate	Low risk	20/12/2012
DCM	MH1275	Buffered Sodium Chloride-Peptone Solution pH 7.0	Low risk	22/04/2019
DCM	M1640	Burkholderia Cepacia Agar Base	Low risk	20/12/2012
DCM	MCD1640	Burkholderia cepacia HiCynth™ Agar Base	Low risk	25/08/2016
DCM	M2089	Burkholderia Cepacia Selectie Agar	Low risk	10/11/2020
DCM	MU2089	Burkholderia Cepacia Selective Agar (BCSA)	Low risk	10/11/2020
DCM	M470	BYE Agar	Low risk	20/12/2012
DCM	MV470	BYE HiVeg™ Agar	Low risk	20/12/2012
DCM	M911	C. botulinum Isolation Agar Base	Low risk	20/12/2012
DCM	MV911	C. botulinum Isolation HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1146	C.L.E.D. Agar Base w/o Indicator	Low risk	20/12/2012
DCM	M792	C.L.E.D. Agar w/ Bromo Thymol Blue	Low risk	20/12/2012
DCM	MCD792	C.L.E.D. HiCynth™ Agar w/BTB	Low risk	12/08/2015
DCM	MCD352	C.L.E.D. HiCynth™ Agar w/Andrade Indicator	Low risk	12/08/2015
DCM	MV1146	C.L.E.D. HiVeg™ Agar Base w/o Indicator	Low risk	20/12/2012
DCM	MV352	C.L.E.D. HiVeg™ Agar w/ Andrade Indicator	Low risk	20/12/2012
DCM	MV792	C.L.E.D. HiVeg™ Agar w/ Bromo Thymol Blue	Low risk	20/12/2012
DCM	M352	C.L.E.D.Agar w/ Andrade Indicator	Low risk	20/12/2012
DCM	M352M	C.L.E.D.Agar w/ Andrades Indicator	Low risk	22/04/2019
DCM	M352A	C.L.E.D.Agar w/o Lactose & w/ Andrades Indicator	Low risk	22/04/2019
DCM	M563	Caffeic Acid Ferric Citrate Test Agar (CAFC Medium)	Low risk	20/12/2012
DCM	M893	CAL Agar (Cellobiose Arginine Lysine Agar)	Low risk	20/12/2012
DCM	M894	CAL Broth (Cellobiose Arginine Lysine Broth)	Low risk	20/12/2012
DCM	MV893	CAL HiVeg™ Agar (Cellobiose Arginine Lysine HiVeg™ Agar)	Low risk	20/12/2012
DCM	MV894	CAL HiVeg [™] Broth (Cellobiose Arginine Lysine HiVeg [™] Broth)	Low risk	20/12/2012
DCM	MV908	Campylo Thioglycollate HiVeg [™] Medium Base	Low risk	20/12/2012
DCM	M908	Campylo Thioglycollate Medium Base	Low risk	20/12/2012
DCM	M994	Campylobacter Agar Base	Low risk	20/12/2012
DCM	M1267	Campylobacter Cefex Agar Base	Low risk	20/12/2012
DCM	M899	Campylobacter Enrichment Broth Base (Preston Enrichment Broth Base)	Low risk	20/12/2012

ниеріл	Declaration of Conformity	Document ref.: DoC 2022 vs. 15
	Microbiology Products	Page 7 of 130

DCM	MV899	Campylobacter Enrichment HiVeg™ Broth Base (Preston Enrichment HiVeg™ Broth Base)	Low risk	20/12/2012
DCM	MV994	Campylobacter HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1240	Campylobacter Nitrate Broth	Low risk	20/12/2012
DCM	MV1240	Campylobacter Nitrate HiVeg™ Broth	Low risk	20/12/2012
DCM	M1602	Candida Agar	Low risk	20/12/2012
DCM	M355	Candida BCG Agar Base	Low risk	20/12/2012
DCM	MV355	Candida BCG HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV104	Candida HiVeg™ Medium	Low risk	20/12/2012
DCM	M104	Candida Medium	Low risk	20/12/2012
DCM	M202	Cary - Blair Medium Base (Transport Medium w/o Charcoal)	Low risk	20/12/2012
DCM	M202A	Cary Blair Medium, Liquid w/o charcoal	Low risk	25/08/2016
DCM	M794	Casitose Agar w/ 2.5% Agar	Low risk	20/12/2012
DCM	M200	Casitose Broth	Low risk	20/12/2012
DCM	M910	Casitose Yeast Extract Broth (CAYE)	Low risk	20/12/2012
DCM	MV910	Casitose Yeast Extract HiVeg™ Broth (CAYE)	Low risk	20/12/2012
DCM	M201	Casman Agar Base	Low risk	20/12/2012
DCM	M766	Casman Broth Base	Low risk	20/12/2012
DCM	MV201	Casman HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV766	Casman HiVeg™ Broth Base	Low risk	20/12/2012
DCM	MH024	Cetrimide Agar	Low risk	22/04/2019
DCM	M024	Cetrimide Agar Base	Low risk	20/12/2012
DCM	M1742	Cetrimide Agar Base (w 1.3% Agar)	Low risk	20/12/2012
DCM	M862	Cetrimide Broth	Low risk	20/12/2012
DCM	MCD024	Cetrimide HiCynth™ Agar Base	Low risk	12/08/2015
DCM	MV024	Cetrimide HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV862	Cetrimide HiVeg™ Broth	Low risk	20/12/2012
DCM	M344	Charcoal Agar Base	Low risk	10/11/2020
DCM	MV344	Charcoal Agar Base, HiVeg™	Low risk	10/11/2020
DCM	M1053	Charcoal Agar Base with Niacin	Low risk	16/12/2017
DCM	M646	Charcoal Blood Agar Base	Low risk	10/11/2020
DCM	MV646	Charcoal Blood Agar Base, HiVeg™	Low risk	10/11/2020
DCM	M103	Chocolate Agar Base	Low risk	20/12/2012
DCM	MV103	Chocolate HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1548	Chocolate No. 2 Agar Base	Low risk	20/12/2012
DCM	MV1548	Chocolate No. 2 HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV558	Cholera HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M558	Cholera Medium Base	Low risk	20/12/2012
DCM	M143	Christensen Citrate Agar	Low risk	20/12/2012
DCM	M1820	Chrysoidin Agar with MUG	Low risk	16/12/2017

М		IA

Document ref.: DoC 2022 vs. 15

Page 8 of 130

DCM	M497	Clostridial Agar	Low risk	20/12/2012
DCM	MV497	Clostridial HiVeg™ Agar	Low risk	20/12/2012
DCM	M836	Clostridium Difficile Agar Base	Low risk	20/12/2012
DCM	MV836	Clostridium Difficile HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1976	Clostridium difficile Mannitol Taurocholate Broth base (CCMB -TAL Broth)	Low risk	20/12/2012
DCM	M272	Coagulase Mannitol Agar Base	Low risk	20/12/2012
DCM	M277	Coagulase Mannitol Broth Base	Low risk	20/12/2012
DCM	MV272	Coagulase Mannitol HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV277	Coagulase Mannitol HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1826	Coliform Broth w/SLS	Low risk	22/04/2019
DCM	MV1826	Coliform HiVeg Broth w/ SLS	Low risk	22/04/2019
DCM	MH144	Columbia Agar	Low risk	22/04/2019
DCM	M144M	Columbia Agar	Low risk	22/04/2019
DCM	M144PM	Columbia Blood Agar Base	Low risk	22/04/2019
DCM	M144R	Columbia Blood Agar Base	Low risk	25/08/2016
DCM	M144	Columbia Blood Agar Base	Low risk	20/12/2012
DCM	M144A	Columbia Blood Agar Base w/ 1% Agar	Low risk	20/12/2012
DCM	MV144A	Columbia Blood Agar Base w/ 1% Agar, HiVeg™	Low risk	20/12/2012
DCM	M1133	Columbia Blood Agar Base w/ Hemin	Low risk	20/12/2012
DCM	MV144	Columbia Blood Agar Base, HiVeg™	Low risk	20/12/2012
DCM	MCD144	Columbia Blood HiCynth™ Agar Base	Low risk	12/08/2015
DCM	MCD144A	Columbia Blood HiCynth™ Agar Base w/1% Agar	Low risk	12/08/2015
DCM	M145	Columbia Broth Base	Low risk	20/12/2012
DCM	MV145	Columbia Broth Base, HiVeg™	Low risk	20/12/2012
DCM	M560	Columbia C.N.A. Agar Base	Low risk	20/12/2012
DCM	M560A	Columbia C.N.A. Agar Base w/ 1% Agar	Low risk	20/12/2012
DCM	MV560	Columbia C.N.A. HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV560A	Columbia C.N.A. HiVeg™ Agar Base w/ 1% Agar	Low risk	20/12/2012
DCM	MCD145	Columbia HiCynth™ Broth	Low risk	12/08/2015
DCM	M2103	Congo Red Magnesium Oxalate (CR-MOX) Agar	Low risk	22/04/2019
DCM	M730	Conn's Agar	Low risk	20/12/2012
DCM	M149	Cooked M Medium (R.C .Medium)	Low risk	16/12/2017
DCM	M1040	Cooked M Medium w/ Glucose, Hemin & Vitamin K	Low risk	16/12/2017
DCM	MV731	Corn Meal HiVeg™ Peptone Yeast Agar	Low risk	20/12/2012
DCM	M731	Corn Meal Peptone Yeast Agar	Low risk	20/12/2012
DCM	M897	Crystal Violet Lactose Agar	Low risk	10/11/2020
DCM	MV897	Crystal Violet Lactose HiVeg™ Agar	Low risk	10/11/202
DCM	M1892	CTAS Agar Base (Carnobacterium Selective Agar Base)	Low risk	20/12/2012
DCM	M172	Cystine H Agar Base	Low risk	20/12/2012

HH	

Document ref.: DoC 2022 vs. 15

Page 9 of 130

DCM	MV172	Cystine HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M881	Cystine Tellurite Agar Base	Low risk	20/12/2012
DCM	M160	D.C.L.S. Agar	Low risk	20/12/2012
DCM	M178	D.C.L.S. Agar, Hajna	Low risk	20/12/2012
DCM	MV160	D.C.L.S. HiVeg™ Agar	Low risk	20/12/2012
DCM	MV178	D.C.L.S. HiVeg™ Agar	Low risk	20/12/2012
DCM	M188	D.T.M. Agar Base (Dermatophyte Test Agar Base)	Low risk	20/12/2012
DCM	M501	Decarboxylase Agar Base	Low risk	20/12/2012
DCM	M393	Decarboxylase Broth Base, Moeller (Moeller Decarboxylase Broth Base)	Low risk	20/12/2012
DCM	MV501	Decarboxylase HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV393	Decarboxylase HiVeg™ Broth Base, Moeller (Moeller Decarboxylase HiVeg™ Broth Base)	Low risk	20/12/2012
DCM	M030	Deoxycholate Agar	Low risk	20/12/2012
DCM	MV030	Deoxycholate Agar, HiVeg™	Low risk	20/12/2012
DCM	M065	Deoxycholate Citrate Agar	Low risk	20/12/2012
DCM	M1639	Deoxycholate Citrate Agar w/1.5% Agar	Low risk	20/12/2012
DCM	M222	Deoxycholate Citrate Agar w/o Sucrose	Low risk	20/12/2012
DCM	MV065	Deoxycholate Citrate Agar, HiVeg™	Low risk	20/12/2012
DCM	MCD065	Deoxycholate Citrate HiCynth™ Agar	Low risk	12/08/2015
DCM	M084	Dextrose Agar	Low risk	20/12/2012
DCM	M286	Dextrose Agar Base, Emmons (Sabouraud Dextrose Agar Base, Modified)	Low risk	20/12/2012
DCM	MV084	Dextrose HiVeg™ Agar	Low risk	20/12/2012
DCM	MV286	Dextrose HiVeg™ Agar Base, Emmons (Sabouraud Dextrose HiVeg™ AgarBase, Modified)	Low risk	20/12/2012
DCM	M734	Dextrose Proteose Peptone Agar Base	Low risk	20/12/2012
DCM	MV734	Dextrose Proteose Peptone HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M502	Diagnostic Sensitivity Test Agar (D.S.T. Agar)	Low risk	20/12/2012
DCM	M111	Diagnostic Stuart's Urea Broth Base (Urea Broth Base)	Low risk	20/12/2012
DCM	MV191	Diagnostic Thioglycollate HiVeg™ Medium (Thioglycollate HiVeg™ Medium w/o Indicator)	Low risk	20/12/2012
DCM	M191	Diagnostic Thioglycollate Medium (Thioglycollate Medium w/o Indicator)	Low risk	20/12/2012
DCM	M1129	Dichloran Glycerol Medium Base	Low risk	22/04/2019
DCM	M1049	Differential Agar for Group D Streptococci	Low risk	10/11/2020
DCM	M814	Differential Buffered Charcoal Yeast Extract Agar Base	Low risk	20/12/2012
DCM	M1603	Differential Reinforced Clostridial Agar	Low risk	10/11/2020
DCM	M915	Dihydrolase Broth Base	Low risk	20/12/2012
DCM	MV915	Dihydrolase HiVeg™ Broth Base	Low risk	20/12/2012
DCM	MM1276	Dilute Sautans Medium (Twin Pack)	Low risk	20/12/2012
DCM	M882	Diphtheria Virulence Agar Base	Low risk	25/08/2016
DCM	M882R	Diphtheria Virulence Agar Base Modified	Low risk	25/08/2016

пп	ED	
		HA

Document ref.: DoC 2022 vs. 15

Page 10 of 130

DCM	MV882	Diphtheria Virulence HiVeg™ Agar Base	Low risk	25/08/2016
DCM	M1984	Dixon's Agar	Low risk	20/12/2012
DCM	M1419	DNase Test Agar w/ Methyl Green	Low risk	10/11/2020
DCM	M057	Double Sugar Agar, Russell (Russell Double Sugar Agar)	Low risk	20/12/2012
DCM	MV057	Double Sugar HiVeg [™] Agar (Russell Double Sugar HiVeg [™] Agar)	Low risk	20/12/2012
DCM	M916	Doyle's Enrichment Broth Base	Low risk	20/12/2012
DCM	MV916	Doyle's Enrichment HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1378	Drigalski Lactose Agar, Modified	Low risk	20/12/2012
DCM	M1761	Drigalski Lactose Selective Agar	Low risk	20/12/2012
DCM	M659	Drigalski Litmus Lactose Agar	Low risk	20/12/2012
DCM	MV659	Drigalski Litmus Lactose HiVeg™ Agar	Low risk	20/12/2012
DCM	M5349	DTP Medium	Low risk	30/10/2018
DCM	M067	Dubos Broth Base	Low risk	20/12/2012
DCM	MV067	Dubos HiVeg [™] Broth Base	Low risk	20/12/2012
DCM	M179	Dubos Oleic Agar Base	Low risk	20/12/2012
DCM	M839	Dubos Oleic Broth Base	Low risk	20/12/2012
DCM	MV179	Dubos Oleic HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV839	Dubos Oleic HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1536	Dulcitol Selenite Broth (Selenite-F Broth w/ Dulcitol) (Twin Pack)	Low risk	20/12/2012
DCM	M854	E.T. Medium	Low risk	20/12/2012
DCM	M1768	EC Blue Broth	Low risk	20/12/2012
DCM	MV1768	EC Blue HiVeg™ Broth	Low risk	20/12/2012
DCM	M127	EC Broth	Low risk	20/12/2012
DCM	M127I	EC Broth	Low risk	20/12/2012
DCM	MV127	EC HiVeg™ Broth	Low risk	20/12/2012
DCM	M748	Edward's Medium Base, Modified	Low risk	20/12/2012
DCM	MV748	Edward's Medium HiVeg™ Base, Modified	Low risk	20/12/2012
DCM	M294	Edwards and Bruner Semisolid Medium	Low risk	20/12/2012
DCM	M808	Egg Yolk Agar Base	Low risk	20/12/2012
DCM	MV808	Egg Yolk Agar Base, HiVeg™	Low risk	20/12/2012
DCM	M1043	Egg Yolk Agar Base, Modified	Low risk	20/12/2012
DCM	M086	Eijkman Lactose Broth	Low risk	20/12/2012
DCM	MV086	Eijkman Lactose HiVeg™ Broth	Low risk	20/12/2012
DCM	M368	Elliker Broth (Lactobacilli Broth)	Low risk	10/11/202
DCM	MV368	Elliker HiVeg™ Broth (Lactobacilli HiVeg™ Broth)	Low risk	10/11/202
DCM	M317	EMB Agar	Low risk	20/12/2012
DCM	M301	EMB Agar Base	Low risk	20/12/2012
DCM	M022	EMB Agar, Levine	Low risk	20/12/2012
DCM	M022S	EMB Agar, Levine	Low risk	20/12/2012
DCM	M503	EMB Broth	Low risk	20/12/2012

НĤ	┛	

Document ref.: DoC 2022 vs. 15

Page 11 of 130

DCM	MV317	EMB HiVeg™ Agar	Low risk	20/12/201
DCM	MV022	EMB HiVeg™ Agar, Levine	Low risk	20/12/201
DCM	MV503	EMB HiVeg™ Broth	Low risk	20/12/201
DCM	M325	Emerson Agar	Low risk	20/12/201
DCM	MV325	Emerson HiVeg™ Agar	Low risk	20/12/201
DCM	M773	Emerson YSS Agar	Low risk	20/12/201
DCM	M029	Endo Agar	Low risk	20/12/201
DCM	M1077	Endo Agar Base	Low risk	20/12/201
DCM	M1258	Endo Agar w/ NaCl	Low risk	20/12/201
DCM	M1075	Endo Agar, Modified	Low risk	20/12/201
DCM	M029R	Endo Agar, Special	Low risk	25/08/201
DCM	MCD029	Endo HiCynth™ Agar	Low risk	12/08/201
DCM	MV029	Endo HiVeg™ Agar	Low risk	20/12/201
DCM	MV1077	Endo HiVeg™ Agar Base	Low risk	20/12/201
DCM	MV1258	Endo HiVeg™ Agar w/ NaCl	Low risk	20/12/201
DCM	MV1075	Endo HiVeg™ Agar, Modified	Low risk	20/12/20:
DCM	M738	Enriched Thioglycollate Broth	Low risk	20/12/202
DCM	MV738	Enriched Thioglycollate HiVeg™ Broth	Low risk	20/12/202
DCM	MV077	Entamoeba HiVeg™ Medium	Low risk	20/12/202
DCM	M077	Entamoeba Medium	Low risk	20/12/202
DCM	M1662	Enteric Fermentation Base	Low risk	20/12/202
DCM	MH287	Enterobacteria Enrichment Broth, Mossel	Low risk	22/04/202
DCM	M426	Ethyl Violet Azide Broth (E.V.A. Broth)	Low risk	20/12/202
DCM	M426S	Ethyl Violet Azide Broth (E.V.A. Broth)	Low risk	20/12/202
DCM	M1397	Ethyl Violet Azide Dextrose Agar	Low risk	20/12/202
DCM	MV426	Ethyl Violet Azide HiVeg™ Broth (E.V.A. HiVeg™ Broth)	Low risk	20/12/20:
DCM	M428	Eugonic Agar	Low risk	20/12/202
DCM	M429	Eugonic Broth	Low risk	20/12/20:
DCM	MV428	Eugonic HiVeg™ Agar	Low risk	20/12/202
DCM	MV429	Eugonic HiVeg™ Broth	Low risk	20/12/202
DCM	M1517	Eugonic LT 100 Broth Base w/o Tween 80	Low risk	20/12/20:
DCM	M1517Z	Eugonic LT 100 Broth Base w/o Tween 80	Low risk	17/06/202
DCM	M811	Feeley Gorman Agar (F.G. Agar)	Low risk	20/12/20:
DCM	M812	Feeley Gorman Broth (F.G. Broth)	Low risk	20/12/20:
DCM	MV811	Feeley Gorman HiVeg™ Agar (F.G. HiVeg™ Agar)	Low risk	20/12/20:
DCM	MV812	Feeley Gorman HiVeg™ Broth (F.G. HiVeg™ Broth)	Low risk	20/12/201
DCM	M827	Fermentation Medium for Staphylococcus and Micrococcus	Low risk	20/12/20:
DCM	MV919	Fermentation HiVeg [™] Medium Base for C. perfringens	Low risk	20/12/202
DCM	MV825	Fermentation HiVeg [™] Medium for Neisseriae	Low risk	20/12/20:
DCM	MV827	Fermentation HiVeg™ Medium for Staphylococcus and Micrococcus	Low risk	20/12/20:

Document ref.: DoC 2022 vs. 15

Page 12 of 130

DCM	M919	Fermentation Medium Base for C. perfringens	Low risk	20/12/2012
DCM	M825	Fermentation Medium for Neisseriae	Low risk	20/12/2012
DCM	M1028	Field's Tryptic Digest Broth (Tryptic Digest Broth)	Low risk	20/12/2012
DCM	MV1028	Field's Tryptic digest Broth, HiVeg™ (Tryptic Digest Broth, HiVeg™)	Low risk	20/12/2012
DCM	MV239	Fletcher Leptospira HiVeg™ Medium Base (Leptospira HiVeg™ MediumBase, Fletcher)	Low risk	20/12/2012
DCM	M239	Fletcher Leptospira Medium Base (Leptospira Medium Base, Fletcher)	Low risk	20/12/2012
DCM	M1209	Fluconazole Testing Medium (Twin Pack)	Low risk	20/12/2012
DCM	MV013	Fluid Sabouraud HiVeg™ Medium (Sabouraud Medium, Fluid, HiVeg™)	Low risk	20/12/2012
DCM	M013	Fluid Sabouraud Medium (Sabouraud Medium, Fluid)	Low risk	20/12/2012
DCM	M1533I	Fluid Selenite Cystine Broth (Twin Pack)	Low risk	20/12/2012
DCM	MV025	Fluid Selenite Cystine HiVeg™ Medium (Selenite Cystine HiVeg™ Broth) (Twin Pack)	Low risk	20/12/2012
DCM	M025	Fluid Selenite Cystine Medium (Selenite Cystine Broth) (Twin Pack)	Low risk	20/12/2012
DCM	MM025	Fluid Selenite Cystine Medium (Twin Pack)	Low risk	20/12/2012
DCM	MU025	Fluid Selenite Cystine Medium (Twin Pack)	Low risk	20/12/2012
DCM	MCD032	Fluid Tetrathionate HiCynth™ Medium w/o lodine and BG	Low risk	25/08/2016
DCM	MV032	Fluid Tetrathionate HiVeg™ Medium w/o lodine and BG (Tetrathionate HiVeg™ Broth Base w/o lodine & BG)	Low risk	20/12/2012
DCM	M032	Fluid Tetrathionate Medium w/o lodine and BG (Tetrathionate Broth Base w/o lodine and BG)	Low risk	20/12/2012
DCM	MV009	Fluid Thioglycollate HiVeg™ Medium	Low risk	22/04/2019
DCM	M009	Fluid Thioglycollate medium (Thioglycollate medium Fluid)	Low risk	22/04/2019
DCM	M543	Folic Acid Casei Medium	Low risk	20/12/2012
DCM	M2014	Folic Acid Casei Medium, Modified	Low risk	25/08/2016
DCM	M1050	Frey Mycoplasma Broth Base	Low risk	20/12/2012
DCM	M475	Fungobiotic Agar (Mycobio Agar)	Low risk	10/11/2020
DCM	M476	Garrod Actinomyces Medium	Low risk	10/11/2020
DCM	M1073	GBS Medium Base	Low risk	28/04/2017
DCM	M434	GC Agar Base	Low risk	25/08/2016
DCM	MV434	GC HiVeg™ Agar Base	Low risk	04/07/2018
DCM	M5397	Gifu Anaerobic Broth w/o starch & dextrose	Low risk	22/04/2019
DCM	M2079	Gifu Anaerobic Broth, Modified (GAM)	Low risk	04/07/2018
DCM	M1746	Glucose Agar	Low risk	10/11/2020
DCM	M435	Glucose Citrate Broth Base	Low risk	20/12/2012
DCM	M433	Glucose Cysteine Agar Base w/ Thiamine	Low risk	20/12/2012
DCM	MV433	Glucose Cysteine HiVeg™ Agar Base w/ Thiamine	Low risk	20/12/2012
DCM	M070	Glucose Phosphate Broth (Buffered Glucose Broth)	Low risk	20/12/2012
DCM	MV070	Glucose Phosphate HiVeg™ Broth (Buffered Glucose HiVeg™ Broth)	Low risk	20/12/2012
DCM	M621	Glucose Salt Teepol Broth (Twin Pack)	Low risk	20/12/2012

IM		

Document ref.: DoC 2022 vs. 15

Page 13 of 130

DCM	MV621	Glucose Salt Teepol HiVeg™ Broth (Twin Pack)	Low risk	20/12/2012
DCM	M1935	Glycerol Mannitol Acetamide Cetrimide Agar	Low risk	20/12/2012
DCM	M242	GN Broth, Hajna	Low risk	20/12/2012
DCM	MV242	GN HiVeg™ Broth	Low risk	20/12/2012
DCM	M1888	Group A Streptococci Selective Agar (BETA-SSA Agar)	Low risk	20/12/2012
DCM	M1607	Gum Listeria Medium	Low risk	20/12/2012
DCM	M243	H Broth	Low risk	20/12/2012
DCM	MV116	H.S. Vaccine HiVeg™ Medium (Standard Nutrient HiVeg™ Broth)	Low risk	20/12/2012
DCM	M116	H.S. Vaccine Medium (Standard Nutrient Broth)	Low risk	20/12/2012
DCM	M1259	Haemophilus Test Agar Base	Low risk	20/12/2012
DCM	M551	Hartley's Digest Broth	Low risk	20/12/2012
DCM	MV551	Hartley's Digest HiVeg™ Broth	Low risk	20/12/2012
DCM	M467	Hektoen Enteric Agar	Low risk	20/12/2012
DCM	MU467	Hektoen Enteric Agar Medium	Low risk	20/12/2012
DCM	MCD467	Hektoen Enteric HiCynth™ Agar	Low risk	12/08/2015
DCM	MV467	Hektoen Enteric HiVeg™ Agar	Low risk	20/12/2012
DCM	M5390	Helicobacter Pylori Selective Agar	Low risk	30/10/2018
DCM	M1158	Hemorrhagic Coli (HC) Agar	Low risk	20/12/2012
DCM	M169	HI Agar	Low risk	20/12/2012
DCM	MV169	HI Agar, HiVeg™	Low risk	20/12/2012
DCM	M170	HI Broth	Low risk	20/12/2012
DCM	MV170	HI Broth, HiVeg™	Low risk	20/12/2012
DCM	M1938	HiCrome™ Acinetobacter Agar Base	Low risk	20/12/2012
DCM	M1651	HiCrome™ Bacillus Agar	Low risk	25/08/2016
DCM	MCD1651	HiCrome™ Bacillus HiCynth™ Agar	Low risk	25/08/2016
DCM	M1960	HiCrome™ Bifidobacterium Agar	Low risk	20/12/2012
DCM	M1456AR	HiCrome™ Candida Differential Agar,Modified	Low risk	25/08/2016
DCM	MCD1297A	HiCrome™ Candida Differential HiCynth™ Agar	Low risk	12/08/2015
DCM	M1832	HiCrome Coliform Agar Modified	Low risk	22/04/2019
DCM	MV1300	HiCrome Coliform HiVeg Agar w/ SLS	Low risk	22/04/2019
DCM	MV1295	HiCrome E. coli HiVegTM Agar	Low risk	22/04/2019
DCM	MV1293	HiCrome ECC HiVeg [™] Agar	Low risk	22/04/2019
DCM	MV1294	HiCrome ECC Selective HiVeg Agar Base	Low risk	22/04/2019
DCM	M1598	HiCrome Enrichment Broth Base for EC 0157:H7	Low risk	22/04/2019
DCM	M1577	HiCrome™ Enterobacter sakazakii Agar	Low risk	22/04/2019
DCM	M1641	HiCrome Enterobacter sakazakii Agar, Modified	Low risk	22/04/2019
DCM	MV1577	HiCrome Enterobacter sakazakii HiVeg™ Agar	Low risk	22/04/2019
DCM	MV1641	HiCrome Enterobacter sakazakii HiVeg™ Agar, Modified	Low risk	22/04/2019
DCM	M1580	HiCrome™ Enterococcus faecium Agar Base	Low risk	25/08/2016
DCM	MCD1466	HiCrome [™] Improved Salmonella HiCynth [™] Agar	Low risk	12/08/2015

ЛА

Document ref.: DoC 2022 vs. 15

Page 14 of 130

DCM	M1569	HiCrome M-Lauryl Sulphate Agar	Low risk	22/04/2019
DCM	M1862	HiCrome M-Modified ECO157:H7 Selective Agar Base	Low risk	22/04/2019
DCM	M1571	HiCrome M-TEC Agar	Low risk	22/04/2019
DCM	M1713	HiCrome M-TEC Broth	Low risk	22/04/2019
DCM	M1985	HiCrome [™] Malassezia Agar	Low risk	20/12/2012
DCM	M1953R	HiCrome™ MeReSa Agar Base (Modified)	Low risk	25/08/2016
DCM	M1953	HiCrome™ MeReSa Agar Base (Modified)	Low risk	25/08/2016
DCM	M2010	HiCrome [™] Mueller Hinton Agar	Low risk	25/08/2016
DCM	M1974	HiCrome™ Rapid MRSA Agar Base	Low risk	20/12/2012
DCM	M1842	HiCrome Selective Salmonella Agar Base	Low risk	22/04/2019
DCM	M1353R	HiCrome™ UTI Agar	Low risk	25/08/2016
DCM	MCD1353	HiCrome™ UTI HiCynth™M Agar	Low risk	12/08/2015
DCM	MV1353R	HiCrome™ UTI HiVeg™ Agar	Low risk	25/08/2016
DCM	MV1682	HiCrome Vibrio HiVeg™ Agar	Low risk	22/04/2019
DCM	M2114	HiCrome™ C.auris (MDR) Selective Agar Base	Low risk	10/11/2020
DCM	M2020	HiCrome™ Campylobacter Agar Base	Low risk	16/12/2017
DCM	M1297A	HiCrome™ Candida Differential Agar	Low risk	20/12/2012
DCM	M1297AR	HiCrome™ Candida Differential Agar Base	Low risk	20/12/2012
DCM	M1456A	HiCrome™ Candida Differential Agar Base, Modified	Low risk	20/12/2012
DCM	MV1297A	HiCrome™ Candida Differential HiVeg™ Agar	Low risk	20/12/2012
DCM	MV1456A	HiCrome™ Candida Differential HiVeg™ Agar Base, Modified	Low risk	20/12/2012
DCM	M2099	HiCrome™ CarbaResist Agar Base	Low risk	22/04/2019
DCM	M1991I	HiCrome™ Chromogenic Coliform Agar (CCA)	Low risk	22/04/2019
DCM	M2026	HiCrome™ Clostridial Agar Base	Low risk	25/08/2016
DCM	M1300	HiCrome™ Coliform Agar w/ SLS	Low risk	22/04/2019
DCM	MCD1300	HiCrome™ Coliform HiCynth™ Agar w/ SLS	Low risk	10/11/2020
DCM	M2094	HiCrome™ Colistin Resistant Agar Base	Low risk	30/10/2018
DCM	M2062I	HiCrome™ Cronobacter Isolation Agar (CCI Agar)	Low risk	10/11/2020
DCM	M1295	HiCrome™ E. coli Agar	Low risk	22/04/2019
DCM	M1295I	HiCrome™ E. coli Agar	Low risk	22/04/2019
DCM	MCD1295	HiCrome™ E.coli HiCynth™ Agar	Low risk	22/04/2019
DCM	MCD1580	HiCrome™ E.faecium HiCynth™Agar Base	Low risk	25/08/2016
DCM	M1575A	HiCrome™ EC 0157 : H7 Selective Agar Base, Modified	Low risk	10/11/2020
DCM	MV1575A	HiCrome™ EC O157 : H7 Selective HiVeg™ Agar Base, Modified	Low risk	10/11/2020
DCM	MCD1575A	HiCrome™ EC 0157:H7 HiCynth™ Agar Base, Modified	Low risk	10/11/2020
DCM	M1574A	HiCrome™ EC O157:H7 Agar,Modified	Low risk	22/04/2019
DCM	M1293	HiCrome™ ECC Agar	Low risk	22/04/2019
DCM	M1294	HiCrome™ ECC Selective Agar Base	Low risk	22/04/2019
DCM	M2056	HiCrome™ ECC Selective Agar Base, Modified	Low risk	22/04/2019
DCM	M1488	HiCrome™ ECD Agar w/ MUG	Low risk	10/11/2020

	М	ED	
l i l			

Document ref.: DoC 2022 vs. 15

Page 15 of 130

DCM	MV1488	HiCrome™ ECD HiVeg™ Agar w/ MUG	Low risk	10/11/2020
DCM	MCD1598	HiCrome™ Enrichment HiCynth™ Broth Base for EC0157:H7	Low risk	10/11/2020
DCM	MCD1641	HiCrome™ Enterobacter sakazakii HiCynth™ Agar, Modified (HiCrome™ Cronobacter sakazakii HiCynth™ Agar, Modified)	Low risk	10/11/2020
DCM	M1376	HiCrome™ Enterococci Broth	Low risk	10/11/2020
DCM	MCD1376	HiCrome™ Enterococci HiCynth™ Broth	Low risk	10/11/2020
DCM	MV1376	HiCrome™ Enterococci HiVeg™ Broth	Low risk	10/11/2020
DCM	MV1580	HiCrome™ Enterococcus faecium HiVeg™ Agar Base	Low risk	10/11/2020
DCM	M1829	HiCrome™ ESBL Agar Base	Low risk	20/12/2012
DCM	M2128	HiCrome™ Haemophilus Agar Base	Low risk	17/06/2021
DCM	M1466	HiCrome™ Improved Salmonella Agar	Low risk	20/12/2012
DCM	MV1466	HiCrome™ Improved Salmonella HiVeg™ Agar	Low risk	20/12/2012
DCM	M1573	HiCrome™ Klebsiella Selective Agar Base	Low risk	10/11/2020
DCM	MV1573	HiCrome™ Klebsiella Selective HiVeg™ Agar Base	Low risk	10/11/2020
DCM	M1831	HiCrome™ KPC Agar Base	Low risk	20/12/2012
DCM	M2009	HiCrome™ L mono differential Agar Base	Low risk	10/11/2020
DCM	M1924	HiCrome™ L.mono Rapid Differential Agar Base	Low risk	10/11/2020
DCM	M2065	HiCrome™ Lactobacillus Selective Agar Base	Low risk	10/11/2020
DCM	M1417F	HiCrome™ Listeria Agar Base	Low risk	10/11/2020
DCM	M1417	HiCrome™ Listeria Agar Base, Modified	Low risk	10/11/2020
DCM	MCD1417	HiCrome™ Listeria HiCynth™ Agar Base, Modified	Low risk	10/11/2020
DCM	M1340	HiCrome™ MacConkey Sorbitol Agar Base	Low risk	20/12/2012
DCM	MCD1340	HiCrome™ MacConkey Sorbitol HiCynth™ Agar	Low risk	25/08/2016
DCM	M2058	HiCrome™ M-Coliconfirm Agar Base	Low risk	10/11/2020
DCM	M2064	HiCrome™ M-Coliconfirm Broth Base	Low risk	22/04/2019
DCM	M1674	HiCrome™ MeReSa Agar Base	Low risk	20/12/2012
DCM	MCD1674	HiCrome™ MeReSa HiCynth™ Agar Base	Low risk	25/08/2016
DCM	MV1674	HiCrome™ MeReSa HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1393	HiCrome™ MM Agar	Low risk	20/12/2012
DCM	M1816	HiCrome™ MM Agar , Modified	Low risk	04/07/2018
DCM	M1816R	HiCrome [™] MM Agar , Modified	Low risk	04/07/2018
DCM	MCD1816	HiCrome™ MM HiCynth™ Agar, Modified (Hicrome™ Miller and Mallinson HiCynth™ Agar)	Low risk	10/11/2020
DCM	MV1393	HiCrome™ MM HiVeg™ Agar	Low risk	20/12/2012
DCM	MCD1571	HiCrome™ M-TEC HiCynth™ Agar	Low risk	10/11/2020
DCM	MCD1713	HiCrome [™] M-TEC HiCynth [™] Broth	Low risk	10/11/2020
DCM	M2067	HiCrome™ Mueller Hinton Agar (for antifungal)	Low risk	16/12/2017
DCM	M1712	HiCrome [™] Nickels and Leesment Medium	Low risk	10/11/2020
DCM	MV1712	HiCrome™ Nickels & Leesment HiVeg™ Agar Base	Low risk	10/11/2020
DCM	MCD1633	HiCrome™ RajHans HiCynth™ Medium (Salmonella HiCynth™ Agar)	Low risk	25/08/2016

ΠП	IM		
		┛	

Document ref.: DoC 2022 vs. 15

Page 16 of 130

DCM	M1633	HiCrome™ RajHans Medium (Salmonella Agar)	Low risk	20/12/2012
DCM	M1634	HiCrome [™] RajHans Medium, Modified (Salmonella Agar, Modified)	Low risk	20/12/2012
DCM	M2011	HiCrome™ Rapid ECC Broth	Low risk	22/04/2019
DCM	MCD1974	HiCrome™ Rapid MRSA HiCynth™ Agar Base	Low risk	25/08/2016
DCM	M2116	HiCrome™ Salmoconfirm Selective Agar	Low risk	10/11/2020
DCM	M1296	HiCrome™ Salmonella Agar	Low risk	20/12/2012
DCM	MV1296	HiCrome™ Salmonella HiVeg™ Agar	Low risk	20/12/2012
DCM	MCD1842	HiCrome™ Selective Salmonella HiCynth™ Agar Base	Low risk	10/11/2020
DCM	M1837	HiCrome™ Staph Agar Base, Modified	Low risk	20/12/2012
DCM	M1931	HiCrome™ Staph Selective Agar	Low risk	10/11/2020
DCM	M2092	HiCrome™ STEC Agar Base	Low risk	30/10/2018
DCM	M1840	HiCrome™ Strep B Selective Agar Base	Low risk	04/07/2018
DCM	M1966	HiCrome™ Strep B Selective Agar Base, Modified	Low risk	20/12/2012
DCM	MCD1840	HiCrome™ Strep B Selective HiCynth™Agar Base	Low risk	04/07/2018
DCM	M1600	HiCrome™ Universal Differential Medium	Low risk	20/12/2012
DCM	MCD1418	HiCrome™ UTI HiCynth™ Agar, Modified	Low risk	25/08/2016
DCM	M1353	HiCrome™ UTI Agar	Low risk	20/12/2012
DCM	M1418	HiCrome™ UTI Agar, Modified	Low risk	20/12/2012
DCM	MV1353	HiCrome™ UTI HiVeg™ Agar	Low risk	20/12/2012
DCM	MV1418	HiCrome™ UTI HiVeg™ Agar, Modified	Low risk	20/12/2012
DCM	M1505	HiCrome™ UTI Selective Agar	Low risk	20/12/2012
DCM	MV1505	HiCrome™ UTI Selective HiVeg™ Agar	Low risk	20/12/2012
DCM	M1682	HiCrome™ Vibrio Agar	Low risk	22/04/2019
DCM	MCD1682	HiCrome™ Vibrio HiCynth™ Agar	Low risk	10/11/2020
DCM	M1830	HiCrome™ VRE Agar Base	Low risk	20/12/2012
DCM	M1925	HiCrome™ VRE Agar Base, Modified	Low risk	20/12/2012
DCM	M2025	HiCrome™ Yersinia Agar Base	Low risk	25/08/2016
DCM	M1951	HiCrome™M-Coliform Differential Agar Base	Low risk	22/04/2019
DCM	M2048	HiFast™ Listeria Enrichment Broth Base	Low risk	10/11/2020
DCM	M1469	HiFluoro Pseudomonas Agar Base	Low risk	20/12/2012
DCM	MV1469	HiFluoro Pseudomonas HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M2126	HiMRSA™ Confirmation Agar Base	Low risk	18/06/2021
DCM	M1218	High Salt Nutrient Agar	Low risk	20/12/2012
DCM	M1219	High Salt Peptone Yeast Extract Agar	Low risk	20/12/2012
DCM	M1054	Hippurate Hydrolysis Broth	Low risk	20/12/2012
DCM	M485	Hi-Sensitivity Test Agar	Low risk	20/12/2012
DCM	M486	Hi-Sensitivity Test Broth	Low risk	20/12/2012
DCM	MV485	Hi-Sensitivity Test HiVeg™ Agar	Low risk	20/12/2012
DCM	MV486	Hi-Sensitivity Test HiVeg™ Broth	Low risk	20/12/2012

IM		

Document ref.: DoC 2022 vs. 15

Page 17 of 130

DCM	M485A	HiSitest Agar	Low risk	20/12/2012
DCM	MV806	HiVeg™ Extract Agar	Low risk	20/12/2012
DCM	MV807	HiVeg™ Extract Broth	Low risk	20/12/2012
DCM	MV028	HiVeg™ Peptone Water	Low risk	20/12/2012
DCM	M806	HM Peptone B Agar	Low risk	20/12/2012
DCM	M807	HM Peptone B Broth	Low risk	20/12/2012
DCM	M924	Horie Arabinose Ethyl Violet Broth	Low risk	20/12/2012
DCM	M5385	Horse Blood agar	Low risk	30/10/2018
DCM	M1425	Hottinger Broth	Low risk	20/12/2012
DCM	MV015	Hoyle HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M015	Hoyle Medium Base	Low risk	20/12/2012
DCM	MV871	Hugh Leifson Glucose HiVeg™ Medium	Low risk	20/12/2012
DCM	M871	Hugh Leifson Glucose Medium	Low risk	20/12/2012
DCM	MV826	Hugh Leifson HiVeg™ Medium	Low risk	20/12/2012
DCM	M826	Hugh Leifson Medium	Low risk	20/12/2012
DCM	M826S	Hugh Leifson Medium	Low risk	20/12/2012
DCM	MV364	Indole Nitrate HiVeg™ Medium (Tryptone Nitrate HiVeg™ Medium)	Low risk	20/12/2012
DCM	M364	Indole Nitrate Medium (Tryptone Nitrate Medium)	Low risk	20/12/2012
DCM	M574	Inositol Brilliant Green Bile Agar (Plesiomonas Differential Agar)	Low risk	20/12/2012
DCM	MV574	Inositol Brilliant Green HiVeg™ Agar (Plesiomonas Differential HiVeg™ Agar)	Low risk	20/12/2012
DCM	M1222	Karmali Campylobacter Agar Base	Low risk	10/11/2020
DCM	M248	KF Streptococcal Agar Base	Low risk	22/04/2019
DCM	M249	KF Streptococcal Broth Base	Low risk	20/12/2012
DCM	MV248	KF Streptococcal HiVeg Agar Base	Low risk	22/04/2019
DCM	MV249	KF Streptococcal HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1007	KF Streptococcus Agar Base w/ BCP	Low risk	20/12/2012
DCM	M1021	KF Streptococcus Broth Base w/ BCP	Low risk	20/12/2012
DCM	MV1021	KF Streptococcus HiVeg™ Broth Base w/ BCP	Low risk	20/12/2012
DCM	M1232	Kimmig Fungi Agar Base	Low risk	20/12/2012
DCM	MV1232	Kimmig Fungi HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1543	King's Medium A Base	Low risk	20/12/2012
DCM	M1235	King's OF Medium Base	Low risk	20/12/2012
DCM	MV1235	Kings OF Medium Base, HiVeg™	Low risk	20/12/2012
DCM	M2040	Kirchner Medium Base	Low risk	28/04/2017
DCM	M161	Kirchner Medium Base, Modified	Low risk	20/12/2012
DCM	M078	Kligler Iron Agar	Low risk	20/12/2012
DCM	M078I	Kligler Iron Agar	Low risk	20/12/2012
DCM	M078A	Kligler Iron Agar, Modified	Low risk	20/12/2012
DCM	MCD078	Kligler Iron HiCynth™ Agar	Low risk	12/08/2015

hatt		

Document ref.: DoC 2022 vs. 15

Page 18 of 130

DCM	MV078	Kligler Iron HiVeg™ Agar	Low risk	20/12/2012
DCM	MV142	Kohn Two Tube HiVeg™ Medium No.1 Base	Low risk	20/12/2012
DCM	MV802	Kohn Two Tube HiVeg™ Medium No.2	Low risk	20/12/2012
DCM	M142	Kohn Two Tube Medium No.1 Base	Low risk	20/12/2012
DCM	M802	Kohn Two Tube Medium No.2	Low risk	20/12/2012
DCM	M069	Koser Citrate Medium	Low risk	20/12/2012
DCM	MV171	Kracke Blood Culture HiVeg™ Medium	Low risk	20/12/2012
DCM	M171	Kracke Blood Culture Medium	Low risk	20/12/2012
DCM	M305	Kupferberg Trichomonas Broth Base (Trichomonas Broth Base, Kupferberg)	Low risk	20/12/2012
DCM	MV305	Kupferberg Trichomonas HiVeg™ Broth Base (Trichomonas HiVeg™ Broth Base, Kupferberg)	Low risk	20/12/2012
DCM	M928	L Broth	Low risk	20/12/2012
DCM	M1312	L Broth, Modified	Low risk	20/12/2012
DCM	M162R	L J Medium Base, Modified (Lowenstein Jensen Medium Base, Modified)	Low risk	25/08/2016
DCM	M1552	L. mono Confirmatory Agar Base	Low risk	20/12/2012
DCM	MV1552	L. mono Confirmatory HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M742	L.D. Agar	Low risk	20/12/2012
DCM	M744	L.D. Egg Yolk Agar Base	Low risk	20/12/2012
DCM	M743	L.D. Esculin Agar	Low risk	20/12/2012
DCM	MV743	L.D. Esculin HiVeg™ Agar	Low risk	20/12/2012
DCM	MV742	L.D. HiVeg™ Agar	Low risk	20/12/2012
DCM	M1540	L.mono Differential Agar Base	Low risk	22/04/2019
DCM	M1540I	HiCrome™ Listeria Ottaviani-Agosti Agar Base	Low risk	10/11/2020
DCM	M1540IR	L.mono Differential Agar Base	Low risk	10/11/2020
DCM	MCD1540	L.mono Differential HiCynth™ Agar Base	Low risk	22/04/2019
DCM	MV1540	L.mono Differential HiVeg™ Agar Base	Low risk	22/04/2019
DCM	M926	Lactic Streak Agar (Reddy's Differential Agar, Modified)	Low risk	20/12/2012
DCM	MV926	Lactic Streak HiVeg™ Agar	Low risk	20/12/2012
DCM	MV368	Lactobacilli HiVeg™Broth (Elliker HiVeg™ Broth)	Low risk	20/12/2012
DCM	M927	Lactobacillus Bulgaricus Agar Base	Low risk	20/12/2012
DCM	MV927	Lactobacillus Bulgaricus HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M641	Lactobacillus MRS Agar (MRS Agar)	Low risk	20/12/2012
DCM	M641I	Lactobacillus MRS Agar (MRS Agar)	Low risk	20/12/2012
DCM	M369	Lactobacillus MRS Broth (MRS Broth)	Low risk	20/12/2012
DCM	MV641	Lactobacillus MRS HiVeg™ Agar (MRS HiVeg™ Agar)	Low risk	20/12/2012
DCM	MV369	Lactobacillus MRS HiVeg™ Broth (MRS HiVeg™ Broth)	Low risk	20/12/2012
DCM	M1165	Lactobacillus Selection Bile Agar Base (LBS Bile Agar)	Low risk	20/12/2012
DCM	M1081	Lactose Blue Agar (B.T.B. Lactose Agar, Modified)	Low risk	20/12/2012
DCM	MV1081	Lactose Blue HiVeg™ Agar (B.T.B. Lactose HiVeg™ Agar, Modified)	Low risk	20/12/2012

ТМ	

Document ref.: DoC 2022 vs. 15

Page 19 of 130

DCM	M1003	Lactose Broth	Low risk	22/04/2019
DCM	MV1003	Lactose HiVeg™ Broth	Low risk	22/04/2019
DCM	M1047	Lactose Lecithin Agar	Low risk	04/07/2018
DCM	M080	Lauryl Sulphate Broth (Lauryl Tryptose Broth)	Low risk	22/04/2019
DCM	MV080	Lauryl SulphateHiVeg™ Broth (Lauryl Tryptose HiVeg™ Broth)	Low risk	22/04/2019
DCM	M180	Lead Acetate Agar	Low risk	10/11/2020
DCM	M1839	Leeds Acinetobacter Agar Base	Low risk	20/12/2012
DCM	M1938R	Leeds Acinetobacter Agar Base (HiCrome™ Acinetobacter Agar Base)	Low risk	25/08/2016
DCM	M1845	Legionella Agar Base w/o Charcoal	Low risk	10/11/2020
DCM	M1380	Leifson Agar	Low risk	20/12/2012
DCM	MV1380	Leifson HiVeg™ Agar	Low risk	20/12/2012
DCM	M1138	Leifson's Deoxycholate Agar, Modified	Low risk	20/12/2012
DCM	MV1138	Leifson's Deoxycholate HiVeg™ Agar, Modified	Low risk	20/12/2012
DCM	MV239	Leptospira HiVeg™ Medium Base, Fletcher (Fletcher Leptospira HiVeg™ Medium Base)	Low risk	20/12/2012
DCM	MV457	Leptospira HiVeg [™] Medium Base, Korthof, Modified	Low risk	20/12/2012
DCM	M1009	Leptospira Medium Base	Low risk	20/12/2012
DCM	M239	Leptospira Medium Base, Fletcher (Fletcher Leptospira Medium Base)	Low risk	20/12/2012
DCM	M457	Leptospira Medium Base, Korthof, Modified	Low risk	20/12/2012
DCM	MV472	Levinthal's HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M472	Levinthal's Medium Base	Low risk	20/12/2012
DCM	M374	LI Agar	Low risk	20/12/2012
DCM	MV374	LI Agar, HiVeg™	Low risk	20/12/2012
DCM	M153	LI Broth	Low risk	20/12/2012
DCM	MV153	LI Broth, HiVeg™	Low risk	20/12/2012
DCM	M627	Lipovitellin Salt Mannitol Agar Base	Low risk	20/12/2012
DCM	M817	Liquoid Broth	Low risk	20/12/2012
DCM	MV817	Liquoid HiVeg™ Broth	Low risk	20/12/2012
DCM	M569	Listeria Enrichment Broth (Twin Pack)	Low risk	20/12/2012
DCM	MV569	Listeria Enrichment HiVeg™ Broth (Twin Pack)	Low risk	20/12/2012
DCM	MV890A	Listeria Enrichment HiVeg™ Medium Base (UVM)	Low risk	20/12/2012
DCM	M890A	Listeria Enrichment Medium Base (UVM)	Low risk	20/12/2012
DCM	M1064	Listeria Identification Agar Base (PALCAM)	Low risk	22/04/2019
DCM	M1090	Listeria Identification Broth Base (PALCAM)	Low risk	22/04/2019
DCM	MV1064	Listeria Identification HiVeg Agar Base (PALCAM)	Low risk	22/04/2019
DCM	MV1090	Listeria Identification HiVeg Broth Base (PALCAM)	Low risk	22/04/2019
DCM	MCD1145	Listeria Oxford HiCynth™ Medium Base	Low risk	25/08/2016
DCM	MV1145	Listeria Oxford HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M1145R	Listeria Oxford Medium Base	Low risk	25/08/2016

	ED	

Document ref.: DoC 2022 vs. 15

Page 20 of 130

DCM	M1145	Listeria Oxford Medium Base	Low risk	20/12/2012
DCM	M1781	Listeria Oxford Medium Base, Modified	Low risk	20/12/2012
DCM	M567	Listeria Selective Agar (Twin Pack)	Low risk	20/12/2012
DCM	M1474	Listeria Selective Agar Base	Low risk	20/12/2012
DCM	M889	Listeria Selective Broth Base	Low risk	20/12/2012
DCM	M1865	Listeria Selective Enrichment Broth	Low risk	22/04/2019
DCM	MV567	Listeria Selective HiVeg™ Agar (Twin Pack)	Low risk	20/12/2012
DCM	MV889	Listeria Selective HiVeg [™] Broth Base	Low risk	20/12/2012
DCM	M507	Litmus Lactose Bile Salt Agar (LLBSA)	Low risk	10/11/2020
DCM	MV507	Litmus Lactose HiVeg™ Agar	Low risk	10/11/2020
DCM	M373	Littman Bile Agar Base	Low risk	20/12/2012
DCM	M663	Littman Bile Broth Base	Low risk	20/12/2012
DCM	MV373	Littman HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV663	Littman HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1001	LM Agar	Low risk	20/12/2012
DCM	M1934	LM Agar, Modified	Low risk	20/12/2012
DCM	MV537	Loeffler HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M537	Loeffler Medium Base	Low risk	20/12/2012
DCM	M1189	Loeffler Serum Medium Base	Low risk	20/12/2012
DCM	MM162	Lowenstein - Jensen Medium (L.J. Medium) (Twin Pack)	Low risk	20/12/2012
DCM	M162R	Lowenstein Jensen Medium Base, Modified (L J Medium Base, Modified)	Low risk	25/08/2016
DCM	M162	Lowenstein Jensen Medium Base (L.J. Medium)	Low risk	20/12/2012
DCM	M1542	Lowenstein Jensen Medium Base w/o Starch	Low risk	20/12/2012
DCM	M2032	Lowenstein Jensen Medium Base, Modified	Low risk	25/08/2016
DCM	M176	LV Agar (Liver Veal Agar)	Low risk	10/11/2020
DCM	M1977	Lysine Indole Motility Medium, Modified	Low risk	10/11/2020
DCM	MH081	MacConkey Agar	Low risk	22/04/2019
DCM	M1024	MacConkey Agar Base	Low risk	20/12/2012
DCM	M1819	MacConkey Agar II w/o CV	Low risk	20/12/2012
DCM	M008E	MacConkey Agar Medium	Low risk	20/12/2012
DCM	M081	MacConkey Agar w/ 0.15% Bile Salts, CV and NaCl	Low risk	20/12/2012
DCM	M061	MacConkey Agar w/ Bromo Thymol Blue	Low risk	20/12/2012
DCM	M1582	MacConkey Agar w/ CV and w/o NaCl	Low risk	20/12/2012
DCM	M081A	MacConkey Agar w/ CV, NaCl, and 0.15% Bile Salts	Low risk	20/12/2012
DCM	M008	MacConkey Agar w/o CV w/ 0.15% Bile Salts	Low risk	20/12/2012
DCM	M082A	MacConkey Agar w/o CV, NaCl w/ 0.5% Bile Salts	Low risk	20/12/2012
DCM	M082	MacConkey Agar w/o CV, NaCl w/ 0.5% Sodium Taurocholate	Low risk	20/12/2012
DCM	M008A	MacConkey Agar w/o CV, w/ 0.5% Bile Salts	Low risk	20/12/2012
DCM	M008B	MacConkey Agar w/o CV, w/ 1.2% Agar	Low risk	20/12/2012

IM		

Document ref.: DoC 2022 vs. 15

Page 21 of 130

DCM	M1785	MacConkey Agar w/o CV, w/0.5% Sodium Taurocholate	Low risk	20/12/201
DCM	M1702	MacConkey Agar, RS	Low risk	20/12/201
DCM	MH083	MacConkey Broth	Low risk	22/04/201
DCM	M083	MacConkey Broth Purple w/BCP	Low risk	22/04/201
DCM	MCD081	MacConkey HiCynth™ Agar w/ 0.15% Bile Salts	Low risk	25/08/201
DCM	MCD082	MacConkey HiCynth™ Agar w/o CV, NaCl	Low risk	25/08/201
DCM	MV1024	MacConkey HiVeg™ Agar Base	Low risk	20/12/201
DCM	MV061	MacConkey HiVeg™ Agar w/ Bromo Thymol Blue	Low risk	20/12/201
DCM	MV081	MacConkey HiVeg™ Agar w/ CV, NaCl, 0.003% NR and 1.5% Agar	Low risk	20/12/201
DCM	MV081A	MacConkey HiVeg™ Agar w/ CV, NaCl, 0.005% NR and 1.5% Agar	Low risk	20/12/201
DCM	MV082	MacConkey HiVeg™ Agar w/o CV and NaCl, w/ 0.004% NR and 2.0% Agar	Low risk	20/12/201
DCM	MV082A	MacConkey HiVeg™ Agar w/o CV and NaCl, w/ 0.0075% NR and 1.2% Agar	Low risk	20/12/201
DCM	MV008B	MacConkey HiVeg [™] Agar w/o CV, w/ 0.003% NR and 1.2% Agar	Low risk	20/12/201
DCM	MV008	MacConkey HiVeg [™] Agar w/o CV, w/ 0.003% NR and 1.5% Agar	Low risk	20/12/201
DCM	MV008A	MacConkey HiVeg [™] Agar w/o CV, w/ 0.0075% NR and 1.2% Agar	Low risk	20/12/202
DCM	MV083	MacConkey HiVeg™ Broth Purple w/ BCP	Low risk	22/04/203
DCM	M298	MacConkey Sorbitol Agar (Sorbitol Agar)	Low risk	20/12/20:
DCM	M298I	MacConkey Sorbitol Agar Base	Low risk	20/12/20:
DCM	M1727R	MacConkey Sorbitol Agar Base (w/ Rhamnose)	Low risk	25/08/202
DCM	M1727	MacConkey Sorbitol Agar Base w/ Rhamnose	Low risk	20/12/20:
DCM	MCD298	MacConkey Sorbitol HiCynth™ Agar (Sorbitol HiCynth™ Agar)	Low risk	28/04/202
DCM	MV298	MacConkey Sorbitol HiVeg™ Agar (Sorbitol HiVeg™Agar)	Low risk	20/12/20:
DCM	M2074	MacConkey Sorbitol Rhamnose Selective Agar Base	Low risk	16/12/202
DCM	M382	Malonate Broth	Low risk	25/08/202
DCM	M137	Malt Extract Agar Base (w/ Mycological Peptone)	Low risk	20/12/20
DCM	M995	Malt Extract Agar Base, Modified as per Thom and Church	Low risk	20/12/20:
DCM	M255	Malt Extract Broth Base	Low risk	20/12/202
DCM	M1128	Malt Extract Broth, Modified as per Thom and Church	Low risk	20/12/20
DCM	MV137	Malt Extract HiVeg™ Agar Base	Low risk	20/12/202
DCM	MV995	Malt Extract HiVeg™ Agar Base, Modified	Low risk	20/12/20:
DCM	MV255	Malt Extract HiVeg™ Broth Base	Low risk	20/12/20:
DCM	M1967	Malt Yeast Agar	Low risk	20/12/20
DCM	M1624	Mannitol Agar w/Prilion	Low risk	20/12/20
DCM	M1071	Mannitol Lysine Agar	Low risk	20/12/20
DCM	MCD1071	Mannitol Lysine HiCynth™Agar	Low risk	25/08/20:
DCM	M1320	Mannitol Motility Nitrate Medium	Low risk	20/12/20
DCM	MV770	Mannitol Motility Test HiVeg™ Medium	Low risk	20/12/20
DCM	M770	Mannitol Motility Test Medium	Low risk	20/12/20
DCM	MH118	Mannitol Salt Agar	Low risk	22/04/203

IM	ED	

Document ref.: DoC 2022 vs. 15

Page 22 of 130

DCM	M118	Mannitol Salt Agar Base	Low risk	20/12/2012
DCM	M383	Mannitol Salt Broth	Low risk	20/12/2012
DCM	MCD118	Mannitol Salt HiCynth™ Agar Base	Low risk	12/08/2015
DCM	MV118	Mannitol Salt HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV383	Mannitol Salt HiVeg™ Broth	Low risk	20/12/2012
DCM	M1534	Mannitol Selenite Broth (Selenite Mannitol Broth) (Twin Pack)	Low risk	20/12/2012
DCM	M1537	Mannitol Selenite Broth w/Brilliant Green (Twin Pack)	Low risk	04/07/201
DCM	MV379	Marine Oxidation Fermentation HiVeg [™] Medium	Low risk	20/12/201
DCM	M379	Marine Oxidation Fermentation Medium	Low risk	20/12/201
DCM	M2085	Martin Lewis Agar Base	Low risk	22/04/201
DCM	M1030	Maximum Recovery Diluent	Low risk	22/04/201
DCM	MV1030	Maximum Recovery Diluent HiVeg™	Low risk	22/04/201
DCM	M386	McBride Listeria Agar Base	Low risk	20/12/201
DCM	MV386	McBride Listeria HiVeg™ Agar Base	Low risk	20/12/201
DCM	M1354	M-CP Agar Base	Low risk	10/11/202
DCM	MV1354	M-CP HiVeg™Agar Base	Low risk	10/11/202
DCM	M1426	M-E.coli Broth	Low risk	22/04/201
DCM	M1594	MeReSa Agar Base	Low risk	20/12/201
DCM	M1974R	MeReSa Agar Base (HiCrome™ Rapid MRSA Agar)	Low risk	25/08/201
DCM	M1812	M-FC Basal Medium	Low risk	10/11/202
DCM	M199	Middlebrook 7H10 Agar Base	Low risk	20/12/201
DCM	M196	Middlebrook 7H10 Agar Base, Special	Low risk	20/12/201
DCM	M511	Middlebrook 7H11 Agar Base	Low risk	20/12/201
DCM	M511A	Middlebrook 7H11 Agar Base w/o Malachite Green	Low risk	20/12/201
DCM	MV511	Middlebrook 7H11 HiVeg™ Agar Base	Low risk	20/12/201
DCM	M197	Middlebrook 7H9 Agar Base	Low risk	20/12/201
DCM	M198	Middlebrook 7H9 Broth Base	Low risk	20/12/201
DCM	M259	Mitis Salivarius Agar Base	Low risk	20/12/201
DCM	MV259	Mitis Salivarius HiVeg™ Agar Base	Low risk	20/12/201
DCM	M5319	Modified B.Q. Vaccine Medium	Low risk	28/04/201
DCM	M1150	Modified Bile Esculin Azide Agar	Low risk	20/12/201
DCM	M892	Modified Buffered Charcoal Agar Base	Low risk	20/12/201
DCM	MV892	Modified Buffered Charcoal HiVeg™ Agar Base	Low risk	20/12/201
DCM	M1660	Modified Cary-Blair Medium	Low risk	20/12/201
DCM	MV460	Modified CPLM HiVeg [™] Medium Base (Trichomonas Modified CPLM HiVeg [™] Medium Base)	Low risk	20/12/201
DCM	M460	Modified CPLM Medium Base (Trichomonas Modified CPLM Medium Base)	Low risk	20/12/201
DCM	M1170	Modified Czapek Dox Agar	Low risk	20/12/201
DCM	M1285	Modified EC Broth Base	Low risk	20/12/201
DCM	M1445	Modified Lactobacillus Agar	Low risk	20/12/201

ΠT		

Document ref.: DoC 2022 vs. 15

Page 23 of 130

DCM	M1643	Modified Lauryl Sulphate Tryptose Broth Base	Low risk	20/12/2012
DCM	M1457R	Modified Listeria Lecithinase Agar Base	Low risk	25/08/2016
DCM	M1897	Modified Listeria Oxford Agar Base	Low risk	25/11/2017
DCM	M891	Modified McBride Listeria Agar Base	Low risk	20/12/2012
DCM	MV891	Modified McBride Listeria HiVeg™M Agar Base	Low risk	20/12/2012
DCM	M1139	Modified MYP Agar Base	Low risk	20/12/2012
DCM	MV1139	Modified MYP HiVeg [™] Agar Base	Low risk	20/12/2012
DCM	M1606	Modified Protease Agar	Low risk	20/12/2012
DCM	M1681	Modified Sabourauds Chloramphenicol Agar	Low risk	20/12/2012
DCM	M1068	Modified Salt Broth	Low risk	20/12/2012
DCM	M2049	Modified Shieh Agar (LMG Medium 215)	Low risk	28/04/2017
DCM	M1286I	Modified Soyabean Bile Broth Base	Low risk	22/04/2019
DCM	M795	Modified Thayer Martin Medium Base (w/o Supplement)	Low risk	20/12/2012
DCM	M393	Moeller Decarboxylase Broth Base (Decarboxylase Broth Base, Moeller)	Low risk	25/08/2016
DCM	MCD393	Moeller Decarboxylase HiCynth™ Broth Bas	Low risk	25/08/2016
DCM	M246	Mold Inhibitory Agar, Ulrich	Low risk	20/12/2012
DCM	M474	Monsur Medium Base	Low risk	20/12/2012
DCM	M1927	MRS Agar w/ Low pH	Low risk	10/11/2020
DCM	M1864	MSM Broth Base	Low risk	20/12/2012
DCM	M173	Mueller Hinton Agar	Low risk	20/12/2012
DCM	M1825	Mueller Hinton Agar 2% Glucose w/ Methylene blue	Low risk	20/12/2012
DCM	M1825R	Mueller Hinton Agar Modified (As per CLSI)	Low risk	25/08/2016
DCM	M1084	Mueller Hinton Agar No. 2	Low risk	20/12/2012
DCM	M5389	Mueller Hinton Agar w/ 2% NaCL	Low risk	30/10/2018
DCM	M391	Mueller Hinton Broth	Low risk	20/12/2012
DCM	M1657	Mueller Hinton Broth No. 2 Control Cations	Low risk	20/12/2012
DCM	MV173	Mueller Hinton HiVeg™ Agar	Low risk	20/12/2012
DCM	MV1084	Mueller Hinton HiVeg™ Agar No. 2	Low risk	20/12/2012
DCM	MV391	Mueller Hinton HiVeg™ Broth	Low risk	20/12/2012
DCM	M1202	Mueller Tellurite Agar Base	Low risk	20/12/2012
DCM	M1373	MUG EC 0157 Agar	Low risk	16/12/2017
DCM	M1429	MUG EC 0157 Agar, Modified	Low risk	20/12/2012
DCM	M1080	MUG MacConkey Agar	Low risk	20/12/2012
DCM	MV1080	MUG MacConkey HiVeg™ Agar	Low risk	20/12/2012
DCM	M1205	MUG Sorbitol Agar	Low risk	20/12/2012
DCM	M977	Mutans-Sanguis Agar	Low risk	20/12/2012
DCM	M094	Mycological Agar	Low risk	20/12/2012
DCM	M095	Mycological Agar w/ Low pH	Low risk	20/12/2012
DCM	M1422	Mycological Agar, Modified	Low risk	20/12/2012

М	ED	

Document ref.: DoC 2022 vs. 15

Page 24 of 130

DCM	M264	Mycological Broth	Low risk	20/12/2012
DCM	M265	Mycological Broth w/ Low pH	Low risk	20/12/2012
DCM	M266	Mycoplasma Agar Base (PPLO Agar Base)	Low risk	20/12/2012
DCM	M268	Mycoplasma Broth Base w/ CV (PPLO Broth Base w/ CV)	Low risk	20/12/2012
DCM	M267	Mycoplasma Broth Base w/o CV (PPLO Broth Base w/o CV)	Low risk	20/12/2012
DCM	M1498	Mycoplasma Cultivation Broth Base	Low risk	20/12/2012
DCM	MV266	Mycoplasma HiVeg™ Agar Base (PPLO HiVeg™ Agar Base)	Low risk	20/12/2012
DCM	MV268	Mycoplasma HiVeg [™] Broth Base w/ CV (PPLO HiVeg [™] Broth Base w/ CV)	Low risk	20/12/2012
DCM	MV267	Mycoplasma HiVeg™ Broth Base w/o CV (PPLO HiVeg™ Broth Base w/o CV)	Low risk	20/12/2012
DCM	MV624	Mycoplasma Synoviae HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M624	Mycoplasma Synoviae Medium Base	Low risk	20/12/2012
DCM	M1374	Mycoplasma Urogenital Broth Base (Urogenital Mycoplasma Broth Base)	Low risk	20/12/2012
DCM	M636	MYP Agar Base (Phenol Red Egg Yolk Polymyxin Agar Base)	Low risk	20/12/2012
DCM	MCD636	MYP HiCynth™ Agar Base (Phenol Red Egg Yolk Polymyxin HiCynth™ Agar Base	Low risk	28/04/2017
DCM	MV636	MYP HiVeg™ Agar Base (Phenol Red Polymyxin HiVeg™ Agar Base)	Low risk	20/12/2012
DCM	MV217	Nickerson HiVeg [™] Medium (Bi.G.G.Y. HiVeg [™] Agar)	Low risk	20/12/2012
DCM	M217	Nickerson Medium (Bi.G.G.Y. Agar)	Low risk	20/12/2012
DCM	M072	Nitrate Agar	Low risk	10/11/2020
DCM	MV072	Nitrate HiVeg™ Agar	Low risk	10/11/2020
DCM	M681	NNN Modified Medium (Twin Pack)	Low risk	10/11/2020
DCM	M001	Nutrient Agar	Low risk	20/12/2012
DCM	M001A	Nutrient Agar	Low risk	20/12/2012
DCM	M087	Nutrient Agar 1.5%	Low risk	20/12/2012
DCM	M1269	Nutrient Agar No.2	Low risk	20/12/2012
DCM	M012	Nutrient Agar w/ 1% Peptone	Low risk	20/12/2012
DCM	M561	Nutrient Agar, pH 6.8	Low risk	20/12/2012
DCM	M002	Nutrient Broth	Low risk	20/12/2012
DCM	M1362	Nutrient Broth No. 2	Low risk	20/12/2012
DCM	M1902	Nutrient Broth No.3	Low risk	20/12/2012
DCM	M060	Nutrient Gelatin	Low risk	20/12/2012
DCM	MCD001	Nutrient HiCynth™ Agar	Low risk	12/08/2015
DCM	MCD002	Nutrient HiCynth™ Broth	Low risk	12/08/2015
DCM	MV001	Nutrient HiVeg™ Agar	Low risk	20/12/2012
DCM	MV087	Nutrient HiVeg™ Agar 1.5%	Low risk	20/12/2012
DCM	MV1269	Nutrient HiVeg™ Agar No.2	Low risk	20/12/2012
DCM	MV012	Nutrient HiVeg™ Agar w/ 1% HiVeg™ Peptone	Low risk	20/12/2012
DCM	MV561	Nutrient HiVeg™ Agar, pH 6.8	Low risk	20/12/2012

IM		

Document ref.: DoC 2022 vs. 15

Page 25 of 130

DCM	MV002	Nutrient HiVeg™ Broth	Low risk	20/12/2012
DCM	M1348	NYC Agar Base	Low risk	20/12/2012
DCM	MCD395	OF Basal HiCynth™ Medium	Low risk	25/08/2016
DCM	MV395	OF Basal HiVeg™ Medium	Low risk	20/12/2012
DCM	M395	OF Basal Medium	Low risk	20/12/2012
DCM	M1811	OFPBL Agar Base (Oxidation Fermentation Polymyxin Bacitracin Lactose Agar Base)	Low risk	20/12/2012
DCM	M1930	ONPG BROTH	Low risk	20/12/2012
DCM	M933	Orange Serum Agar	Low risk	22/04/2019
DCM	MV933	Orange SerumHiVeg [™] Agar	Low risk	22/04/2019
DCM	M1454	Oxacillin Resistance Screening Agar Base	Low risk	20/12/2012
DCM	M1390	Pagano Levin Base	Low risk	20/12/2012
DCM	M867	Peizer TB Medium Base	Low risk	20/12/2012
DCM	M1207	Pepted M Broth	Low risk	20/12/2012
DCM	M028	Peptone Water	Low risk	20/12/2012
DCM	MCD837	Perfringens HiCynth™ Agar Base (T.S.C/S.F.P HiCynth™ Agar Base)	Low risk	28/04/2017
DCM	MV837	Perfringens HiVeg™ Agar Base (T.S.C/S.F.P HiCynth™ Agar Base)	Low risk	28/04/2017
DCM	M269A	Phenylethanol Agar Base	Low risk	20/12/2012
DCM	M269	Phenylethyl Alcohol Agar Base	Low risk	20/12/2012
DCM	MV269	Phenylethyl Alcohol HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M540	Phenylethyl Blood Agar Base (Anaerobic)	Low risk	20/12/2012
DCM	M1866	Phosphate Buffered Saline (PBS) pH 7.4	Low risk	22/04/2019
DCM	M519	Pike Streptococcal Broth Base	Low risk	20/12/2012
DCM	MV519	Pike Streptococcal HiVeg [™] Broth Base	Low risk	20/12/2012
DCM	M282	PKU Test Agar Base	Low risk	20/12/2012
DCM	M398	PKU Test Agar w/ Thienylalanine	Low risk	20/12/2012
DCM	M091	Plate Count Agar (Standard Methods Agar)	Low risk	28/04/2017
DCM	MCD091	Plate Count HiCynth™Agar (Standard Methods HiCynth™ Agar)	Low risk	28/04/2017
DCM	MV091	Plate Count HiVeg™ Agar (Standard Methods HiVeg™ Agar)	Low risk	28/04/2017
DCM	M574	Plesiomonas Differential Agar (Inositol Brilliant Green Bile Agar)	Low risk	20/12/2012
DCM	MV574	Plesiomonas Differential HiVeg™ Agar (Inositol Brilliant Green HiVeg™ Agar)	Low risk	20/12/2012
DCM	M1446	PLET Agar Base	Low risk	20/12/2012
DCM	M1451	PLET Agar Base, Modified	Low risk	20/12/2012
DCM	M835	PNY Medium	Low risk	20/12/2012
DCM	MH096	Potato Dextrose Agar	Low risk	22/04/2019
DCM	M096	Potato Dextrose Agar	Low risk	22/04/2019
DCM	M5391	PPLO Agar Base	Low risk	30/10/2018
DCM	M1586	PPLO Modified Broth Base w/o CV	Low risk	20/12/2012

ниеріл	Declaration of Conformity	Document ref.: DoC 2022 vs. 15
	Microbiology Products	Page 26 of 130

DCM	M899	Preston Enrichment Broth Base (Campylobacter Enrichment Broth Base)	Low risk	20/12/2012
DCM	MV899	Preston Enrichment HiVeg™ Broth Base (Campylobacter Enrichment HiVeg™ Broth Base)	Low risk	20/12/2012
DCM	M956	Propionibacter Isolation Agar Base	Low risk	20/12/2012
DCM	M1697	Proskauer Beck medium	Low risk	20/12/2012
DCM	M085	Pseudomonas Agar Base	Low risk	22/04/2019
DCM	MV085	Pseudomonas HiVeg Agar Base	Low risk	22/04/2019
DCM	M406	Pseudomonas Isolation Agar Base	Low risk	20/12/2012
DCM	MCD406	Pseudomonas Isolation HiCynth™ Agar	Low risk	25/08/2016
DCM	MV406	Pseudomonas Isolation HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1489	PYR Agar	Low risk	10/11/2020
DCM	M1743	R2A Agar, Modified	Low risk	22/04/2019
DCM	MV1078	RajHans HiVeg™ Medium (Salmonella Differential HiVeg™ Agar) (Twin Pack)	Low risk	20/12/2012
DCM	M1078	RajHans Medium (Salmonella Differential Agar) (Twin Pack)	Low risk	20/12/2012
DCM	M1453A	Rapid HiColiform Broth w/Tryptophan	Low risk	22/04/2019
DCM	MCD1465	Rapid HiColiform HiCynth™ Agar	Low risk	10/11/2020
DCM	M1465	Rapid HiColiform™ Agar	Low risk	10/11/2020
DCM	MV1465	Rapid HiColiform™ HiVeg™ Agar	Low risk	10/11/202
DCM	MCD1491	Rappaport Vassiliadis HiCynth™ Broth	Low risk	12/08/201
DCM	M1530	Rappaport Vassiliadis R10 Medium	Low risk	20/12/2012
DCM	MH1491	Rappaport Vassiliadis Salmonella Enrichment Broth	Low risk	22/04/2019
DCM	M1491	Rappaport Vassiliadis Soya Broth (RVS Broth)	Low risk	20/12/201
DCM	M1448	Rappaport Vassiliadis Soyabean Meal Broth (RVSM)	Low risk	20/12/201
DCM	MH443	Reinforced Medium for Clostridia	Low risk	22/04/201
DCM	M1626	Reuter's Sorbic Acid Agar Base	Low risk	20/12/201
DCM	M459	Robinson Medium for Entamoeba (Twin Pack)	Low risk	20/12/2012
DCM	M149	Robinson'c Cooked M Medium (R.C. Medium)	Low risk	16/12/201
DCM	M1899	Rogosa Agar, Modified	Low risk	20/12/2012
DCM	M130	Rogosa SL Agar	Low risk	20/12/2012
DCM	M958	Rogosa SL Agar w/ 0.15% Bile	Low risk	20/12/2012
DCM	M407	Rogosa SL Broth	Low risk	20/12/2012
DCM	MCD130	Rogosa SL HiCynth™ Agar	Low risk	28/04/201
DCM	MV130	Rogosa SL HiVeg™ Agar	Low risk	20/12/2012
DCM	MV407	Rogosa SL HiVeg™ Broth	Low risk	20/12/2012
DCM	M842	Rose Bengal Agar Base	Low risk	20/12/2012
DCM	M640	Rose Bengal Chloramphenicol Agar	Low risk	22/04/201
DCM	MV640	Rose Bengal Chloramphenicol HiVeg [™] Agar	Low risk	22/04/201
DCM	M1972	RPMI 1640 Agar w/ MOPS & 2% Glucose w/o Sodium Bicarbonate (Twin Pack)	Low risk	20/12/2012
DCM	MV576	RS HiVeg Medium Base	Low risk	22/04/2019

	ED	$1\mathbf{\Lambda}$

Document ref.: DoC 2022 vs. 15

Page 27 of 130

DCM	M576	RS Medium Base	Low risk	22/04/2019
DCM	M409	SABHI Agar Base	Low risk	20/12/2012
DCM	MV409	SABHI HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M1744	Sabouraud Agar Glucose 4%	Low risk	20/12/2012
DCM	M1067	Sabouraud Chloramphenicol Agar	Low risk	20/12/2012
DCM	MV1067	Sabouraud Chloramphenicol HiVeg™ Agar	Low risk	20/12/2012
DCM	M664	Sabouraud Cycloheximide Chloramphenicol Agar	Low risk	20/12/2012
DCM	MV664	Sabouraud Cycloheximide Chloramphenicol HiVeg™ Agar	Low risk	20/12/2012
DCM	MH063	Sabouraud Dextrose Agar	Low risk	22/04/2019
DCM	M063	Sabouraud Dextrose Agar	Low risk	20/12/2012
DCM	M286	Sabouraud Dextrose Agar Base, Modified (Dextrose Agar Base, Emmons)	Low risk	20/12/2012
DCM	MH033	Sabouraud Dextrose Broth	Low risk	22/04/2019
DCM	M033	Sabouraud Dextrose Broth (Sabouraud Liquid Medium)	Low risk	20/12/2012
DCM	MCD063	Sabouraud Dextrose HiCynth™ Agar	Low risk	12/08/2015
DCM	MCD033	Sabouraud Dextrose HiCynth™ Broth	Low risk	12/08/2015
DCM	MV063	Sabouraud Dextrose HiVeg™ Agar	Low risk	20/12/2012
DCM	MV286	Sabouraud Dextrose HiVeg™ Agar Base, Modified (Dextrose HiVeg™ Agar Base, Emmons)	Low risk	20/12/2012
DCM	MV033	Sabouraud Dextrose HiVeg™ Broth (Sabouraud Liquid HiVeg™ Medium)	Low risk	20/12/2012
DCM	M1313	Sabouraud Dextrose Maltose Agar	Low risk	20/12/2012
DCM	M1460	Sabouraud Dextrose Maltose Broth	Low risk	20/12/2012
DCM	MV1313	Sabouraud Dextrose Maltose HiVeg™ Agar	Low risk	20/12/2012
DCM	MCD013	Sabouraud Fluid HiCynth™ Medium	Low risk	12/08/2015
DCM	M1472	Sabouraud Glucose Agar Base w/ Antibiotics	Low risk	20/12/2012
DCM	M062	Sabouraud Maltose Agar	Low risk	20/12/2012
DCM	M064	Sabouraud Maltose Broth	Low risk	20/12/2012
DCM	MV062	Sabouraud Maltose HiVeg [™] Agar	Low risk	20/12/2012
DCM	MV064	Sabouraud Maltose HiVeg [™] Broth	Low risk	20/12/2012
DCM	M844	Saccharose Broth	Low risk	20/12/2012
DCM	M1619	Sakazakii DHL Agar	Low risk	20/12/2012
DCM	M942	Saline Agar	Low risk	20/12/2012
DCM	M1778	Saline Lysine Decarboxylase Medium	Low risk	20/12/2012
DCM	M1633	Salmonella Agar (HiCrome™ RajHans Medium)	Low risk	20/12/2012
DCM	M1634	Salmonella Agar, Modified (HiCrome™ RajHans Medium, Modified)	Low risk	20/12/2012
DCM	M573	Salmonella Agar, ONOZ	Low risk	20/12/2012
DCM	M1078	Salmonella Differential Agar (Twin Pack) (RajHans Medium)	Low risk	20/12/2012
DCM	M1082	Salmonella Differential Agar, Modified (Twin Pack)	Low risk	20/12/2012
DCM	MCD1078	Salmonella Differential HiCynth™ Agar (Twin Pack)	Low risk	25/08/2016

	MEDIA	Declaration of Conformity Document ref.: DoC 2		t ref.: DoC 20)22 vs. 15	
			Microbiology Products		Page 28 of 130	
DCM	MV1078		ılmonella Differential HiVeg™ Agar (RajHans HiVeg' win Pack)	[™] Medium)	Low risk	20/12/2012
DCM	MV1082	Sa	Ilmonella Differential HiVeg™ Agar, Modified (Twin	Pack)	Low risk	20/12/2012
DCM	MV573	Sa	Ilmonella HiVeg™ Agar, ONOZ		Low risk	20/12/2012
DCM	M1767	Sa	It Agar, Modified		Low risk	20/12/2012
DCM	M1290	Sa	It Broth, Modified		Low risk	20/12/2012
DCM	M155	Sa	lt M Broth		Low risk	20/12/2012
DCM	M821	Sa	It Polymyxin Broth Base		Low risk	20/12/2012
DCM	MV821	Sa	lt Polymyxin HiVeg™ Broth Base		Low risk	20/12/2012
DCM	M1276	Sa	uton's Fluid Medium Base		Low risk	20/12/2012
DCM	M1535	SB	3G Enrichment Broth (Twin Pack)		Low risk	20/12/2012
DCM	M291	Sc	haedler Agar		Low risk	20/12/2012
DCM	M292	Sc	haedler Broth		Low risk	20/12/2012
DCM	MV291	Sc	haedler HiVeg™ Agar		Low risk	20/12/2012
DCM	MV292	Sc	haedler HiVeg™ Broth		Low risk	20/12/2012
DCM	M1882	Se	elective Broth for MRSA		Low risk	20/12/2012
DCM	M052	Se	elenite Broth (Selenite F Broth) (Twin Pack)		Low risk	20/12/2012
DCM	M970	Se	Selenite Broth Base w/o Biselenite		Low risk	20/12/2012
DCM	M1079	Se	Selenite Cystine Broth Base w/o Biselenite		Low risk	20/12/2012
DCM	M1536	Se	Selenite F Broth w/ Dulcitol (Dulcitol Selenite Broth) (Twin Pack)		Low risk	20/12/2012
DCM	M1534	Se	Selenite Mannitol Broth (Mannitol Selenite Broth) (Twin Pack)		Low risk	20/12/2012
DCM	M1321	Se	Semisolid LM Medium		Low risk	20/12/2012
DCM	M1282	Se	emisolid Rappaport Vassiliadis Medium, Modified		Low risk	22/04/2019
DCM	M1998	Se	emisolid RV Medium w/ 0.9% Agar		Low risk	25/08/2016
DCM	MV296	Se	ensitivity Test HiVeg™ Medium		Low risk	20/12/2012
DCM	M296	Se	ensitivity Test Medium		Low risk	20/12/2012
DCM	M1301	Sh	neep Blood Agar Base		Low risk	20/12/2012
DCM	M1739	Sh	nepard's Differential Agar Base (A7 Agar Base)		Low risk	20/12/2012
DCM	M411	Sii	mmons Agar Base		Low risk	20/12/2012
DCM	M099	Sii	mmons Citrate Agar		Low risk	20/12/2012
DCM	M099S	Sii	mmons Citrate Agar		Low risk	20/12/2012
DCM	M612A	Sla	Slanetz and Bartley Medium w/o TTC		Low risk	10/11/2020
DCM	M5296	SN	SM Tryptone Glucose Glycerin Medium		Low risk	25/11/2017
DCM	M960	Sn	nibert's Semisolid Brucella Medium		Low risk	20/12/2012
DCM	M106	Sn	nyder Test Agar (B.C.G Dextrose Agar)		Low risk	20/12/2012
DCM	MV106	Sn	nyder Test HiVeg™ Agar (B.C.G Dextrose HiVeg™ /	Agar)	Low risk	20/12/2012
DCM	M767	So	odium Azide Crystal Violet Blood Agar Base		Low risk	20/12/2012
DCM	M1079B	So	odium Biselenite		Low risk	22/04/2019
DCM	M298	Sc	orbitol Agar (MacConkey Sorbitol Agar)		Low risk	20/12/2012
DCM	MV298	Sc	orbitol HiVeg™Agar (MacConkey Sorbitol HiVeg™ A	gar)	Low risk	20/12/2012

М	

Document ref.: DoC 2022 vs. 15

Page 29 of 130

DCM	M299	Sorbitol Iron Agar	Low risk	20/12/2012
DCM	MV299	Sorbitol Iron HiVeg™ Agar	Low risk	20/12/2012
DCM	M935	Soya Peptone Yeast Extract Agar	Low risk	20/12/2012
DCM	M1286	Soyabean Bile Broth Base	Low risk	20/12/2012
DCM	M290	Soyabean Casein Digest Agar (Tryptone Soya Agar)	Low risk	22/04/2019
DCM	M109	Soyabean Casein Digest Agar w/ Yeast Extract and Hemin (Tryptone Soya Agar w/ Yeast Extract and Hemin)	Low risk	20/12/2012
DCM	M011	Soyabean Casein Digest Medium (Tryptone Soya Broth)	Low risk	22/04/2019
DCM	M323	Soyabean Casein Digest Medium w/ 0.1% Agar (Tryptone Soya Broth w/ 0.1% Agar)	Low risk	20/12/2012
DCM	M207	Soyabean Casein Digest Medium w/ Yeast Extract and Ferric pyrophosphate	Low risk	20/12/2012
DCM	M322	Soyabean Casein Digest Medium w/o Dextrose (Tryptone SoyaBroth w/o Dextrose)	Low risk	28/04/2017
DCM	MV1286	Soyabean HiVeg™ Broth Base	Low risk	20/12/2012
DCM	MV011	Soyabean HiVeg™ Medium	Low risk	22/04/2019
DCM	MV323	Soyabean HiVeg™ Medium w/ 0.1% Agar (Tryptone Soya HiVeg™ Broth w/ 0.1% Agar)	Low risk	20/12/2012
DCM	MV207	Soyabean HiVeg™ Medium w/ Yeast Extract and Ferric pyrophosphate	Low risk	20/12/2012
DCM	MV290	SoyabeanHiVeg™ Agar	Low risk	22/04/2019
DCM	MH011	Soybean Casein Digest Medium (Casein Soybean Digest Broth)	Low risk	22/04/2019
DCM	MH290	Soybean-Casein Digest Agar (Casein Soyabean Digest Agar)	Low risk	22/04/2019
DCM	M211	Special Infusion Agar (BHI Agar)	Low risk	20/12/2012
DCM	MV211	Special Infusion Agar, HiVeg™ (BHI Agar, HiVeg™)	Low risk	20/12/2012
DCM	M1613	Special YM Medium	Low risk	20/12/2012
DCM	M300	Specimen Preservative Medium Base (SP Hajna)	Low risk	20/12/2012
DCM	M445	Spirit Blue Agar	Low risk	20/12/2012
DCM	MV445	Spirit Blue HiVeg™ Agar	Low risk	20/12/2012
DCM	M412	Spirolate Broth, OMATA	Low risk	20/12/2012
DCM	MV412	Spirolate HiVeg™ Broth, OMATA	Low risk	20/12/2012
DCM	MCD108	SS HiCynth™ Agar (Salmonella Shigella HiCynth™ Agar)	Low risk	12/08/2015
DCM	M108	SS Agar (Salmonella Shigella Agar)	Low risk	20/12/2012
DCM	M108D	SS Agar (Salmonella Shigella Agar)	Low risk	16/12/2017
DCM	M1979R	SS Agar Modified (w/sucrose)	Low risk	25/08/2010
DCM	M1979	SS Agar w/sucrose	Low risk	20/12/2012
DCM	M1032	SS Agar, Modified	Low risk	20/12/2012
DCM	MV108	SS HiVeg™ Agar (Salmonella Shigella HiVeg™ Agar)	Low risk	20/12/2012
DCM	M1959	SS Selective Agar, Improved	Low risk	20/12/2012
DCM	M1703	SSDC agar	Low risk	20/12/2012
DCM	M1608	ß-Streptococcus Selective Agar Base	Low risk	20/12/2012
DCM	M675	Staib's Medium (Bird Seed Agar)	Low risk	20/12/2012
DCM	M883	Standard Infusion Agar	Low risk	20/12/2012

IN		
HHY		

Document ref.: DoC 2022 vs. 15

Page 30 of 130

DCM	MV883	Standard Infusion Agar, HiVeg™	Low risk	20/12/2012
DCM	M116	Standard Nutrient Broth (H.S. Vaccine Medium)	Low risk	20/12/2012
DCM	MV116	Standard Nutrient HiVeg™ Broth (H.S. Vaccine HiVeg™ Medium)	Low risk	20/12/2012
DCM	M578	Standard Staphylococcus Broth	Low risk	20/12/2012
DCM	MV578	Standard Staphylococcus HiVeg™ Broth	Low risk	20/12/2012
DCM	M156	Staphylococcus Agar No. 110 w/ Azide	Low risk	20/12/2012
DCM	M521	Staphylococcus Agar No.110	Low risk	20/12/2012
DCM	MV521	Staphylococcus HiVeg™ Agar No. 110	Low risk	20/12/2012
DCM	M1965	Stenotrophomonas Selective Agar Base	Low risk	20/12/2012
DCM	M1840R	Streptococcus Agalactiae Selective Agar Base (HiCrome™ Strep B Selective Agar Base)	Low risk	30/10/2018
DCM	M465	Streptococcus Enrichment Broth (SE Broth)	Low risk	20/12/2012
DCM	MV465	Streptococcus Enrichment HiVeg™ Broth (SE HiVeg™ Broth)	Low risk	20/12/2012
DCM	M304	Streptococcus Selection Agar	Low risk	20/12/2012
DCM	M303	Streptococcus Selection Broth	Low risk	20/12/2012
DCM	MV304	Streptococcus Selection HiVeg™ Agar	Low risk	20/12/2012
DCM	MV303	Streptococcus Selection HiVeg™ Broth	Low risk	20/12/2012
DCM	M1735	Stuart Medium w/o Methylene Blue with Charcoal	Low risk	20/12/2012
DCM	M306	Stuart Transport Medium (Transport Medium, Stuart)	Low risk	20/12/2012
DCM	M1131	Stuart Transport Medium w/o Methylene Blue	Low risk	20/12/2012
DCM	M1203	Stuart Transport Medium w/o Sodium Glycerophosphate	Low risk	20/12/2012
DCM	M308	Sulpha Sensitivity Test Agar	Low risk	20/12/2012
DCM	MV837	T.S.C./S.F.P. HiVeg™ Agar Base (Perfringens HiVeg™ Agar Base)	Low risk	20/12/2012
DCM	M100	TB Broth Base	Low risk	20/12/2012
DCM	M034	TB Broth Base w/o Tween 80	Low risk	20/12/2012
DCM	MV100	TB HiVeg™ Broth Base	Low risk	20/12/2012
DCM	MV034	TB HiVeg™ Broth Base w/o Tween 80	Low risk	20/12/2012
DCM	M189	TCBS Agar	Low risk	20/12/2012
DCM	M870	TCBS Agar (Selective)	Low risk	20/12/2012
DCM	M870A	TCBS Agar, Modified	Low risk	20/12/2012
DCM	MCD870	TCBS HiCynth [™] Agar (Selective)	Low risk	25/08/2016
DCM	MV189	TCBS HiVeg™ Agar	Low risk	20/12/2012
DCM	MV870	TCBS HiVeg™ Agar (Selective)	Low risk	20/12/2012
DCM	M529	Teepol Broth (Twin Pack)	Low risk	10/11/2020
DCM	MV529	Teepol HiVeg [™] Broth (Twin Pack)	Low risk	10/11/2020
DCM	M1260	Tellurite Blood Agar Base	Low risk	20/12/2012
DCM	M448	Tellurite Glycine Agar Base	Low risk	20/12/2012
DCM	M616	Tergitol-7 Agar Base	Low risk	20/12/2012
DCM	M850	Tergitol-7 Agar H	Low risk	20/12/2012
DCM	M851	Tergitol-7 Broth	Low risk	20/12/2012

IN		

Document ref.: DoC 2022 vs. 15

Page 31 of 130

DCM	MV616	Tergitol-7 HiVeg™ Agar Base	Low risk	20/12/2013
DCM	MV850	Tergitol-7 HiVeg™ Agar H	Low risk	20/12/2013
DCM	MV851	Tergitol-7 HiVeg™ Broth	Low risk	20/12/2012
DCM	M032	Tetrathionate Broth Base (w/o lodine and BG) (Fluid Tetrathionate Medium w/o lodine and BG)	Low risk	20/12/2012
DCM	MV032	Tetrathionate HiVeg™ Broth Base (w/o lodine and BG) (Fluid Tetrathionate HiVeg™ Medium w/o lodine and BG)	Low risk	20/12/2013
DCM	MV413	Thayer Martin HiVeg™ Medium Base	Low risk	20/12/2012
DCM	M413	Thayer Martin Medium Base	Low risk	20/12/2012
DCM	M610	Thiogel Medium	Low risk	20/12/2013
DCM	M608	Thioglycollate Agar	Low risk	20/12/201
DCM	M010	Thioglycollate Broth, Alternative (Alternative Thioglycollate Medium)(NIH Thioglycollate Broth)	Low risk	20/12/201
DCM	MCD010	Thioglycollate HiCynth™ Broth, Alternative (Alternative Thioglycollate HiCynth™ Medium)(NIH Thioglycollate HiCynth™ Broth)	Low risk	12/08/201
DCM	MV608	Thioglycollate HiVeg™ Agar	Low risk	20/12/201
DCM	MV010	Thioglycollate HiVeg™ Broth, Alternative (Alternative Thioglycollate HiVeg™ Medium)(NIH HiVeg™ Thioglycollate Broth)	Low risk	20/12/201
DCM	MV195	Thioglycollate HiVeg™ Medium, Linden (Brewer Thioglycollate HiVeg™ Medium, Modified)	Low risk	20/12/201
DCM	M979	Thioglycollate Medium w/ Hemin and Vitamin K	Low risk	20/12/201
DCM	M195	Thioglycollate Medium, Linden (Brewer Thioglycollate Medium, Modified)	Low risk	20/12/201
DCM	M853	Thiol Broth	Low risk	20/12/201
DCM	MV853	Thiol HiVeg™ Broth	Low risk	20/12/201
DCM	MV852	Thiol HiVeg™ Medium	Low risk	20/12/201
DCM	M852	Thiol Medium	Low risk	20/12/201
DCM	M314	Tinsdale Agar Base	Low risk	20/12/201
DCM	MV314	Tinsdale HiVeg™ Agar Base	Low risk	20/12/201
DCM	M313	Todd Hewitt Broth	Low risk	20/12/201
DCM	MV313	Todd Hewitt HiVeg™ Broth	Low risk	20/12/201
DCM	M2127	Todd Hewitt Broth w/colistin & Nalidixic Acid	Low risk	17/06/202
DCM	M879	Tomato Juice Agar, Special	Low risk	20/12/201
DCM	MV879	Tomato Juice HiVeg™ Agar, Special	Low risk	20/12/201
DCM	M1149	Transgrow Medium Base	Low risk	20/12/201
DCM	M315	Transport Charcoal Medium	Low risk	20/12/201
DCM	M1487	Transport Liquid Medium	Low risk	20/12/201
DCM	M306	Transport Medium Stuart (Stuart Transport Medium)	Low risk	20/12/201
DCM	M202	Transport Medium w/o Charcoal (Cary - Blair Medium Base)	Low risk	20/12/201
DCM	M684	Transport Medium, Amies w/o Charcoal	Low risk	20/12/201
DCM	M665	Trichomonas Agar Base	Low risk	20/12/201
DCM	M1204	Trichomonas Broth Base No. 2	Low risk	20/12/201

LIMEDIA	Declaration of Conformity	Document ref.: DoC 2022 vs. 15
	Microbiology Products	Page 32 of 130

DCM	M305	Trichomonas Broth Base, Kupferberg (Kupferberg Trichomonas Broth Base)	Low risk	20/12/2012
DCM	MV665	Trichomonas HiVeg™ Agar Base	Low risk	20/12/2012
DCM	MV305	Trichomonas HiVeg™ Broth Base, Kupferberg (Kupferberg Trichomonas HiVeg™ Broth Base)	Low risk	20/12/2012
DCM	MV460	Trichomonas Modified CPLM HiVeg™ Medium Base (Modified CPLM HiVeg™ Medium Base)	Low risk	20/12/2012
DCM	M460	Trichomonas Modified CPLM Medium Base (Modified CPLM Medium Base)	Low risk	20/12/2012
DCM	M531	Trichophyton Agar-1	Low risk	20/12/2012
DCM	M532	Trichophyton Agar-2	Low risk	20/12/2012
DCM	M533	Trichophyton Agar-3	Low risk	20/12/2012
DCM	M534	Trichophyton Agar-4	Low risk	20/12/2012
DCM	M535	Trichophyton Agar-5	Low risk	20/12/2012
DCM	M536	Trichophyton Agar-6	Low risk	20/12/2012
DCM	M152	Trichophyton Agar-7	Low risk	20/12/2012
DCM	MV531	Trichophyton HiVeg™ Agar-1	Low risk	20/12/2012
DCM	MV532	Trichophyton HiVeg™ Agar-2	Low risk	20/12/2012
DCM	MV533	Trichophyton HiVeg™ Agar-3	Low risk	20/12/2012
DCM	MV534	Trichophyton HiVeg™ Agar-4	Low risk	20/12/2012
DCM	MV535	Trichophyton HiVeg™ Agar-5	Low risk	20/12/2012
DCM	M021	Triple Sugar Iron Agar	Low risk	22/04/2019
DCM	MV021	Triple Sugar Iron HiVeg™ Agar	Low risk	22/04/2019
DCM	M1028	Tryptic Digest Broth(Field's Tryptic Digest Broth)	Low risk	20/12/2012
DCM	MV1028	Tryptic Digest Broth, HiVeg™ (Field's Tryptic Digest Broth, HiVeg™)	Low risk	20/12/2012
DCM	M1591	Tryptone Bile Glucuronic Agar (TBX Agar)	Low risk	22/04/2019
DCM	M463	Tryptone Broth (Tryptone Water)	Low risk	22/04/2019
DCM	MV364	Tryptone Nitrate HiVeg™ Medium (Indole Nitrate HiVeg™ Medium)	Low risk	20/12/2012
DCM	M364	Tryptone Nitrate Medium (Indole Nitrate Medium)	Low risk	20/12/2012
DCM	M969	Tryptone Peptone Glucose Yeast Extract Broth Base w/o Trypsin	Low risk	20/12/2012
DCM	MV969	Tryptone Peptone Glucose Yeast Extract HiVeg™ Broth Base w/o Trypsin	Low risk	20/12/2012
DCM	M323	Tryptone Soya Broth w/ 0.1% Agar (Soyabean Casein Digest Medium w/ 0.1% Agar)	Low risk	20/12/2012
DCM	MV323	Tryptone Soya HiVeg™ Broth w/ 0.1% Agar (Soyabean HiVeg™ Medium w/ 0.1% Agar)	Low risk	20/12/2012
DCM	M1948	Tryptone Soya Serum Bacitracin Vancomycin Agar (TSBV)	Low risk	08/12/2017
DCM	M1217	Tryptone Sucrose Tetrazolium Agar Base (TSTA)	Low risk	20/12/2012
DCM	M1056	Tryptone Tellurite Agar Base	Low risk	20/12/2012
DCM	MV463	Tryptone Water, HiVeg™ (Tryptone Broth,HiVeg™)	Low risk	22/04/2019
DCM	M1975	Tryptone yeast extract cystine w/sucrose and w/O bacitracin agar (TYCSB)	Low risk	20/12/2012
DCM	M2046I	Tryptone Yeast Sodium Sulphite Agar Base	Low risk	10/11/2020

IM	ED	IA

Document ref.: DoC 2022 vs. 15

Page 33 of 130

DCM	M538	Tryptose Agar	Low risk	20/12/2012
DCM	M996	Tryptose Agar w/ Thiamine HCl	Low risk	20/12/2012
DCM	MV996	Tryptose Agar w/ Thiamine HCl, HiVeg™	Low risk	20/12/2012
DCM	MV538	Tryptose Agar, HiVeg™	Low risk	20/12/2012
DCM	M097	Tryptose Blood Agar Base	Low risk	20/12/2012
DCM	M450	Tryptose Blood Agar Base w/ Yeast Extract	Low risk	20/12/2012
DCM	MV450	Tryptose Blood Agar Base w/ Yeast Extract, HiVeg™	Low risk	20/12/2012
DCM	MV097	Tryptose Blood Agar Base, HiVeg™	Low risk	20/12/2012
DCM	M177	Tryptose Broth	Low risk	20/12/2012
DCM	M997	Tryptose Broth w/ Thiamine HCl	Low risk	20/12/2012
DCM	MV177	Tryptose Broth, HiVeg™	Low risk	20/12/2012
DCM	M5393	Tryptose Phosphate Broth	Low risk	30/10/2018
DCM	M093	Tryptose Phosphate Broth	Low risk	20/12/2012
DCM	MV093	Tryptose Phosphate Broth, HiVeg™	Low risk	20/12/2012
DCM	M1532	Tryptose Phosphate Broth, Modified	Low risk	20/12/2012
DCM	M093G	Tryptose Phosphate Broth, Sterile	Low risk	22/04/2019
DCM	M2060	Tryptose Serum Agar Base	Low risk	10/11/2020
DCM	M2019	Tryptose Serum Broth Base(Modified Newin	Low risk	25/08/2016
DCM	M837	Tryptose Sulphite Cycloserine (T.S.C. / S.F.P.) Agar Base (Perfringens Agar Base)	Low risk	20/12/2012
DCM	M1780	TS Saline Agar (Triple Sugar Saline Iron Agar)	Low risk	20/12/2012
DCM	M2016	TSB w/6.5% NaCL	Low risk	25/08/2016
DCM	M1220	TTC Broth Base (Triclosan Ticarcillin Chlorate Broth)	Low risk	20/12/2012
DCM	MV1220	TTC HiVeg™ Broth Base	Low risk	20/12/2012
DCM	M1912	Tween Esterase Test Agar Base	Low risk	20/12/2012
DCM	M1817	Universal Fastidious Culture Agar	Low risk	20/12/2012
DCM	M1818	Universal Fastidious Culture Broth	Low risk	10/11/2020
DCM	M112S	Urea Agar Base (Christensen)	Low risk	20/12/2012
DCM	M112	Urea Agar Base (Christensen) (Autoclavable)	Low risk	20/12/2012
DCM	M112A	Urea Agar Base (Filter Sterilizable) (w/o Agar)	Low risk	20/12/2012
DCM	M112I	Urea Agar Base, Christensen	Low risk	20/12/2012
DCM	M111A	Urea Broth (Filter Sterilizable)	Low risk	20/12/2012
DCM	M111	Urea Broth Base (Diagnostic Stuart's Urea Broth Base)	Low risk	20/12/2012
DCM	MV112	Urea HiVeg™ Agar Base (Christensen) (Autoclavable)	Low risk	20/12/2012
DCM	M1784I	Urea Indole Broth, Modified	Low risk	20/12/2012
DCM	M1784	Urea Indole Medium	Low risk	20/12/2012
DCM	M328	V Infusion Agar	Low risk	20/12/2012
DCM	M329	V Infusion Broth	Low risk	20/12/2012
DCM	M1057	Vaginalis Agar Base	Low risk	20/12/2012
DCM	M1763	Vancomycin Resistant Enterococci (VRE) Agar Base	Low risk	20/12/2012

	ED	$1\mathbf{\Lambda}$

Document ref.: DoC 2022 vs. 15

Page 34 of 130

DCM	M1762	Vancomycin Resistant Enterococci (VRE) Broth Base	Low risk	20/12/2012
DCM	M416	Veillonella Agar Base	Low risk	20/12/2012
DCM	MV416	Veillonella HiVeg™ Agar Base	Low risk	20/12/2012
DCM	M820	Vibrio Agar	Low risk	20/12/2012
DCM	MV820	Vibrio HiVeg™ Agar	Low risk	20/12/2012
DCM	M049	Violet Red Bile Agar	Low risk	28/04/2017
DCM	M049A	Violet Red Bile Agar	Low risk	16/12/2017
DCM	M1684	Violet Red Bile Agar w/ Glucose and Lactose	Low risk	22/04/2019
DCM	MH581	Violet Red Bile Glucose Agar	Low risk	22/04/2019
DCM	M581	Violet Red Bile Glucose Agar w/o Lactose	Low risk	25/11/201
DCM	MCD581	Violet Red Bile Glucose HiCynth™ Agar w/o Lactose	Low risk	04/07/2018
DCM	MV581	Violet Red Bile Glucose HiVeg™ Agar w/o Lactose	Low risk	04/07/2018
DCM	MCD049	Violet Red Bile HiCynth™ Agar	Low risk	28/04/201
DCM	MV049	Violet Red HiVeg™ Agar	Low risk	28/04/201
DCM	MCD023	Vogel Johnson HiCynth™ Agar Base w/o Tellurite (V.J. HiCynth™ Agar)	Low risk	12/08/201
DCM	M023	Vogel-Johnson Agar Base w/o Tellurite (V.J. Agar)	Low risk	20/12/201
DCM	MU023	Vogel-Johnson Agar Medium	Low risk	20/12/201
DCM	MV023	Vogel-Johnson HiVeg™ Agar Base w/o Tellurite (V. J. HiVeg™ Agar)	Low risk	20/12/201
DCM	MV662	VP HiVeg™ Medium	Low risk	20/12/201
DCM	M662	VP Medium	Low risk	20/12/201
DCM	M626	Wagatsuma Agar Base	Low risk	20/12/201
DCM	MV626	Wagatsuma HiVeg™ Agar Base	Low risk	20/12/201
DCM	M1059	Wayne Sulphatase Agar Base	Low risk	20/12/201
DCM	M832	Wilkins Chalgren Anaerobic Agar Base	Low risk	20/12/201
DCM	M863	Wilkins Chalgren Anaerobic Broth Base	Low risk	20/12/201
DCM	MV832	Wilkins Chalgren Anaerobic HiVeg™ Agar Base	Low risk	20/12/201
DCM	MV863	Wilkins Chalgren Anaerobic HiVeg™ Broth Base	Low risk	25/08/201
DCM	M331	Wilson Blair Agar Base	Low risk	20/12/201
DCM	M332	Wilson Blair Agar w/ BG	Low risk	20/12/201
DCM	MV331	Wilson Blair HiVeg™ Agar Base	Low risk	20/12/201
DCM	MV332	Wilson Blair HiVeg™ Agar w/ BG	Low risk	20/12/201
DCM	MV031	XLD HiVeg™ Agar	Low risk	20/12/201
DCM	M1147	XLT4 Agar Base	Low risk	20/12/201
DCM	MV1147	XLT4 HiVeg™ Agar Base	Low risk	20/12/201
DCM	M336	Xylose Lysine Agar Base	Low risk	20/12/201
DCM	M031	Xylose Lysine Deoxycholate Agar (XLD Agar)	Low risk	20/12/201
DCM	MCD031	Xylose Lysine Deoxycholate HiCynth™ Agar (XLD HiCynth™ Agar)	Low risk	12/08/201
DCM	MH031	Xylose-Lysine-Deoxycholate Agar	Low risk	22/04/201

	ED	$1\mathbf{\Lambda}$

Document ref.: DoC 2022 vs. 15

Page 35 of 130

DCM	M424	Yeast Malt Agar (YM Agar) (ISP Medium No. 2)	Low risk	22/04/2019
DCM	M425	Yeast Malt Broth (YM Broth)	Low risk	20/12/2012
DCM	MV424	Yeast Malt HiVeg™ Agar (YM HiVeg™ Agar)	Low risk	22/04/2019
DCM	MV425	Yeast Malt HiVeg [™] Broth (YM HiVeg [™] Broth)	Low risk	20/12/2012
DCM	M1421	YEP Agar	Low risk	30/10/2018
DCM	M1823	YEP Agar, Modified	Low risk	10/11/2020
DCM	M1367	Yersinia Enrichment Broth Base	Low risk	20/12/2012
DCM	M843	Yersinia Selective Agar Base	Low risk	20/12/2012
DCM	M1861	Yersinia Selective Broth Base	Low risk	20/12/2012
DCM	MV843	Yersinia Selective HiVeg™ Agar Base	Low risk	20/12/2012
DCM	EC211CR	BHI Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC210CR	BHI Broth (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC073DR	Blood Agar Base (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1297ACR	HiCrome™ Candida Differential Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1297ARDR	HiCrome™ Candida Differential Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1297ADR	HiCrome™ Candida Differential Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1674CCLR	HiCrome™ MeReSa Agar Base (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1353CCLR	HiCrome™ UTI Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1353CR	HiCrome™ UTI Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC1353DR	HiCrome™ UTI Agar (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC211CCL	HiEncap™ BHI Agar (HiEncap™ Special Infusion Agar)	Low risk	12/08/2015
DCM	EC210D	HiEncap™ BHI Broth	Low risk	12/08/2015
DCM	EC210CCL	HiEncap™ BHI Broth	Low risk	12/08/2015
DCM	EC073D	HiEncap™ Blood Agar Base	Low risk	12/08/2015
DCM	EC073CCL	HiEncap™ Blood Agar Base	Low risk	12/08/2015
DCM	EC081CCL	HiEncap™ MacConkey Agar w/0.15% Bile Salt	Low risk	12/08/2015
DCM	EC082ACCL	HiEncap™ MacConkey Agar w/o CV, NaCl w/Bile Salts	Low risk	12/08/2015
DCM	EC173CCL	HiEncap™ Mueller Hinton Agar	Low risk	12/08/2015
DCM	EC173D	HiEncap™ Mueller Hinton Agar	Low risk	12/08/2015
DCM	EC1084CCL	HiEncap™ Mueller Hinton Agar No.2	Low risk	12/08/2015
DCM	EC1084D	HiEncap™ Mueller Hinton Agar No.2	Low risk	12/08/2015
DCM	EC391CCL	HiEncap™ Mueller Hinton Broth	Low risk	12/08/2015
DCM	EC391D	HiEncap™ Mueller Hinton Broth	Low risk	12/08/2015
DCM	EC001DR	HiEncap™ Nutrient Agar	Low risk	25/08/2016
DCM	EC001CCL	HiEncap™ Nutrient Agar	Low risk	12/08/2015
DCM	EC001D	HiEncap™ Nutrient Agar	Low risk	12/08/2015
DCM	EC002CCL	HiEncap™ Nutrient Broth	Low risk	12/08/2015
DCM	EC002D	HiEncap™ Nutrient Broth	Low risk	12/08/2015

Document ref.: DoC 2022 vs. 15

Page 36 of 130

DCM	EC002M	HiEncap™ Nutrient Broth	Low risk	12/08/2015
DCM	EC091D	HiEncap™ Plate Count Agar	Low risk	16/12/2017
DCM	EC091CCL	HiEncap™ Plate Count Agar	Low risk	16/12/2017
DCM	EC063CCL	HiEncap™ Sabouraud Dextrose Agar	Low risk	12/08/2015
DCM	EC033CCL	HiEncap [™] Sabouraud Dextrose Broth	Low risk	12/08/2015
DCM	EC033D	HiEncap™ Sabouraud Dextrose Broth	Low risk	12/08/2015
DCM	EC173DR	Mueller Hinton Agar (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC1084DR	Mueller Hinton Agar No.2 (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	EC391CR	Mueller Hinton Broth (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC002CR	Nutrient Broth (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC063CCLR	Sabouraud Dextrose Agar (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC033CR	Sabouraud Dextrose Broth (HiEncap [™] water-soluble capsule)	Low risk	25/08/2016
DCM	EC031CCLR	Xylose Deoxycholate Agar (XLD Agar) (HiEncap™ water-soluble capsule)	Low risk	25/08/2016
DCM	GM618	Alkaline Peptone Water, Granulated	Low Risk	12/08/2015
DCM	GM491	Anaerobic Agar (Brewer), Granulated	Low Risk	12/08/2015
DCM	GM672	Aspargine Broth (Coccidiodin and Histoplasmin Broth), Granulated	Low Risk	12/08/2015
DCM	GM043	Baird Parker Agar Base, Granulated	Low Risk	12/08/2015
DCM	GM1091	Baird Staphylococcus Enrichment Broth Base, Granulated	Low risk	10/11/2020
DCM	GM211	BHI Agar (Special Infusion Agar), Granulated	Low Risk	12/08/2015
DCM	GM210	BHI Broth, Granulated	Low Risk	12/08/2015
DCM	GM217	Bi.G.G.Y. Agar (Nickerson Medium), Granulated	Low Risk	12/08/2015
DCM	GM027	Bismuth Sulphite Agar, Granulated	Low Risk	12/08/2015
DCM	GM073	Blood Agar Base (Infusion Agar), Granulated	Low Risk	12/08/2015
DCM	GM073R	Blood Agar Base (Infusion Agar) w/o Blood, Granulated	Low risk	25/08/2016
DCM	GM834A	Blood Agar Base No. 2 w/ 1.2% Agar, Granulated	Low Risk	12/08/2015
DCM	GM016A	Brilliant Green Agar Base w/ 1.2% Agar, Granulated	Low Risk	12/08/2015
DCM	GM971	Brilliant Green Agar Base w/ Phosphates, Granulated	Low risk	20/12/2012
DCM	GM074	Brucella Agar Base, Granulated	Low Risk	12/08/2015
DCM	GM614	Buffered Peptone Water , Granulated	Low risk	22/04/2019
DCM	GM1275	Buffered Peptone Water w/ NaCl, Granulated	Low Risk	12/08/2015
DCM	GMH1275	Buffered Sodium Chloride-Peptone Solution pH 7.0 , Granulated	Low risk	22/04/2019
DCM	GM792	C.L.E.D. Agar w/ Bromo Thymol Blue, Granulated	Low Risk	12/08/2015
DCM	GMH024	Cetrimide Agar , Granulated	Low risk	22/04/2019
DCM	GM024	Cetrimide Agar Base, Granulated	Low Risk	12/08/2015
DCM	GM497	Clostridial Agar, Granulated	Low risk	25/08/2016
DCM	GMH144	Columbia Agar , Granulated	Low risk	22/04/2019
DCM	GM144	Columbia Blood Agar Base, Granulated	Low Risk	12/08/2015
DCM	GM188	D.T.M. Agar Base (Dermatophyte Test Agar Base) , Granulated	Low Risk	12/08/2015

M	ED	

Document ref.: DoC 2022 vs. 15

Page 37 of 130

DCM	GM030	Deoxycholate Agar, Granulated	Low Risk	12/08/201
DCM	GM065	Deoxycholate Citrate Agar, Granulated	Low Risk	12/08/201
DCM	GM286	Dextrose Agar Base, Emmons (Sabouraud Dextrose Agar Base, Modified), Granulated	Low Risk	12/08/201
DCM	GM1129	Dichloran Glycerol Medium Base , Granulated	Low risk	22/04/201
DCM	GM1603	Differential Reinforced Clostridial Agar, Granulated	Low risk	10/11/202
DCM	GM127	EC Broth, Granulated	Low Risk	12/08/201
DCM	GM317	EMB Agar, Granulated	Low Risk	12/08/201
DCM	GM022	EMB Agar, Levine, Granulated	Low Risk	12/08/201
DCM	GM029	Endo Agar, Granulated	Low Risk	12/08/201
DCM	GM029R	Endo Agar, Special	Low risk	25/08/201
DCM	GM1075	Endo Agar, Modified, Granulated	Low Risk	12/08/201
DCM	GMH287	Enterobacteria Enrichment Broth, Mossel , Granulated	Low risk	22/04/201
DCM	GM013	Fluid Sabouraud Medium (Sabouraud Medium,Fluid), Granulated	Low Risk	12/08/201
DCM	GM025	Fluid Selenite Cystine Medium (Selenite Cystine Broth) (Twin Pack), Granulated	Low Risk	12/08/201
DCM	GM032	Fluid Tetrathionate Medium w/o lodine and BG (Tetrathionate Broth Base w/o lodine and BG) , Granulated	Low Risk	12/08/201
DCM	GM009	Fluid Thioglycollate medium (Thioglycollate medium Fluid), Granulated	Low risk	22/04/201
DCM	GM434	GC Agar Base, Granulated	Low Risk	04/07/201
DCM	GM070	Glucose Phosphate Broth (Buffered Glucose Broth) , Granulated	Low risk	12/08/201
DCM	GM070R	Glucose Phosphate Broth (Buffered Glucose Broth) , Granulated	Low risk	04/07/201
DCM	GMV070	Glucose Phosphate HiVeg™ Broth (Buffered Glucose HiVeg™ Broth) , Granulated	Low risk	20/12/201
DCM	GM242	GN Broth, Hajna, Granulated	Low Risk	12/08/201
DCM	GM467	Hektoen Enteric Agar, Granulated	Low Risk	12/08/202
DCM	GM1297A	HiCrome™ Candida Differential Agar, Granulated	Low Risk	12/08/201
DCM	GM1353	HiCrome™ UTI Agar, Granulated	Low Risk	12/08/202
DCM	GM1007	KF Streptococcus Agar Base w/ BCP, Granulated	Low Risk	12/08/201
DCM	GM1232	Kimmig Fungi Agar Base, Granulated	Low Risk	12/08/201
DCM	GM1543	King's Medium A Base, Granulated	Low Risk	12/08/202
DCM	GM078	Kligler Iron Agar, Granulated	Low Risk	12/08/202
DCM	GM641	Lactobacillus MRS Agar (MRS Agar) , Granulated	Low Risk	12/08/202
DCM	GM369	Lactobacillus MRS Broth (MRS Broth) , Granulated	Low Risk	12/08/202
DCM	GM1003	Lactose Broth , Granulated	Low risk	22/04/20:
DCM	GM080	Lauryl Sulphate Broth (Lauryl Tryptose Broth) , Granulated	Low risk	22/04/202
DCM	GM1380	Leifson Agar, Granulated	Low Risk	12/08/202
DCM	GM890A	Listeria Enrichment Medium Base (UVM) , Granulated	Low Risk	12/08/202
DCM	GM1064	Listeria Identification Agar Base (PALCAM) , Granulated	Low risk	22/04/20:
DCM	GM1090	Listeria Identification Broth Base (PALCAM), Granulated	Low risk	22/04/202

	MA		

Document ref.: DoC 2022 vs. 15

Page 38 of 130

DCM	GM1145	Listeria Oxford Medium Base, Granulated	Low Risk	12/08/2015
DCM	GM889	Listeria Selective Broth Base, Granulated	Low Risk	12/08/2015
DCM	GM1865	Listeria Selective Enrichment Broth , Granulated	Low risk	22/04/2019
DCM	GM1001	LM Agar, Granulated	Low Risk	12/08/2015
DCM	GM162	Lowenstein Jensen Medium Base (L.J. Medium) , Granulated	Low Risk	12/08/2015
DCM	GMH081	MacConkey Agar , Granulated	Low risk	22/04/2019
DCM	GM081	MacConkey Agar w/0.15% Bile Salts,CV and NaCL, Granulated	Low Risk	12/08/2015
DCM	GM082A	MacConkey Agar w/o CV,NaCL w/0.5% Bile Salts, Granulated	Low Risk	12/08/2015
DCM	GM082	MacConkey Agar w/o CV,NaCLw/0.5% Sodium Taurocholate, Granulated	Low Risk	12/08/2015
DCM	GMH083	MacConkey Broth , Granulated	Low risk	22/04/2019
DCM	GM083	MacConkey Broth Purple w/BCP , Granulated	Low risk	22/04/2019
DCM	GM137	Malt Extract Agar Base (w/ Mycological Peptone) , Granulated	Low Risk	12/08/2015
DCM	GM255	Malt Extract Broth Base, Granulated	Low Risk	12/08/2015
DCM	GMH118	Mannitol Salt Agar , Granulated	Low risk	22/04/2019
DCM	GM118	Mannitol Salt Agar Base , Granulated	Low risk	12/08/201
DCM	GM1030	Maximum Recovery Diluent , Granulated	Low risk	22/04/201
DCM	GM1170	Modified Czapek Dox Agar, Granulated	Low risk	25/08/201
DCM	GM1285	Modified EC Broth Base, Granulated	Low Risk	12/08/201
DCM	GM1286I	Modified Soyabean Bile Broth Base , Granulated	Low risk	22/04/201
DCM	GM1084	Mueller Hinton Agar No. 2, Granulated	Low Risk	12/08/201
DCM	GM173	Mueller Hinton Agar, Granulated	Low Risk	12/08/201
DCM	GM391	Mueller Hinton Broth, Granulated	Low Risk	12/08/201
DCM	GM636	MYP Agar Base (Phenol Red Egg Yolk Polymyxin Agar Base), Granulated	Low Risk	12/08/201
DCM	GM1269	Nutrient Agar No.2 , Granulated	Low risk	12/08/201
DCM	GM001	Nutrient Agar, Granulated	Low Risk	12/08/201
DCM	GM002	Nutrient Broth, Granulated	Low Risk	12/08/201
DCM	GM395	OF Basal Medium, Granulated	Low Risk	12/08/201
DCM	GM933	Orange Serum Agar, Granulated	Low risk	22/04/201
DCM	GM028	Peptone Water, Granulated	Low Risk	04/07/201
DCM	GM837	Perfringens Agar Base (Tryptose Sulphite Cycloserine Agar Base) (T.S.C./S.F.P. Agar Base), Granulated	Low Risk	12/08/201
DCM	GM091	Plate Count Agar (Standard Methods Agar), Granulated	Low Risk	28/04/201
DCM	GMH096	Potato Dextrose Agar , Granulated	Low risk	22/04/201
DCM	GM096	Potato Dextrose Agar , Granulated	Low risk	22/04/201
DCM	GM085	Pseudomonas Agar Base , Granulated	Low risk	22/04/201
DCM	GM085	Pseudomonas Agar Base, Granulated	Low Risk	22/04/201
DCM	GMH1491	Rappaport Vassiliadis Salmonella Enrichment Broth , Granulated	Low risk	22/04/201
DCM	GM1491	Rappaport Vassiliadis Soya Broth (RVS Broth), Granulated	Low Risk	12/08/201
DCM	GMH443	Reinforced Medium for Clostridia , Granulated	Low risk	22/04/201

	М		

Document ref.: DoC 2022 vs. 15

icts

Page 39 of 130

DCM	GM149	Robinson's Cooked M Medium (R.C. Medium), Granulated	Low Risk	16/12/2017
DCM	GM130	Rogosa SL Agar, Granulated	Low Risk	12/08/2015
DCM	GM842	Rose Bengal Agar Base, Granulated	Low risk	12/08/2015
DCM	GM1067	Sabouraud Chloramphenicol Agar, Granulated	Low risk	25/08/2016
DCM	GM063	Sabouraud Dextrose Agar, Granulated	Low Risk	12/08/2015
DCM	GMH063	Sabouraud Dextrose Agar, Granulated	Low risk	22/04/2019
DCM	GM033	Sabouraud Dextrose Broth (Sabouraud Liquid Medium), Granulated	Low Risk	12/08/2015
DCM	GMH033	Sabouraud Dextrose Broth, Granulated	Low risk	22/04/2019
DCM	GMV033	Sabouraud Dextrose HiVeg™ Broth (Sabouraud Liquid HiVeg™ Medium) , Granulated	Low Risk	12/08/2015
DCM	GM1313	Sabouraud Dextrose Maltose Agar, Granulated	Low Risk	12/08/2015
DCM	GM062	Sabouraud Maltose Agar, Granulated	Low Risk	12/08/2015
DCM	GM1619	Sakazakii DHL Agar, Granulated	Low Risk	12/08/2015
DCM	GM1078	Salmonella Differential Agar (Twin Pack), Raj Hans Medium (Twin Pack) , Granulated	Low Risk	12/08/2015
DCM	GM052	Selenite Broth (Selenite F Broth) (Twin Pack) , Granulated	Low Risk	12/08/2015
DCM	GM612A	Slanetz and Bartley Medium w/o TTC, Granulated	Low risk	10/11/2020
DCM	GM298R	Sorbitol Agar (Sorbitol MacConkey Agar)	Low risk	25/08/2016
DCM	GM290	Soyabean Casein Digest Agar (Tryptone Soya Agar), Granulated	Low risk	22/04/2019
DCM	GM011	Soyabean Casein Digest Medium (Tryptone Soya Broth), Granulated	Low risk	22/04/2019
DCM	GMH011	Soybean Casein Digest Medium (Casein Soybean Digest Broth), Granulated	Low risk	22/04/2019
DCM	GMH290	Soybean-Casein Digest Agar (Casein Soyabean Digest Agar), Granulated	Low risk	22/04/2019
DCM	GM108	SS Agar (Salmonella Shigella Agar), Granulated	Low Risk	12/08/2015
DCM	GM189	TCBS Agar, Granulated	Low Risk	12/08/2015
DCM	GM010	Thioglycollate Broth, Alternative (Alternative Thioglycollate Medium)(NIH Thioglycollate Broth), Granulated	Low risk	12/08/2015
DCM	GM021	Triple Sugar Iron Agar , Granulated	Low risk	22/04/2019
DCM	GM463	Tryptone Broth (Tryptone Water), Granulated	Low risk	22/04/2019
DCM	GM177	Tryptose Broth, Granulated	Low Risk	12/08/2015
DCM	GM112	Urea Agar Base (Christensen) (Autoclavable)	Low Risk	30/10/2018
DCM	GM112A	Urea Agar Base (Filter sterilizable), Granulated	Low risk	25/08/2016
DCM	GM111A	Urea Broth (Filter sterilizable), Granulated	Low risk	25/08/2016
DCM	GM049	Violet Red Bile Agar, Granulated	Low risk	28/04/2017
DCM	GMH581	Violet Red Bile Glucose Agar , Granulated	Low risk	22/04/2019
DCM	GM581	Violet Red Bile Glucose Agar w/o Lactose, Granulated	Low risk	04/07/2018
DCM	GM031	Xylose Lysine Deoxycholate Agar (XLD Agar), Granulated	Low Risk	12/08/2015
DCM	GMH031	Xylose-Lysine-Deoxycholate Agar , Granulated	Low risk	22/04/2019



Document ref.: DoC 2022 vs. 15

Page 40 of 130

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Dehydrated Culture Media -Supplements				
DCM-S	FD001	Non Spore Anaerobic Supplement	Low risk	20/12/201
DCM-S	FD002	G.N. Spore Anaerobic Supplement	Low risk	20/12/201
DCM-S	FD003	Polymyxin B Selective Supplement	Low risk	20/12/201
DCM-S	FD003B	Polymyxin B Selective Supplement	Low risk	04/07/201
DCM-S	FD004	Bordetella Selective Supplement	Low risk	20/12/201
DCM-S	FD005	Brucella Selective Supplement	Low risk	20/12/201
DCM-S	FD006	Campylobacter Supplement-I (Blaser-Wang)	Low risk	20/12/201
DCM-S	FD007	Campylobacter Supplement - II (Butzler)	Low risk	20/12/201
DCM-S	FD008	Campylobacter Supplement- III (Skirrow)	Low risk	20/12/201
DCM-S	FD009	Campylobacter Growth Supplement	Low risk	20/12/201
DCM-S	FD010	Clostridium Difficile Supplement	Low risk	20/12/201
DCM-S	FD013	S.F.P. Supplement (Perfringens S.F.P. Supplement)	Low risk	20/12/201
DCM-S	FD014	T.S.C. Supplement (Perfringens T.S.C. Supplement)	Low risk	20/12/201
DCM-S	FD015	Dermato Supplement	Low risk	20/12/201
DCM-S	FD017	Legionella Selective Supplement	Low risk	20/12/201
DCM-S	FD018	Middlebrook OADC Growth Supplement	Low risk	20/12/201
DCM-S	FD019	Middlebrook ADC Growth Supplement	Low risk	20/12/201
DCM-S	FD019R	Middlebrook ADC Growth Supplement	Low risk	10/11/202
DCM-S	FD020	Oleic Albumin Supplement	Low risk	20/12/201
DCM-S	FD021	GC Supplement w/ Antibiotics	Low risk	20/12/201
DCM-S	FD022	Haemoglobin Powder	Low risk	20/12/201
DCM-S	FD023	V.C.N. Supplement	Low risk	20/12/201
DCM-S	FD024	V.C.N.T. Supplement	Low risk	20/12/201
DCM-S	FD025	Vitamino Growth Supplement (Twin Pack)	Low risk	20/12/201
DCM-S	FD025R	Vitamino Growth Supplement (Twin Pack)	Low risk	10/11/202
DCM-S	FD026	Linco T Supplement	Low risk	20/12/201
DCM-S	FD026R	Linco T Supplement	Low risk	10/11/202
DCM-S	FD027	Yeast Autolysate Supplement	Low risk	20/12/201
DCM-S	FD028	Vanclo T Supplement	Low risk	20/12/201
DCM-S	FD029	Cetrinix Supplement	Low risk	22/04/201
DCM-S	FD030	Staph-Strepto Supplement	Low risk	20/12/201
DCM-S	FD031	Strepto supplement	Low risk	25/08/201
DCM-S	FD033	Chloramphenicol Selective Supplement	Low risk	20/12/201
DCM-S	FD034	Yersinia Selective Supplement	Low risk	20/12/201
DCM-S	FD035	CC Supplement	Low risk	20/12/201
DCM-S	FD036	CFC Supplement	Low risk	22/04/201
DCM-S	FD037	Legionella Selective Supplement II	Low risk	20/12/201

M	EDI	Λ
	ニレル	

Document ref.: DoC 2022 vs. 15

Page 41 of 130

DCM-S	FD038	Legionella Selective Supplement III	Low risk	20/12/2012
DCM-S	FD039	Aeromonas Selective Supplement	Low risk	20/12/2012
DCM-S	FD040	Legionella Selective Supplement IV (MWY)	Low risk	20/12/2012
DCM-S	FD041A	Legionella Supplement (Twin Pack)	Low risk	20/12/2012
DCM-S	FD041AR	Legionella Growth Supplement (Legionella Supplement) (Twin Pack)	Low risk	25/08/2016
DCM-S	FD042	Campylobacter Selective Supplement IV (Preston Selective Supplement)	Low risk	20/12/2012
DCM-S	FD043	Doyle's Antibiotic Supplement	Low risk	20/12/2012
DCM-S	FD045	Egg Yolk Emulsion (100 ml per vial)	Low risk	20/12/2012
DCM-S	FD045B	Egg Yolk Emulsion	Low risk	04/07/2018
DCM-S	FD045L	Egg Yolk Emulsion (50ml per vial)	Low risk	04/07/2018
DCM-S	FD045R	Egg Yolk Emulsion (100 ml per vial)	Low risk	25/08/2016
DCM-S	FD045RC	Egg Yolk Emulsion (100 ml per vial)	Low risk	10/11/2020
DCM-S	FD046	Egg Yolk Tellurite Emulsion (100 ml per vial)	Low risk	20/12/2012
DCM-S	FD046B	Egg Yolk Tellurite Emulsion	Low risk	04/07/2018
DCM-S	FD046L	Egg Yolk Tellurite Emulsion (50ml per vial)	Low risk	04/07/2018
DCM-S	FD046N	Egg Yolk Tellurite Emulsion, Modified	Low risk	04/07/2018
DCM-S	FD046NL	Egg Yolk Tellurite Emulsion, Modified	Low risk	04/07/2018
DCM-S	FD046R	Egg Yolk Tellurite Emulsion	Low risk	10/11/2020
DCM-S	FD047	Potassium Tellurite 3.5% (1 ml per vial)	Low risk	20/12/2012
DCM-S	FD048	Urea 40% (5 ml per vial)	Low risk	20/12/2012
DCM-S	FD049	C.B.I. Supplement	Low risk	20/12/2012
DCM-S	FD052	Potassium Tellurite 1% (1 ml per vial)	Low risk	20/12/2012
DCM-S	FD053	Gruft Mycobacterial Supplement	Low risk	20/12/2012
DCM-S	FD054	GBS Supplement	Low risk	20/12/2012
DCM-S	FD056	G. Vaginalis Selective Supplement	Low risk	20/12/2012
DCM-S	FD057	TTC Solution 1% (10 ml per vial)	Low risk	20/12/2012
DCM-S	FD059	Basic Fuchsin (6.0 gm per vial)	Low risk	20/12/2012
DCM-S	FD061	Listeria Selective Supplement (PALCAM)	Low risk	22/04/2019
DCM-S	FD061R	Listeria Selective Supplement (PALCAM)	Low risk	04/07/2018
DCM-S	FD062	Bacteroides Selective Supplement	Low risk	20/12/2012
DCM-S	FD063	Listeria Selective Supplement II	Low risk	20/12/2012
DCM-S	FD063I	Listeria Selective Supplement II	Low risk	20/12/2012
DCM-S	FD066	Leptospira Enrichment	Low risk	20/12/2012
DCM-S	FD068	Sulpha Supplement	Low risk	20/12/2012
DCM-S	FD069	B P Sulpha Supplement	Low risk	20/12/2012
DCM-S	FD070	McBride Listeria Supplement	Low risk	20/12/2012
DCM-S	FD071	Oxford Listeria Supplement	Low risk	20/12/2012
DCM-S	FD072	KL Virulence Enrichment (20 ml per vial)	Low risk	20/12/2012
DCM-S	FD072D	KL Virulence Enrichment (500 ml)	Low risk	10/11/2020

M		

Document ref.: DoC 2022 vs. 15

Page 42 of 130

DCM-S	FD072M	KL Virulence Enrichment (1000 ml)	Low risk	10/11/2020
DCM-S	FD073	Diphtheria Virulence Supplement (Part A & B)	Low risk	20/12/2012
DCM-S	FD075	Mycoplasma Enrichment Supplement	Low risk	20/12/2012
DCM-S	FD075R	Mycoplasma Enrichment Supplement	Low risk	10/11/2020
DCM-S	FD078	Campylobacter Selective Supplement (Karmali)	Low risk	10/11/2020
DCM-S	FD082	Ampicillin Supplement	Low risk	20/12/2012
DCM-S	FD090	Campylobacter Selective Supplement	Low risk	20/12/2012
DCM-S	FD091	Bromo Thymol Blue Supplement (20 mg per vial)	Low risk	20/12/2012
DCM-S	FD092	MUG Supplement (50 mg per vial)	Low risk	10/11/2020
DCM-S	FD093	Bromo Cresol Purple	Low risk	22/04/2019
DCM-S	FD094	Trichomonas Selective Supplement II	Low risk	20/12/2012
DCM-S	FD095	10% Lactic Acid Solution (10 ml per vial)	Low risk	20/12/2012
DCM-S	FD096	Novobiocin Supplement	Low risk	22/04/2019
DCM-S	FD099	Trichomonas Selective Supplement I	Low risk	20/12/2012
DCM-S	FD100	Mueller Tellurite Serum (25 ml per vial)	Low risk	20/12/2012
DCM-S	FD102	Ticarcillin Supplement	Low risk	20/12/2012
DCM-S	FD103	Potassium Chlorate Supplement	Low risk	20/12/2012
DCM-S	FD105	Park and Sanders Selective Supplement II	Low risk	20/12/2012
DCM-S	FD106	Campylobacter Supplement VI (Butzler)	Low risk	20/12/2012
DCM-S	FD111	Kimmig Selective Supplement (Twin Pack)	Low risk	20/12/2012
DCM-S	FD112	George Kimmig Selective Supplement	Low risk	20/12/2012
DCM-S	FD114	Vitamin K1 Supplement	Low risk	20/12/2012
DCM-S	FD117	Haemophilus Growth Supplement	Low risk	20/12/2012
DCM-S	FD118	Mucasol	Low risk	20/12/2012
DCM-S	FD119	Streptococcus Selective Supplement	Low risk	20/12/2012
DCM-S	FD120	Chlortetracycline Selective Supplement	Low risk	20/12/2012
DCM-S	FD126	Listeria Moxalactam Supplement	Low risk	20/12/2012
DCM-S	FD130	Nalidixic Selective Supplement	Low risk	20/12/2012
DCM-S	FD132	Campylobacter Selective Supplement w/ Hemin (Karmali)	Low risk	10/11/2020
DCM-S	FD135	CCDA Selective Supplement	Low risk	20/12/2012
DCM-S	FD136	Listeria UVM Supplement I	Low risk	20/12/2012
DCM-S	FD137	Listeria UVM Supplement II	Low risk	20/12/2012
DCM-S	FD142	Legionella Growth Supplement (BCYE)	Low risk	10/11/2020
DCM-S	FD142X	Legionella Growth Supplement	Low risk	10/11/2020
DCM-S	FD143	Legionella (GVPC) Selective Supplement	Low risk	20/12/2012
DCM-S	FD144	Legionella BMPA Selective Supplement	Low risk	10/11/2020
DCM-S	FD147	Tellurite - Cefixime Supplement	Low risk	20/12/2012
DCM-S	FD149	Neomycin Supplement	Low risk	20/12/2012
DCM-S	FD150	NYC Supplement	Low risk	20/12/2012
DCM-S	FD152	XLT4 Supplement	Low risk	20/12/2012

ГМ	ED	

Document ref.: DoC 2022 vs. 15

Page 43 of 130

DCM-S	FD153	M-CP Selective Supplement - I	Low risk	10/11/2020
DCM-S	FD154	M-CP Selective Supplement - II	Low risk	10/11/2020
DCM-S	FD154A	M-CP Selective Supplement, Modified	Low risk	10/11/2020
DCM-S	FD157	Urea 5% (5 ml per vial)	Low risk	20/12/2012
DCM-S	FD158	Campylobacter Selective Supplement IV (Preston), Modified	Low risk	20/12/2012
DCM-S	FD159	Doyle'S Antibiotic Supplement, Modified	Low risk	04/07/2018
DCM-S	FD160	Legionella (GVPA) Selective Supplement, Modified	Low risk	04/07/2018
DCM-S	FD161	Brucella Selective Supplement, Modified	Low risk	04/07/2018
DCM-S	FD163	Listeria Selective Supplement II, Modified	Low risk	04/07/2018
DCM-S	FD164	Park and Sanders Selective Supplement II, Modified	Low risk	04/07/2018
DCM-S	FD165	Campylobacter Supplement -II (Butzler), Modified	Low risk	04/07/2018
DCM-S	FD169	CC Supplement, Modified	Low risk	04/07/2018
DCM-S	FD171	McBride Listeria Supplement, Modified	Low risk	04/07/2018
DCM-S	FD172	Oxford Listeria Supplement, Modified	Low risk	28/04/2017
DCM-S	FD172R	Oxford Listeria Supplement, Modified	Low risk	04/07/2018
DCM-S	FD173	Mycoprep (for 2 tests)	Low risk	16/12/2017
DCM-S	FD173B	Mycoprep (for 10 tests)	Low risk	16/12/2017
DCM-S	FD175	Mycoplasma Urogenital Selective Supplement	Low risk	20/12/2012
DCM-S	FD176	Dermato Supplement, Modified	Low risk	04/07/2018
DCM-S	FD179	Antibiotic Mixture for Borrelia (100 X) (5 ml per vial)	Low risk	20/12/2012
DCM-S	FD180	Rabbit serum	Low risk	25/08/2016
DCM-S	FD181	HiCrome™ Listeria Selective Supplement	Low risk	10/11/2020
DCM-S	FD183	Legionella Selective Supplement II, Modified	Low risk	04/07/2018
DCM-S	FD185	Anthracis Selective Supplement	Low risk	20/12/2012
DCM-S	FD187	HiCrome™ EC 0157 : H7 Selective Supplement	Low risk	05/11/2020
DCM-S	FD190	HiCrome°Hicrome ECC Selective Supplement	Low risk	22/04/2019
DCM-S	FD191	Oxacillin Resistance Selective Supplement	Low risk	20/12/2012
DCM-S	FD192	HiCrome™ Candida Selective Supplement	Low risk	20/12/2012
DCM-S	FD195	Fibrinogen Plasma Trypsin Inhibitor Supplement	Low risk	20/12/2012
DCM-S	FD196	Tetracycline Selective Supplement	Low risk	20/12/2012
DCM-S	FD198	Mycoplasma Cultivation Supplement	Low risk	20/12/2012
DCM-S	FD201	Albumin Glucose Supplement	Low risk	20/12/2012
DCM-S	FD206	Legionella Growth Supplement w/o L-Cysteine	Low risk	05/11/2020
DCM-S	FD206R	Legionella Growth Supplement w/o L-Cysteine	Low risk	10/11/2020
DCM-S	FD212	L. mono Selective Supplement I	Low risk	20/12/2012
DCM-S	FD212A	OA Listeria Selective Supplement	Low risk	10/11/2020
DCM-S	FD212B	L. mono Selective Supplement I	Low risk	04/07/2018
DCM-S	FD213	L. mono Selective Supplement II	Low risk	20/12/2012
DCM-S	FD214	L. mono Enrichment Supplement I	Low risk	20/12/2012
DCM-S	FD215	Vitamino Growth Supplement, Modified (Twin Pack)	Low risk	20/12/2012

	IM		
the second se			

Document ref.: DoC 2022 vs. 15

Page 44 of 130

DCM-S	FD215B	Vitamino Growth Supplement, Modified	Low risk	22/04/201
DCM-S	FD225	Klebsiella Selective Supplement	Low risk	10/11/202
DCM-S	FD226	Enterococcus faecium Selective Supplement	Low risk	10/11/202
DCM-S	FD227	L. mono Enrichment Supplement II	Low risk	20/12/201
DCM-S	FD229	MeReSa Selective Supplement	Low risk	20/12/201
DCM-S	FD230	HiCrome EC 0157: H7 Selective Supplement	Low risk	22/04/201
DCM-S	FD232	Burkholderia Cepacia Selective Supplement	Low risk	20/12/201
DCM-S	FD233	Vancomycin Supplement	Low risk	20/12/201
DCM-S	FD236	Sorbic Acid Supplement	Low risk	20/12/201
DCM-S	FD241	Poctri supplement	Low risk	25/08/201
DCM-S	FD242	Legionella Selective Supplement(GVPN)	Low risk	20/12/201
DCM-S	FD243	Clostridium Difficile Supplement	Low risk	20/12/201
DCM-S	FD245	HiCrome [™] Nickels & Leesment Selective Supplement	Low risk	10/11/202
DCM-S	FD246	Cefixime Supplement	Low risk	20/12/202
DCM-S	FD247	ECO157:H7 Selective Supplement	Low risk	22/04/20:
DCM-S	FD248	Coagulase Plasma	Low risk	04/07/20:
DCM-S	FD248A	Coagulase Plasma w/ EDTA (From Rabbit)	Low risk	22/04/20
DCM-S	FD248B	Rabbit plasma with EDTA and 15% NaCl	Low risk	22/04/20
DCM-S	FD248R	Coagulase Supplement for Staphilococci	Low risk	22/04/20
DCM-S	FD252	Gentamycin Selective Supplement	Low risk	22/04/20
DCM-S	FD253	Urea Solution	Low risk	20/12/20
DCM-S	FD254	Ureaplasma Selective Supplement	Low risk	04/07/20
DCM-S	FD255	Ureaplasma Growth Supplement	Low risk	20/12/20
DCM-S	FD259	Cefoxitin Supplement	Low risk	20/12/20
DCM-S	FD261	Vancomycin Supplement	Low risk	20/12/20
DCM-S	FD266	Listeria Moxalactam Supplement Modified	Low risk	20/12/20
DCM-S	FD269	OFPBL Selective Supplement	Low risk	25/11/20
DCM-S	FD270	Chromogenic Supplement	Low risk	10/11/20
DCM-S	FD271	MDR Acinetobacter Selective Supplement	Low risk	25/08/202
DCM-S	FD274	HiCrome™ Selective Salmonella Agar Supplement	Low risk	22/04/20
DCM-S	FD277	HiCrome™ VRE Agar supplement	Low risk	20/12/20
DCM-S	FD278	HiCrome™ ESBL Agar Supplement	Low risk	20/12/20
DCM-S	FD279	HiCrome™ KPC Agar Supplement	Low risk	20/12/20
DCM-S	FD280	Sterile Charcoal Supplement for Legionella Agar	Low risk	10/11/20
DCM-S	FD283R	HiCrome [™] Candida Differential Selective Supplement	Low risk	20/12/20
DCM-S	FD284	Acriflavin-Cefsulodin-Vancomycin Supplement (ACV Supplement)	Low risk	20/12/20:
DCM-S	FD285	Bifidobacterium Selective Supplement	Low risk	20/12/202
DCM-S	FD286	Yersinia Selective Supplement	Low risk	20/12/202
DCM-S	FD287	Growth Supplement I for MSM	Low risk	20/12/20:
DCM-S	FD288	Growth Supplement II for MSM	Low risk	20/12/202

Document ref.: DoC 2022 vs. 15

Page 45 of 130

DCM-S	FD290	Novobiocin Selective Supplement	Low risk	20/12/2012
DCM-S	FD295	HiCrome™ ECO157:H7 Selective Supplement Modified	Low risk	22/04/2019
DCM-S	FD299	Selective Supplement for MRSA	Low risk	20/12/2012
DCM-S	FD300	Hayflick Supplement	Low risk	20/12/2012
DCM-S	FD302	Group A Selective Supplement	Low risk	20/12/2012
DCM-S	FD304	Arcobacter Selective Supplement	Low risk	05/11/2020
DCM-S	FD306	Modified Listeria Oxford Selective Supplement	Low risk	22/04/2019
DCM-S	FD309	Monensin Selective Supplement	Low risk	22/04/2019
DCM-S	FD312	VIA Supplement	Low risk	20/12/2012
DCM-S	FD319	MRSA Supplement	Low risk	25/08/2016
DCM-S	FD319R	MeReSa Selective Supplement (MRSA Selective Supplement)	Low risk	25/08/2016
DCM-S	FD320	Clostridium difficle Selective Supplement	Low risk	25/08/2016
DCM-S	FD321	TVCSB Supplement	Low risk	25/08/2016
DCM-S	FD322	Middlebrook ADC Growth Supplement, Modified	Low risk	25/08/2016
DCM-S	FD323	TSBV Supplement	Low risk	25/08/2016
DCM-S	FD324	Bacillus Selective Supplement	Low risk	25/08/2016
DCM-S	FD327	NAD Supplement	Low risk	25/08/2010
DCM-S	FD329	Middlebrook OADC Enrichment Supplement	Low risk	25/08/201
DCM-S	FD332	Lecithin solution	Low risk	10/11/202
DCM-S	FD333	Modified L.mono Selective supplement	Low risk	10/11/202
DCM-S	FD334	Mycoplasma selective supplement	Low risk	25/08/201
DCM-S	FD335	Leeds Acinetobacter selective supplement	Low risk	25/08/201
DCM-S	FD335R	MDR Acinetobacter Selective Supplement	Low risk	25/08/201
DCM-S	FD338	LCN Supplement	Low risk	25/08/201
DCM-S	FD340	PACT Supplement	Low risk	28/04/201
DCM-S	FD342	Rapid Listeria Selective Supplement	Low risk	10/11/202
DCM-S	FD343	Growth Supplement for Fastidious Organism	Low risk	16/12/201
DCM-S	FD344	ECC Selective Supplement Modified	Low risk	22/04/201
DCM-S	FD345	Ciprofloxacin Supplement	Low risk	10/11/202
DCM-S	FD347	PCP Supplement	Low risk	04/07/201
DCM-S	FD347B	PCP Supplement	Low risk	10/11/202
DCM-S	FD348	OADS Supplement	Low risk	16/12/201
DCM-S	FD349	Vancomycin Polymyxin B Supplement	Low risk	04/07/201
DCM-S	FD352	Acinetobacter Selective Supplement	Low risk	30/10/201
DCM-S	FD353	VCAT Supplement	Low risk	30/10/201
DCM-S	FD354	STEC Selective Supplement	Low risk	30/10/201
DCM-S	FD355	HiCrome™ Colistin Resistant Selective Supplement	Low risk	30/10/2018
DCM-S	FD356	Diphenyl supplement	Low risk	22/04/201
DCM-S	FD357	Carba Selective Supplement	Low risk	10/11/202
DCM-S	FD360	C.auris Selective Supplement	Low risk	05/11/201
DCM-S	FD361	BCSA Selective Supplement	Low risk	05/11/201

IM		

Document ref.: DoC 2022 vs. 15

Page 46 of 130

DCM-S	FD362	Coagulase Supplement (for M2126)	Low risk	10/11/2020
DCM-S	FD363	HiMRSA Selective Supplement	Low risk	17/06/2021
DCM-S	FD725R	Mycoprep (Modified,Bulk powder)	Low risk	25/08/2016
DCM-S	FD726	Mycoprep (Modified, powder for 1000ml)	Low risk	25/08/2016
DCM-S	FD743R	Bifido Selective Supplement C	Low risk	25/08/2016
DCM-S	FD744R	Bifido Selective Supplement D	Low risk	25/08/2016
DCM-S	FD745R	Bifido Selective Supplement E	Low risk	25/08/2016
DCM-S	FD749	Supplement for HiCrome™ Candida Agar	Low risk	04/07/2018
DCM-S	FD750	L. J. Media Supplement w/ Capreomycin	Low risk	25/08/2016
DCM-S	FD751	L. J. Medium Supplement w/ Clarithromycin	Low risk	25/08/2016
DCM-S	FD752	L. J. Media Supplement w/ D-Cycloserine	Low risk	25/08/2016
DCM-S	FD753	L. J. Media Supplement w/ Ethambutol	Low risk	25/08/2016
DCM-S	FD754	L. J. Media Supplement w/ Ethionamide	Low risk	25/08/2016
DCM-S	FD755	L. J. Medium Supplement w/ Gatifloxacin	Low risk	25/08/2016
DCM-S	FD756	L. J. Media Supplement w/ Isoniazide	Low risk	25/08/2016
DCM-S	FD757	L. J. Media Supplement w/ Kanamycin	Low risk	25/08/2016
DCM-S	FD758	L. J. Medium Supplement w/ Levofloxacin	Low risk	25/08/2016
DCM-S	FD759	L. J. Medium Supplement w/ Lomefloxacin	Low risk	04/07/2018
DCM-S	FD760	L. J. Medium Supplement w/ Ofloxacin	Low risk	04/07/2018
DCM-S	FD761	L. J. Medium Supplement w/ p-Aminosalicylic acid	Low risk	04/07/2018
DCM-S	FD762	L. J. Medium Supplement w/ Pyrazinamide	Low risk	04/07/2018
DCM-S	FD763	L.J.Medium Supplementw/Rifabutin	Low risk	04/07/2018
DCM-S	FD764	L.J.Medium Supplementw/Rifampicin	Low risk	04/07/2018
DCM-S	FD765	L.J.Medium Supplementw/Sodium Salicylate	Low risk	04/07/2018
DCM-S	FD766	L.J.Medium Supplementw/Streptomycin	Low risk	04/07/2018
DCM-S	FD767	L.J.Medium Supplementw/TCH	Low risk	04/07/2018
DCM-S	FD768	Chloramphenicol Supplement	Low risk	04/07/2018
DCM-S	FD772	L.J. Media Supplement w/Amikacin	Low risk	04/07/2018
DCM-S	FD775	L.J. Media Supplement w/ p-Nitrobenzoic acid	Low risk	04/07/2018
DCM-S	FD780	L.J. Media Supplement w/Moxifloxacin	Low risk	04/07/2018
DCM-S	FD804	Enriched growth Supplement for Mycobacteria	Low risk	04/07/2018
DCM-S	FD805	Growth Supplement for Anaerobic cultures	Low risk	10/11/2020
DCM-S	FD808	Supplement for GC Agar Base	Low risk	10/11/2020
DCM-S	FD812	Selective Supplement for Gram positive bacteria (Clostridium, Staphylococcus spp. etc.)	Low risk	10/11/2020
DCM-S	FD814	PANTA Supplement	Low risk	10/11/2020
DCM-S	FD815B	Selective Supplement for SS Agar	Low risk	10/11/2020
DCM-S	FD816	Selective supplement for Enterobacteriaceae	Low risk	10/11/2020
DCM-S	FD817	Selective Supplement for Staphylococcus	Low risk	10/11/2020
DCM-S	FD820	Selective Supplement for SS Agar	Low risk	10/11/2020

Declaration of Conformity	Document ref.: DoC 2022 vs. 15
Microbiology Products	Page 47 of 130



Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Ready Prepared Media			Low risk	10/06/202
RPM - Ready Prepared Plates	HB001	HiCombi™ Nutrient - MacConkey Agar Plate	Low risk	20/12/201
RPM - Ready Prepared Plates	HB003	HiCombi™ CLED - MacConkey Agar Plate	Low risk	20/12/2012
RPM - Ready Prepared Plates	HB004	HiCombi™ XLD - MacConkey Agar Plate	Low risk	20/12/201
RPM - Ready Prepared Plates	HB005	HiCombi™ Cetrimide - MacConkey Agar Plate	Low risk	20/12/201
RPM - Ready Prepared Plates	HB006	HiCombi™ Blood- MacConkey Agar Plate	Low risk	20/12/201
RPM - Ready Prepared Plates	HB007	HiCombi™ MacConkey-Mannitol Salt Agar	Low risk	20/12/201
RPM - Ready Prepared Plates	HB008	HiCombi™ Blood -Chocolate Agar	Low risk	20/12/201
RPM - Ready Prepared Plates	НВ009	HiCombi™ Blood -Mannitol Salt Agar	Low risk	20/12/201
RPM - Ready Prepared Plates	HB010	HiCombi™ Chocolate - MacConkey Agar Plate	Low risk	20/12/201
RPM - Ready Prepared Plates	HB017	HiCombi™ Sabouraud Dextrose-Sheep Blood Agar Plate	Low risk	17/06/202
RPM- HiDip Slides	HD001	HiDip™ Cled-Cetri-Mac Medium	Low risk	20/12/201
RPM- HiDip Slides	HD002	HiDip™ Mac-Cled-Sab Medium	Low risk	20/12/201
RPM- HiDip Slides	HD003	HiDip™ Mac-Cled-Bile Esculin Medium	Low risk	20/12/201
RPM- HiDip Slides	HD004	HiDip™ Cled-Mac Medium	Low risk	20/12/201
RPM- HiDip Slides	HD005	HiDip™ Cled-MUG Mac Medium	Low risk	20/12/201
RPM- HiDip Slides	HD006	HiDip™ Cled-HiCrome™ UTI Medium	Low risk	20/12/201
RPM- HiDip Slides	HD007	HiDip™ Mac-HiCrome™ UTI Medium	Low risk	20/12/201
RPM- HiDip Slides	HD007R	HiDip™ Mac-HiCrome™ UTI Medium	Low risk	10/11/202
RPM- HiDip Slides	HD018	HiDip™ TSA-CLED Agar w/ B.T.B Indicator Medium	Low Risk	20/12/201
RPM- HiDip Slides	HD020	HiDip™ Pseudomonas Agar - MacConkey Agar Medium	Low risk	20/12/201
RPM- HiDip Slides	HD021	HiDip™ PCA - MacConkey Agar Medium	Low risk	20/12/201
RPM- HiDip Slides	HD024	HiDip™ Modified Rogosa Medium-Modified Rogosa Medium	Low risk	20/12/201
RPM- HiDip Slides	HD025	HiDip™ Modified Nickerson Medium-Modified Nickerson Medium	Low risk	20/12/201
RPM- HiDip Slides	HD041	HiDip HiCrome™ Universal Agar-PCA	Low risk	28/04/201
RPM- HiDip Slides	HD042	HiDip HiCrome™ UTI Agar - Dey Engley Neutralzing agar	Low risk	28/04/201
RPM- HiDip Slides	HD046	HiDip TSA-TCBS	Low risk	30/10/201
RPM- HiDip Slides	HD047	HiDip TSA-MRS	Low risk	30/10/201
RPM- HiSafe Blood Culturing System	LQ003	вні	Low risk	20/12/201
RPM- HiSafe Blood Culturing System	LQ003A	вні	Low risk	20/12/201
RPM- HiSafe Blood Culturing System	LQ004	BHI - Supplemented w/ 0.05% SPS	Low risk	20/12/201



Document ref.: DoC 2022 vs. 15

Page 49 of 130

RPM- HiSafe Blood Culturing System	LQ004R	BHI - Supplemented w/ 0.05% SPS	Low risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ004A	BHI - Supplemented w/ 0.05% SPS	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ004AR	BHI - Supplemented w/ 0.05% SPS	Low risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ005	TSB - Tryptone Soya Broth w/ 10% Sucrose	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ005A	TSB - Tryptone Soya Broth w/ 10% Sucrose	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ006	Columbia Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ006A	Columbia Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ007	Thioglycollate Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ007R	Thioglycollate Broth	Low Risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ007A	Thioglycollate Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ007AR	Thioglycollate Broth	Low Risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ008	Schaedler Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ008A	Schaedler Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ009	TSB - Tryptone Soya Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ009A	TSB - Tryptone Soya Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ010	Glucose Broth Supplemented w/ 0.05% SPS	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ010A	Glucose Broth Supplemented w/ 0.05% SPS	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ010AR	Glucose Broth Supplemented w/ 0.05% SPS	Low risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ010V	Glucose Broth supplemented w/0.05% SPS	Low risk	22/04/2019
RPM- HiSafe Blood Culturing System	LQ011	TSB - Tryptone Soya Broth Supplemented w/ 0.05% SPS	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ011A	TSB - Tryptone Soya Broth Supplemented w/ 0.05% SPS	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ011AR	TSB - Tryptone Soya Broth Supplemented w/ 0.05% SPS	Low risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ013V	Hartley Broth	Low risk	22/04/2019
RPM- HiSafe Blood Culturing System	LQ014	Modified Wilkins Chalgren Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ014A	Modified Wilkins Chalgren Broth	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ012	HiCombi™ Dual Performance Medium	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ012R	HiCombi™ Dual Performance Medium	Low Risk	10/11/2020



Document ref.: DoC 2022 vs. 15

Page 50 of 130

RPM- HiSafe Blood Culturing System	LQ013	Hartley Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ013A	Hartley Broth	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ023	Fluid thioglycollate Medium w/0.05% SPS	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ023A	Fluid thioglycollate Medium w/0.05% SPS	Low Risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ029	HiCombi™ Dual Performance Salmonella Medium - SS	Low Risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ029A	HiCombi™ Dual Performance Salmonella Medium - SS	Low Risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ029AR	HiCombi™ Dual Performance Salmonella Medium - SS	Low Risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ030	HiCombi™ Dual Performance Salmonella Medium - XLD	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ030A	HiCombi™ Dual Performance Salmonella Medium - XLD	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ031	HiCombi™ Dual Performance Salmonella Medium - DCA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ031A	HiCombi™ Dual Performance Salmonella Medium - DCA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ031AR	HiCombi™ Dual Performance Salmonella Medium - DCA	Low risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ032	HiCombi™ Dual Performance Salmonella Medium - HEA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ032A	HiCombi™ Dual Performance Salmonella Medium - HEA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ033	HiCombi™ Dual Performance Medium	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ033R	HiCombi™ Dual Performance Medium	Low risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ034	HiCombi™ Dual Performance Fungal Medium Kit	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ034R	HiCombi™ Dual Performance Fungal Medium Kit	Low Risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ034A	HiCombi™ Dual Performance Fungal Medium Kit	Low Risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ034AR	HiCombi™ Dual Performance Fungal Medium Kit	Low Risk	10/11/2020



Document ref.: DoC 2022 vs. 15

Page 51 of 130

RPM- Ready Prepared Dual Media	LQ035	HiCombi™ Dual Performance Selective Medium - HEA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ035A	HiCombi [™] Dual Performance Selective Medium - HEA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ035AR	HiCombi [™] Dual Performance Selective Medium - HEA	Low risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ036	HiCombi [™] Dual Performance Selective Medium - SS	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ036R	HiCombi [™] Dual Performance Selective Medium - SS	Low risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ036A	HiCombi™ Dual Performance Selective Medium - SS	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ036AR	HiCombi [™] Dual Performance Selective Medium - SS	Low risk	10/11/2020
RPM- Ready Prepared Dual Media	LQ037	HiCombi [™] Dual Performance Selective Medium - HEA	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ038	HiCombi™ Dual Performance Selective Medium - SS	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ038A	HiCombi™ Dual Performance Selective Medium - SS	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ004AI	BHI-Supplemented w/0.05% SPS	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ004AL	BHI-Supplemented w/0.05% SPS	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ004V	BHI - Supplemented w/ 0.05% SPS	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ0151	Medium 11. GN Broth	Low risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ069	Alkaline Peptone Water	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ069R	Enrichment Medium For Vibrio	Low Risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ070	Selenite Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ070V	Selenite Broth	Low Risk	25/08/2016

IM	ED	IA
IIVI		

Document ref.: DoC 2022 vs. 15

Page 52 of 130

RPM- Ready Prepared Liquid Medium	LQ077	BHI Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ077V	BHI Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ077R	Enrichment Medium	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ079	Bile Broth	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ079V	Bile Broth	Low Risk	22/04/2019
RPM- Ready Prepared Liquid Medium	LQ080	Cooked M Medium	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ080C	Cooked M Medium	Low Risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ080V	Cooked M Medium	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ088	Tetrathionate Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ089	Peptone Water	Low risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ089X	Peptone Water	Low risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ093	Cooked M Medium w/ Glucose, Hemin & Vitamin K	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ095	Hartley Broth w/ 0.05% SPS	Low Risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ095A	Hartley Broth w/ 0.05% SPS	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ104	Rappaport Vassiliadis Salmonella Enrichment Broth	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ104C	Rappaport Vassiliadis Salmonella Enrichment Broth	Low Risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ104V	Rappaport Vassiliadis Salmonella Enrichment Broth	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ104XX	Rappaport Vassiliadis Salmonella Enrichment Broth	Low Risk	28/04/2017
RPM- Ready Prepared Liquid Medium	LQ105	Kirchner Medium Base	Low Risk	20/12/2012

ΠT	М		Λ
		7 1	

Document ref.: DoC 2022 vs. 15

Page 53 of 130

RPM- Ready Prepared Dual Media	LQ109	HiCombi™ Dual Performance Trans Isolate Medium	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ109R	HiCombi™ Dual Performance Trans Isolate Medium	Low risk	10/11/2020
RPM- Ready Prepared Liquid Medium	LQ126	Urea Indole Medium	Low risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ129	Sabouraud's Dextrose Broth	Low risk	04/07/2018
RPM- Ready Prepared Liquid Medium	LQ129V	Sabouraud's Dextrose Broth	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ132	Campylo Thioglycollate Broth w/Selective Supplement	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ134	L Broth	Low Risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ146	Mannitol Selenite Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ157	GN Broth, Hajna	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ159	Hayflick Medium	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ170	Selective Enrichment Medium For Group B	Low risk	25/08/2016
RPM- Ready Prepared Liquid Medium	LQ180V	Brucella Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ181V	Mannitol Salt Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ182V	Mueller Hinton Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ296X	Hugh Leifson Medium	Low risk	10/11/2020
RPM- HiSafe Blood Culturing System	LQ188	HiCombi™ Dual Performance Fungal Medium, Modified	Low risk	20/12/2012
RPM- HiSafe Blood Culturing System	LQ208	Eugonic LT100 Broth	Low Risk	22/04/2019
RPM- Ready Prepared Liquid Medium	LQ208L	Eugonic LT100 Broth	Low risk	28/04/2017
RPM- Ready Prepared Liquid Medium	LQ208CCL	Eugonic LT100 Broth	Low risk	28/04/2017



Document ref.: DoC 2022 vs. 15

Page 54 of 130

RPM- Ready Prepared Liquid Medium	LQ210C	BHI Broth	Low risk	20/12/2012
RPM- Ready Prepared Liquid Medium	LQ210D	BHI Broth	Low risk	20/12/2012
RPM- Ready Prepared Dual Media	LQ241	HiCombi Trans Isolate Medium	Low risk	28/04/2017
RPM- Ready Prepared Liquid Medium	LQ246CCL	Sauton's Fluid Medium Base	Low risk	16/12/2017
RPM- Ready Prepared Liquid Medium	LQ31411	HiMiC TM Diluent	Low risk	10/11/2020
RPM- Ready Prepared Liquid Medium	LQ319V	Thioglycollate Medium with Hemin & Vitamin K	Low risk	17/06/2021
RPM- Ready Prepared Liquid Medium	LQ319VIII	Thioglycollate Medium with Hemin & Vitamin K	Low risk	17/06/2021
RPM- Ready Prepared Liquid Medium	LQ089CCLR	Peptone Water	Low risk	17/06/2021
RPM -Ready Prepared Plates	MP001	Nutrient Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP001L	Nutrient Agar Plate (150mm plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP015	Hoyles Media Plate with supplements.	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP016	Brilliant Green Agar, Modified Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP022	EMB Agar, Levine Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP023	Vogel Johnson Agar Plate (V.J. Agar Plate)	Low Risk	22/04/2019
RPM -Ready Prepared Plates	MP024	Cetrimide Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP029	Endo Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP031	Xylose Lysine Deoxycholate Agar (XLD Agar) Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP043	Baird Parker Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP043L	Baird Parker Agar Plate	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP043M	Baird Parker Agar Plate (150mm)	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP049	Violet Red Bile Agar Plate	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP063	Sabouraud Dextrose Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP063L	Sabouraud Dextrose Agar Plate (150 mm plate)	Low Risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 55 of 130

RPM -Ready Prepared Plates	MP063M	Sabouraud Dextrose Agar Plate (120 mm plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP065	Deoxycholate Citrate Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP073	Blood Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP074	Brucella Agar Plate	Low Risk	22/04/2019
RPM -Ready Prepared Plates	MP081	MacConkey Agar w/ 0.15% Bile Salts, CV and NaCl Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP081XL	MacConkey Agar w/ 0.15% Bile Salts, CV and NaCl Plate (200mm plate)	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP082	MacConkey Agar w/o CV, NaCl w/ 0.5% Sodium Taurocholate Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP091	Plate Count Agar Plate	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP103	Chocolate Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP108	SS Agar (Salmonella Shigella Agar) Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1032	SS Agar Plate, Modified (Salmonella Shigella Agar Plate, Modified)	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1039	Brucella Agar Plate with Hemin & Vitamin K1	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1057	G. vaginilis Selective Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1067	Sabouraud Chloramphenicol Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1084	Mueller Hinton Agar No. 2 Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1084HB	Mueller Hinton Agar No.2 Plate w/ Horse Blood	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1084SB	Mueller Hinton Agar No.2 Plate w/ Sheep Blood	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1139	Modified MYP Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP118	Mannitol Salt Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1259	Haemophilus Test Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1260	Tellurite Blood Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1295	HiCrome™ E.coli Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1297A	HiCrome™TM Candida Differential Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1301	Sheep Blood Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1301C	Sheep Blood Agar Plate (Individually Packed)	Low risk	28/04/2017
RPM -Ready Prepared Plates	MP1301M	Sheep Blood Agar Plate	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP1345	Anaerobic Blood Agar Plate w/Neomycin	Low risk	30/10/2018



Document ref.: DoC 2022 vs. 15

Page 56 of 130

RPM -Ready Prepared Plates	MP1353	HiCrome™ UTI Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP137	Malt Extract Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP144	Columbia 5% Sheep Blood Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1418	HiCrome™ UTI Agar Plate, Modified	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1454	Oxacillin Resistant Screening Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1540I	HiCrome™ Listeria Ottaviani Agosti Agar Plate	Low Risk	17/06/2021
RPM -Ready Prepared Plates	MP1548	Chocolate No. 2 Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1594	MeReSa Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP160	DCLS Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1600	HiCrome™ Universal Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1640	Burkholderia Cepacia Agar Plate	Low Risk	04/07/2018
RPM -Ready Prepared Plates	MP1674	HiCrome™ MeReSa Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1682	HiCrome™ Vibrio Agar Plate	Low Risk	17/06/2021
RPM -Ready Prepared Plates	MP1702	MacConkey Agar RS Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP173	Mueller Hinton Agar Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP173C	Mueller Hinton Agar Plate (100 mm Plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP173L	Mueller Hinton Agar Plate (150mm plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP173M	Mueller Hinton Agar Plate (120mm plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP173XL	Mueller Hinton Agar Plate (200mm plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP173SP	Mueller Hinton Agar Plate (150 mm scored plate)	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP175	Bordet Gengou Agar Plate w/15% Sheep blood	Low Risk	25/08/2016
RPM -Ready Prepared Plates	MP175SB	Bordet Gengou Agar Plate with 25% Sheep Blood	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1763	VRE Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP180	Lead Acetate Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1806	Mueller Hinton Agar plate w/ 5% Sheep Blood	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1806M	Mueller Hinton Agar plate w/ 5% Sheep Blood	Low Risk	04/07/2018
RPM -Ready Prepared Plates	MP1811	OFBL Agar Plate (Oxidation Fermentation Polymyxin Bacitracin Lactose Agar Plate)	Low risk	10/11/2020



Document ref.: DoC 2022 vs. 15

roducts

Page 57 of 130

RPM -Ready Prepared Plates	MP1825	Mueller Hinton Agar Plate with 2% Glucose w/Methylene Blue	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP1829	HiCrome™ ESBL Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1831	HiCrome™ KPC Agar Plate	Low Risk	28/04/2017
RPM -Ready Prepared Plates	MP1837	HiCrome™ Staph Agar Plate, Modified	Low Risk	28/04/2017
RPM -Ready Prepared Plates	MP1858	Bifidobacterium Agar Modified Plate	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP188	D.T.M Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1832	HiCrome™ Coliform Agar Plate, Modified	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP1925	HiCrome™ VRE Agar Plate	Low Risk	30/10/2018
RPM -Ready Prepared Plates	MP1938	HiCrome™ Acinetobacter Agar Plate	Low Risk	16/12/2017
RPM -Ready Prepared Plates	MP1947	Enriched Tryptone Soya Agar Plate (ETSA)	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1948	Tryptone Soya Serum Bacitracin Vancomycin Agar (TSBV)	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1949	Tryptone Soya Agar w/ Hemin & Menadione	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP1966	HiCrome™ Strep B Selective Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP1974	HiCrome™ Rapid MRSA Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP2062I	HiCrome™ Cronobacter Isolation Agar Plate (CCI Agar Plate)	Low risk	17/06/2021
RPM -Ready Prepared Plates	MP2085	Martin Lewin Agar	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP2089	Burkholderia cepacia Selective Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP211	BHI Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP2116	HiCrome™ Salmoconfirm Selective Agar Plate	Low risk	17/06/2021
RPM -Ready Prepared Plates	MP217	Bi.G.G.Y. Agar Plate (Nickerson Agar Plate)	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP291	Schaedler Agar Plate	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP1296	HiCrome™ Salmonella Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP298	MacConkey Sorbitol Agar Plate	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP317	EMB Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP406	Pseudomonas Isolation Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP413	Thayer Martin Agar Plate w/VCNT	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP467	Hektoen Enteric Agar Plate	Low risk	04/07/2018



Document ref.: DoC 2022 vs. 15

Page 58 of 130

RPM -Ready Prepared Plates	MP491	Anaerobic Agar (Brewer) Plate	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP540	Phenylethyl Blood Agar Plate w/ 5% Sheep Blood	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP5269	Modified Nickerson Medium	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5208	CNA Agar Plate with 5% Sheep Blood	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP5304	Blood agar Plate w/5mg/l Gentamicin	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP5316	Chocolate Agar Plate w/ 5% Sheep Blood	Low risk	28/04/2017
RPM -Ready Prepared Plates	MP5332	Sabouraud Dextrose Agar Plate w/Chloramphenicol & gentamicin	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP5333	Chocolate Agar Plate w/ Bacitracin	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP5334	Sabouraud Dextrose Agar plate w/Penicillin & Streptomycin	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP5339	Regan Lowe Agar Plate (Charcoal Blood Plate w/Cephalexin)	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP5340	Bordet Gengou Blood Agar Plate w/Cephalexin	Low risk	16/12/2017
RPM -Ready Prepared Plates	MP5380	BHI Agar Plate w/ Blood	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5381	BHI Agar Plate w/ Vancomycin	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5382	BHI Blood agar plate w/ Vancomycin	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5383	BCYE Selective Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5384	GBS Agar	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5386	Sabouraud Dextrose Agar Plate w/Gentamicin	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5387	Sabouraud Dextrose Agar Plate w/ Cycloheximide	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5389	Mueller Hinton Agar Plate w/ 2% NaCL	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5390	Helicobacter Pylori Selective Agar	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP5476	Mucormycosis Selective Agar Plate	Low risk	10/06/2021
RPM -Ready Prepared Plates	MP5477	Candida Selective Agar Plate	Low risk	10/06/2021
RPM -Ready Prepared Plates	MP511	Middlebrook 7H11 Agar w/TCH	Low risk	04/07/2018
RPM -Ready Prepared Plates	MP5426	Middlebrook 7H11 Agar w/ PANTA supplement	Low risk	10/11/2020
RPM -Ready Prepared Plates	MP616	Tergitol-7 Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP641	MRS Agar Plate	Low risk	28/04/2017
RPM -Ready Prepared Plates	MP636C	MYP Agar Plate (100mm plate)	Low risk	10/11/2020



Document ref.: DoC 2022 vs. 15

Page 59 of 130

RPM -Ready Prepared Plates	MP641-I	MRS Agar w/ 10 ppm cycloheximide	Low risk	28/04/2017
RPM -Ready Prepared Plates	MP664	Sabouraud Dextrose Agar Plate w/Chloramphenicol (50mg/L) and Cycloheximide 500mg/L	Low Risk	20/12/2012
RPM -Ready Prepared Plates	MP792	CLED Agar w/ Bromothymol Blue Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MP805	Bacteroides Bile Esculin Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP813I	BCYE Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP843	Yersinia Selective Agar Plate	Low risk	30/10/2018
RPM -Ready Prepared Plates	MP870	TCBS Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP975A	Anaerobic Blood Agar Plate	Low risk	25/08/2016
RPM -Ready Prepared Plates	MP994	Campylobacter Agar Plate	Low risk	20/12/2012
RPM -Ready Prepared Plates	MPV081	MacConkey HiVeg™ Agar Plate w/ CV, Nacl, 0.003% NR and 1.5% Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	MPV173	Mueller Hinton HiVeg™ Agar Plate	Low risk	10/11/2020
RPM -Ready Prepared Plates	QP001	Middlebrooke 7H11 Agar Plate	Low risk	04/07/2018
RPM- Transport Medium w/ swabs	MQ651P	HiCulture™ Transport Swabs w/ Amies Medium w/ Charcoal	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MQ5203P	HiCulture™ Transport Swab w/ Enteric Pathogen Transport Medium	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MQ306P	HiCulture™ Transport Swabs w/ Stuart Transport Medium	Low risk	20/12/2012
RPM- Viral Transport Medium w/ swabs	AL167	HiViral Transport Medium	Low risk	20/12/2012
RPM- Viral Transport Medium w/ swabs	MS052A	HiCulture™ Transport Swabs w/Selenite Medium (A)	Low risk	25/08/2016
RPM- Viral Transport Medium w/ swabs	MS316	HiCulture™ Transport Swabs w/CVTR Medium	Low risk	20/12/2012
RPM- Viral Transport Medium w/ swabs	MS316S	HiCulture™ Transport Swabs w/CVTR Medium	Low risk	10/11/2020
RPM- Viral Transport Medium w/ swabs	MS316SR	HiCulture™ Transport Swabs w/CVTR Medium w/metal stick	Low risk	10/11/2020
RPM- Viral Transport Medium w/ swabs	MS316A	HiCulture™ Transport Swabs w/CVTR Medium,Modified	Low risk	25/08/2016
RPM- Viral Transport Medium w/ swabs	MS1145	HiCulture™ Listeria Isolation and Transport Swabs	Low risk	20/12/2012
RPM- Viral Transport Medium w/ swabs	MS1145R	HiCulture™ Listeria Isolation and Transport Swabs	Low risk	10/11/2020



Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 60 of 130

RPM- Viral Transport Medium w/ swabs	MS1145S	HiCulture™ Listeria Isolation and Transport Swabs with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS1514	Hiculture™ Transport swabs w/Modified Campylobacter Thioglycollate Medium	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS1514R	Hiculture™ Transport swabs w/Modified Campylobacter Thioglycollate Medium in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS1557	Hiculture™ Transport swabs w/BHI broth for H.pylori	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS1759	Hiculture™ Transport swabs	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS2016A	HiCulture™ Transport Swabs w/ Soyabean Casein Digest Medium w/6.5% NaCL	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS2016B	HiCulture™ Transport Swabs w/ Soyabean Casein Digest Medium w/6.5% NaCL	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS202	HiCulture™ Transport Swabs w/ Cary Blair Medium	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS202A	HiCulture™ Transport Swabs w/ Cary Blair Medium (A)	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS202R	HiCulture™ Transport Swabs w/ Cary Blair Medium in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS202S	HiCulture™ Transport Swabs w/ Cary Blair Medium with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS2055	HiCulture™ Transport Medium for Helicobacter pylori	Low risk	28/04/2017
RPM- Transport Medium w/ swabs	MS2127	HiCulture™ Transport Swab w/ Todd Hewitt Broth w/Colistin & Nalidixic Acid	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS306	HiCulture™ Transport Swabs w/ Stuart Transport Medium	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS306R	HiCulture™ Transport Swabs w/ Stuart Transport Medium	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS306S	HiCulture™ Transport Swabs w/ Stuart Transport Medium with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS5002	HiCulture™ Transport Swabs w/ 0.85% Sodium chloride and 0.1% Buffered Ppetone Water in polystyrene tube	Low risk	04/07/2018
RPM- Transport Medium w/ swabs	MS5215	HiViral [™] Transport Medium for Cloacal Samples	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS5296	HiCulture™ Skim Milk Tryptone Glucose Glycerin Medium swabs	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS5321	HiCulture Sterile swabs w/ 0.9% Saline	Low risk	22/04/2019
RPM- Transport Medium w/ swabs	MS651	HiCulture™ Transport Swabs w/ Amies Medium w/ Charcoal	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS651R	HiCulture™ Transport Swabs w/ Amies Medium w/ Charcoal in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS651S	HiCulture™ Transport Swabs w/ Amies Medium w/ Charcoal with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS651SR	HiCulture™ Transport Swabs w/ Amies Medium w/ Charcoal with metal stick	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS684	HiCulture™ Transport Swabs w/ Amies Medium w/o Charcoal	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS684R	HiCulture™ Transport Swabs w/ Amies Medium w/o Charcoal in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS684A	HiCulture™ Transport Swabs w/ Amies Medium (A)	Low risk	25/08/2016



Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 61 of 130

RPM- Transport Medium w/ swabs	MS684B	HiCulture™ Transport Swabs w/ Amies Medium (B)	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS684C	HiCulture™ Transport Swabs w/ Amies Medium (C)	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS684D	HiCulture™ Transport Swabs w/ Amies Medium (D)	Low risk	25/08/2016
RPM- Transport Medium w/ swabs	MS684S	HiCulture™ Transport Swabs w/ Amies Medium w/o Charcoal with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS010	HiCulture™ Transport Swabs w/ Alternative Thioglycollate Medium	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS010R	HiCulture™ Transport Swabs w/ Alternative Thioglycollate Medium in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS010S	HiCulture™ Transport Swabs w/ Alternative Thioglycollate Medium with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS113	HiCulture™ Transport Swabs w/ Chlamydospore Medium	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS113R	HiCulture™ Transport Swabs w/ Chlamydospore Medium in polystyrene tube	Low risk	10/11/2020
RPM- Transport Medium w/ swabs	MS113S	HiCulture™ Transport Swabs w/ Chlamydospore Medium with metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS198S	HiCulture™ Transport Swab w/ Middlebrook 7H9 Broth w/metal stick	Low risk	20/12/2012
RPM- Transport Medium w/ swabs	MS5478	HiFungal Transport medium w/ Swab	Low risk	10/06/2021
RPM- Ready Prepared Medium	MT001	Modified Middlebrook 7H9 Broth with Indicator	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001	L.J. Medium Slant	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001H	L.J. Medium in glass bottle	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL001B	L.J. Medium Slant	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001L	L.J. Medium Slant in long tube	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001LD	L.J. Medium Slant (in long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001M	L.J.Medium Slant (In Medium Length tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001T	L.J. Medium Slant in thick glass bottles	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL001X	L.J. Medium Slant	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL002	L.J.Medium Kit	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL003	L.J.Medium Plus Kit	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL004	L.J.Medium w/ Pyruvate	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL004L	L.J.Medium w/ Pyruvate (0.2%)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL005	L.J.Medium w/ Streptomycin (4 mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL005L	L.J.Medium w/Streptomycin (4 mcg / ml)	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 62 of 130

RPM- L.J.Medium Slants	SL006	L.J.Medium w/ INH	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL007	L.J.Medium Slant w/ Rifampicin (40µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL008	Acid Egg Medium Slant	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL009	Acid Egg Medium Slant w/ pyruvate	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL010	Modified L. J. Medium Plus Kit	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL011	L.J. Medium Slant w/ Ciprofloxacin	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL011L	L.J. Medium Slant w/ Ciprofloxacin (12.5 mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL012	L.J. Medium Slant w/ Amikacin	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL013	L.J. Medium Slant w/ Clarithromycin	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL014	L.J. Medium Slant w/Ethionamide (20µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL015	L.J. Medium Slant w/Rifabutin (0.5 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL016	L. J. Medium Plus Kit w/ kanamycin µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL017	L.J. Medium Slant w/ D-Cycloserine (30 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL017L	L.J. Medium Slant w/ D-Cycloserine (30 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL018	L.J.Medium w/Pyrazinamide of pH 5.5	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL018L	L.J. Medium Slant w/ Pyrazinamide pH 5.5	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL019	L.M. Slant (Loeffler Medium)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL020	L.J. Medium w/TCH	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL021	L.J. Medium Slant w/ p-Nitrobenzoic acid (500 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL021L	L.J. Medium Slant w/ p-Nitrobenzoic acid	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL022	L.J. Medium Slant w/o Glycerol	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL023	Tuberculosis First Line Kit (Total 7 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL023L	Tuberculosis First Line Kit (Total 7 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL023LD	Tuberculosis First Line Kit (Total 7slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL023R	Tuberculosis First Line Kit (Total 7 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL024	Tuberculosis Second Line Kit (Total 10 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL024L	Tuberculosis Second Line Kit (Total 10 slants)	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 63 of 130

RPM- L.J.Medium Slants	SL024LD	Tuberculosis Second Line Kit (Total 10 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL024R	Tuberculosis Second Line Kit (Total 8 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL025	Dorset Egg Medium Slant	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL026	L.J. Medium Slant w/Streptomycin (5mcg)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL027	L.J. Medium Slant w/Ethambutol (2mcg)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL029	L.J. Medium Slant w/P-Amino Salicylic acid	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL029L	L.J. Medium Slant w/ p-Aminosalicylic acid	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL031	Dermatophyte Test Medium Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL032	Kligler Iron Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL033	Motility Indole Lysine Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL034	Simmons Citrate Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL034T	Simmon Citrate Agar Slant in long tubes	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL035	Urea Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL035T	Urea Agar Slant in Tube	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL036	Sabouraud Dextrose Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL036L	Sabouraud Dextrose Agar Slant	Low risk	08/12/2017
RPM- L.J.Medium Slants	SL037	Tuberculosis First Line Plus Kit (Total 9 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL037R	Tuberculosis First Line Plus Kit (9 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL038	Tuberculosis Second Line Plus Kit (Total 11 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL038R	Tuberculosis Second Line Plus Kit (11 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL038U	Lowenstein - Jensen Medium Slant with tu	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL040	L.J. Medium Slant w/ Moxifloxacin	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL041	Gelatin Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL042	MIU Medium Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL043	Nitrate Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL044	Phenyl Alanine Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL045	Triple Sugar Iron Agar Slant	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 64 of 130

RPM- Ready Prepared Slants	SL045T	Triple Sugar Iron Agar Slant in Tube	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL047	L.J.Medium Slant w/ Ethambutol (2µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL049	L.J. Medium Slant w/ Ofloxacin (2 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL049L	L.J Medium Slant w/ Ofloxacin (2µg/ml) (long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL055L	L.J.Medium Slant w/ Isoniazide (0.2 mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL061	L.J. Medium Slant w/ Pyrazinamide (50 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL066	L.J. Medium Slant w/ Capreomycin (20 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL067	L.J. Medium Slant w/ Capreomycin (40 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL067L	L.J Medium Slant w/ Capreomycin (40 µg/ml) (long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL067X	L.J Medium Slant w/ Capreomycin (40 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL070	L.J. Medium Slant w/ D-Cycloserine (40 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL071	L.J. Medium Slant w/ Ethambutol (4 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL072	L.J. Medium Slant w/ Ethambutol (5 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL076	L.J. Medium Slant w/Ethionamide (40µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL078	L.J. Medium Slant w/ Isoniazide (0.2 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL079	L.J. Medium Slant w/ Isoniazide (5 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL081	L.J. Medium Slant w/ Kanamycin (20 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL081L	L.J. Medium Slant w/ Kanamycin (20µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL082	L.J. Medium Slant w/ Kanamycin (30 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL091	L.J. Medium Slant w/ p-Aminosalicyclic acid (0.25 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL092	L.J. Medium Slant w/ p-Aminosalicyclic acid (0.5 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL092L	L.J. Medium Slant w/ p-Aminosalicyclic acid	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL094	L.J. Medium Slant w/ Ciprofloxacin 2µg/ml	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL098	L.J. Medium Slant w/ Pyruvate (0.2%)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL099	L.J.Medium Slants w/ Isoniazid (0.2 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL105L	L.J.Medium Slant w/ Rifampicin (20mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL107	L.J. Medium Slant w/ Rifampicin (50 µg/ml)	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 65 of 130

RPM- L.J.Medium Slants	SL109	L.J. Medium Slant w/ Streptomycin (8 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL110	L.J. Medium Slant w/ Streptomycin (25 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL115	L.J. Medium Slant w/ Pyrazinamide of pH 5.5	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL115L	L.J. Medium Slant w/ Pyrazinamide pH 5.5	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL116	Rapid UTI Diagnostic Slants	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL120L	L.J. Medium Slant pH 5.5	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL121	HiPyrazide glass tube w/ PYZ agar	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL121R	HiPyrazide glass tube w/ PYZ agar	Low risk	10/11/2020
RPM- L.J.Medium Slants	SL122	HiCatalase glass tubes w/ 5ml of L.J. medium	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL122R	HiCatalase glass tubes w/ 5ml of L.J. medium	Low risk	10/11/2020
RPM- L.J.Medium Slants	SL123	Tuberculosis first line plus kit (Modified)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL124	L.J. Medium slant (Tubes with Aluminium caps)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL125	L.J. Medium w/Isoniazid (1.0µg/ml) (Tube	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL125L	L.J.Medium Slant w/ Isoniazide (1mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL125M	L.J.Medium Slant w/ Isoniazid in Maccart	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL125X	L. J. Medium Slant w/ Isoniazide (1µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL126	L.J. Medium w/Rifampicin (40.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL126L	L.J.Medium Slant w/ Rifampicin (40mcg/ml	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL126M	L.J.Medium Slant w/ Rifampicin in Maccar	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL126X	L. J. Medium Slant w/ Rifampicin (40.0 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL127	L.J. Medium w/Ethambutol (2.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL127L	L.J. Medium Slant w/Ethambutol (2µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL127X	L. J. Medium Slant w/ Ethambutol (2.0 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL128	L.J. Medium w/Streptomycin (10.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL128L	L.J.Medium w/Streptomycin - 10mcg / MI	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL129	L.J. Medium w/Ethionamide (30.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL130	L.J. Medium w/Kanamycin (30.0µg/ml	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 66 of 130

RPM- L.J.Medium Slants	SL130L	L.J. Medium Slant w/ Kanamycin (30µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL131	L.J. Medium w/Ofloxacin (2.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL132	L.J. Medium w/Capreomycin (30.0µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL133	L.J. Medium w/P-aminosalicylic acid (1.0	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL136L	Tuberculosis Second Line Kit, Modified	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL141	Modified L. J. Medium Plus Kit	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL142	Cystine Tryptone Agar with 1% Sugars	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL143	Tuberculosis First Line Kit, Modified	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL144	L.J Medium slant w/ Amikacin (1.0 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL147	L.J. Medium Slant w/Rifampicin (64µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL148	L.J. Medium Slant w/Ethambutol (6µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL149	L.J. Medium Slant w/Streptomycin (16µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL150	L.J Medium slant w/ Streptomycin (32 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL151	TB Five Antitubercular Kit w/o Control	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL152	Kit for Mycobiograme in Lowenstein Jensen	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL153	Tuberculosis First Line Plus Kit (Modified)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL154	L.J. Medium Plus Kit (total 9 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL155L	L.J. Medium Slant w/ TCH	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL156	L.J.Medium Slant w/Rifampicin (128 µg /ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL157	L.J.Medium Slant w/Pyrazinamide pH 5.5	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL158	L.J.Medium Slant w/Ethambutol (8 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL159	L.J. Medium Slant w/Ethambutol (16 μg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL160L	Tuberculosis kit with antitubercular Age	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL161	L.J. Medium Slant w/ Ciprofloxacin (16 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL162	L.J. Medium Slant w/ Ciprofloxacin	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL163	L.J. Medium Slant w/Amikacin (20 µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL164	L.J. Medium Slant w/Amikacin (700 µg/ml)	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 67 of 130

RPM- L.J.Medium Slants	SL165L	L.J.Medium w/ Pyruvate (0.48%)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL166L	Tuberculosis kit with antitubercular Agent	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL167	L.J. Medium slants w/ Augmentin(20µg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL168	L.J.Medium Slant w/ Ofloxacin (40µg/ml)	Low risk	25/08/2016
RPM- L.J.Medium Slants	SL168L	L.J.Medium Slant w/ Ofloxacin (40µg/ml) (long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL169	L.J.Medium Slant w/ Ethionamide (20µg/ml	Low risk	25/08/2016
RPM- L.J.Medium Slants	SL169L	L.J.Medium Slant w/ Ethionamide (20µg/ml) (long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL170L	L.J Medium Slant w/ Ethionamide (40µg/ml) (long tube)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL170X	L.J Medium Slant w/ Ethionamide (40 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL171L	L.J Medium Slant w/ p-Amino salicylic acid (1µg/ml) (long tube)	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL172	Chocolate Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL173	Nutrient Agar Slant	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL174	B.C.GDextrose Agar Butt (Synder Test Agar)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL175L	L.J.Medium Slant w/ Amikacin (30mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL175X	L. J. Medium Slant w/ Amikacin (30 mcg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL176L	L.J.Medium Slant w/ Ofloxacin (4mcg/ml)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL177	Tuberculosis First Line Kit, Modified (Total 5 slants)	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL179	L.J.Slopes for BCG Vaccines	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL180	BHI Agar Slant w/5% Sheep Blood	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL181	BHI Agar Slant w/10 % Sheep Blood,Chloramphenicol and Gentamicin	Low risk	20/12/2012
RPM- Ready Prepared Slants	SL182	BHI CC Agar Slant w/10 % Sheep Blood and Gentamicin	Low risk	20/12/2012
RPM- L.J.Medium Slants	SL187	L.J.Medium slants w/ LCN Supplement	Low risk	25/08/2016
RPM- L.J.Medium Slants	SL188L	L.J.Medium Slant w/ Levofloxacin (2 mg/ml)	Low risk	16/12/2017
RPM- L.J.Medium Slants	SL188X	L.J Medium Slant w/ Levofloxacin (2 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL189L	L.J.Medium Slant w/ Levofloxacin (2.5 mg/ml)	Low risk	16/12/2017
RPM- L.J.Medium Slants	SL189X	L.J Medium Slant w/ Moxifloxacin (2.5 µg/ml)	Low risk	17/06/2021
RPM- L.J.Medium Slants	SL190	L.J.Medium Slant w/ Rifampicin (20mcg/ml)	Low risk	04/07/2018



Document ref.: DoC 2022 vs. 15

Page 68 of 130

RPM- L.J.Medium Slants	SL191	L.J.Medium Slant w/ Amikacin (8mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL192	L.J.Medium Slant w/ Ofloxacin (5mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL193	L.J.Medium Slant w/ Levofloxacin (5 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL194	L.J.Medium Slant w/ Ethionamide (5 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL195	L.J.Medium Slant w/ Ethionamide (25 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL196	L.J.Medium Slant w/ Prothionamide (5 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL197	L.J.Medium Slant w/ Prothionamide (25 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL198	L.J.Medium Slant w/ Linezolid (30 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL199	L.J.Medium Slant w/ Clofazimine (1 mcg/ml)	Low risk	04/07/2018
RPM- L.J.Medium Slants	SL202	Middlebrook 7H10 Agar Slant	Low risk	30/10/2018
RPM- L.J.Medium Slants	SL204	L.J. Medium Slant w/ Prothionamide (40 mcg/ml)	Low risk	22/04/2019
RPM- L.J.Medium Slants	SL205	L.J. Medium Slant w/ Amikacin (40 mcg/ml)	Low risk	22/04/2019
RPM- L.J.Medium Slants	SL211	BHI Agar Slant	Low risk	30/10/2018
RPM- L.J.Medium Slants	SL1067L	Sabouraus Chloramphenicol Agar Slant	Low risk	16/12/2017
RPM- Ready Prepared Solid Medium	SM001	Nutrient Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM001CCL	Nutrient Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM001D	Nutrient Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM016C	Brilliant Green Agar, Modified	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM027C	Bismuth Sulphite Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM049C	Violet Red Bile Agar	Low risk	17/06/2021
RPM- Ready Prepared Solid Medium	SM049D	Violet Red Bile Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM063	Sabouraud Dextrose Agar	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM063D	Sabouraud Dextrose Agar	Low risk	25/08/2016

Page 69 of 130

RPM- Ready Prepared Solid Medium	SM078	Kligler Iron Agar	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM081	MacConkey Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM081D	MacConkey Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM082	MacConkey Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM082D	MacConkey Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM091	Plate Count Agar	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM091D	Plate Count Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM091DCC	Plate Count Agar	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM091M	Plate Count Agar	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM103A	Modified Chocolate Agar Kit w/o Selective	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM103AR	Modified Chocolate Agar kit w/osupplement	Low risk	10/11/2020
RPM- Ready Prepared Solid Medium	SM103H	Modified Chocolate Agar kit	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM103HR	Modified Chocolate Agar kit w/supplement	Low risk	10/11/2020
RPM- Ready Prepared Solid Medium	SM1067	Sabouraud Chloramphenicol Agar Plate	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM1067C	Sabouraud Chloramphenicol Agar Plate	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM1067D	Sabouraud Chloramphenicol Agar	Low risk	17/06/2021
RPM- Ready Prepared Solid Medium	SM1067CCL	Sabouraud Chloramphenicol Agar Plate	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM1296D	HiCrome™ Salmonella Agar	Low risk	04/07/2018

	JA

Page 70 of 130

RPM- Ready Prepared Solid Medium	SM1297A	HiCrome™ Candida Differential Agar	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM1353	HiCrome™ UTI Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM1353CC	HiCrome™ UTI Agar	Low risk	04/07/2018
RPM- Ready Prepared Solid Medium	SM154D	Reinforced Clostridial Agar	Low risk	10/11/2020
RPM- Ready Prepared Solid Medium	SM173	Mueller Hinton Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM173CCL	Mueller Hinton Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM173D	Mueller Hinton Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM211	BHI Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM211D	BHI Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM331C	Wilson Blair Agar	Low risk	22/04/2019
RPM- Ready Prepared Solid Medium	SM434	GC Agar	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM434R	Modified GC Agar Kit	Low risk	10/11/2020
RPM- Ready Prepared Solid Medium	SM434H	GC Agar,Modified	Low risk	25/08/2016
RPM- Ready Prepared Solid Medium	SM467	Hektoen Enteric Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM467D	Hektoen Enteric Agar	Low risk	20/12/2012
RPM- Ready Prepared Solid Medium	SM792	C.L.E.D. Agar w/ Bromothymol Blue	Low risk	30/10/2018
RPM- Ready Prepared Solid Medium	SM837	Tryptose Sulphite Cycloserine(T.S.C) Agar	Low risk	17/06/2021
RPM- Ready Prepared Solid Medium	SM933D	Orange Serum Agar	Low risk	22/04/2019



Page 71 of 130

RPM- Ready Prepared UTI Diagnostic Kits	K041	Rapid UTI ABST Kit	Low Risk	20/12/2012
RPM- Ready Prepared UTI Diagnostic Kits	K084A	Ecopathology Uro Kit-1	Low risk	20/12/2012
RPM- Ready Prepared UTI Diagnostic Kits	K084B	Ecopathology Uro Kit-1, Modified	Low risk	30/10/2018
RPM- Ready Prepared UTI Diagnostic Kits	K085A	Ecopathology Uro Kit-2	Low risk	20/12/2012
RPM- Ready Prepared UTI Diagnostic Kits	К089	Ecopathology Uro Kit-3	Low risk	20/12/2012
RPM- Ready Prepared UTI Diagnostic Kits	к090	Ecopathology Uro Kit-4	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	К043	Nitrate Reduction Test Kit for Mycobacteria	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	КО44	Catalase Test Kit for Mycobacteria	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	K044R	Catalase Test Kit for Mycobacteria	Low risk	10/11/2020
RPM- Biochemical Kits for Mycobacteria	КО45	Pyrazinmidase Test Kit for Mycobacteria	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	K045R	Pyrazinmidase Test Kit for Mycobacteria (Low risk	10/11/2020
RPM- Biochemical Kits for Mycobacteria	К046	Thiopene Carboxylic Hydrazide Test Kit for Mycobacteria	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	КО47	Niacin Detection Kit w/ syringe	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	КО48	Niacin Detection Kit Modified w/o syringe	Low risk	20/12/2012
RPM- Biochemical Kits for Mycobacteria	к050	Kit for Selective Isolation of M.tuberculosis	Low risk	20/12/2012
RPM-MRSA Kits	K058S	MRSA Alert kit (w/swabs)	Low risk	25/08/2016
RPM-MRSA Kits	K058SR	MeReSa Agar Base, MRSA Alert Kit (w/swabs)	Low risk	25/08/2016
RPM-MRSA Kits	K086R	Enterococcus Presumptive Broth (VRE Alert)	Low risk	25/08/2016
RPM- Ready Prepared Diagnostic Kits	K144	Mucormycosis Detection Kit	Low risk	10/06/2021
RPM- Biochemical Identification Kits	KB001	HilMViC™ Biochemical Test Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB001R	HilMViC Biochemical Test Kit	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 72 of 130

RPM- Biochemical Identification Kits	КВ002	HiAssorted™ Biochemical Test Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB002R	HiAssorted Biochemical Test Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВООЗ	Hi25™ Enterobacteriaceae Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB003R	Hi25 Enterobacteriaceae Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ004	HiStaph™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB004R	HiStaph Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB005A	HiStrep™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB005AR	HiStrep Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ006	HiCandida™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB006R	HiCandida Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ007	HiVibrio™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB007R	HiVibrio Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ008	HiNeisseria™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB008R	HiNeisseria Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ009	HiCarbo™ Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB009R	HiCarbo Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ009А	HiCarbo™ Kit- Part A	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB009AR	HiCarbo Kit- Part A	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB009B1	HiCarbo™ Kit- Part B	Low risk	20/12/2012
RPM- Biochemical Identification Kits	КВ009С	HiCarbo™ Kit- Part C	Low risk	20/12/2012
RPM- Biochemical Identification Kits	КВ010	HiE. coli™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB010R	HiE.coli™ Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB011	HiSalmonella™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB011R	HiSalmonella Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB012A	HiListeria™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB012AR	HiListeria Identification Kit	Low risk	25/08/2016
RPM- Biochemical Identification Kits	КВ013	HiBacillus™ Identification Kit	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 73 of 130

RPM- Biochemical Identification Kits	KB013R	HiCarbo Kit (HiBacillus Identification Kit)	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB014	HiAcinetobacter™ Identification Kit	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KB014R	HiCarbo Kit (HiAcinetobacter Identification Kit)	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KB015	HiCorynebacteria Identification Kit	Low risk	12/08/2015
RPM- Biochemical Identification Kits	KB016	Hi24 [™] Enterobacteriaceae Identification Kit,Modified	Low risk	12/08/2015
RPM- Biochemical Identification Kits	КВ019	Hi24 [™] Nonfermenters Identification Kit	Low risk	28/04/2017
RPM- Biochemical Identification Kits	КВ020	HiLacto Identification Kit	Low risk	28/04/2017
RPM- Biochemical Identification Kits	KB021	HiBifido Identification Kit	Low risk	28/04/2017
RPM- Biochemical Identification Kits	KBM001	HiMotility™ Biochemical Kit for E.coli	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KBM001R	HiMotility Biochemical Kit for E.coli	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KBM002	HiMotility™ Biochemical Kit for Salmonella	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KBM002R	HiMotility™ Biochemical Kit for Salmonella	Low risk	25/08/2016
RPM- Biochemical Identification Kits	KBM003A	HiMotility™ Biochemical Kit for Listeria	Low risk	20/12/2012
RPM- Biochemical Identification Kits	KBM003AR	HiMotility™ Biochemical Kit for Listeria	Low risk	25/08/2016

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Epidemeology Screening Kit				
ESK- Hi Aureus Confirmation Kits	K053AD	Hiaureus Coagulase Confrimation Kit (w/o swabs)	Low risk	07/02/2012
ESK- Hi Aureus Confirmation Kits	K053ADS	Hiaureus Coagulase Confrimation Kit (w/ swabs)	Low risk	07/02/2012



Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Bacteriological Differentiation Aids				
BDA- HiDtect Rapid Identification Discs	DT001	HiDtect™ UTI Identification Disc	Low risk	20/12/2012
BDA- HiDtect Rapid Identification Discs	DT003	HiDtect™ Pseudomonas Identification Disc	Low risk	20/12/2012
BDA- HiDtect Rapid Identification Discs	DT015	HiDtect [™] Universal Enviro Identification Disc	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1001	Andrade's Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1002	Bromocresol Green Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1003	Bromocresol Purple Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1004	Bromophenol Blue Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1005	Bromothymol Blue Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1006	Methyl Orange Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1007	Methyl Red Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1008	Neutral Red Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1009	Phenolphthalein, 0.1% w/v	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1010	Phenol Red Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1011	Thymol Blue Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1012	Thymolphthalein Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1013	Universal Indicator	Low risk	20/12/201
BDA- Readymade Indicators in Liquid	1014	Mixed Indicator Solution (25X)	Low risk	20/12/201
BDA- Readymade Stains in Liquid	K001	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	20/12/201
BDA- Readymade Stains in Liquid	K001CCL	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	04/07/201
BDA- Readymade Stains in Liquid	K001D	Gram Staining Kit	Low risk	04/07/201
BDA- Readymade Stains in Liquid	K001L	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	20/12/201
BDA- Readymade Stains in Liquid	K001M	Gram Stains - Kit	Low risk	22/04/201
BDA- Readymade Stains in Liquid	КОО2	Albert`s Metachromatic Stains - Kit	Low risk	20/12/201
BDA- Readymade Stains in Liquid	K002L	Albert`s Metachromatic Stains - Kit	Low risk	20/12/201
BDA- Readymade Stains in Liquid	кооз	Neisser's Metachromatic Stains - Kit (contains S013, S023 and S037)	Low risk	20/12/201



Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 75 of 130

BDA- Readymade Stains in Liquid	K003L	Neisser's Metachromatic Stains - Kit (contains S013, S023 and S037)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	коо4	Capsule Stains - Kit (contains S021, S025 and S047)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K004L	Capsule Stains - Kit (contains S021, S025 and S047)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	коо5	ZN Acid Fast Stains - Kit (contains S033,S005 and S022)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K005CCL	ZN Acid Fast Stains - Kit (contains S033,S005 and S022)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K005D	ZN Acid Fast Stains - Kit	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K005L	ZN Acid Fast Stains - Kit (contains S033, S005 & S022)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K005M	ZN Acid Fast Stains - Kit (contains S033, S005 & S022)	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	кооб	Schaeffer & Fulton's Spore Stains - Kit (contains S028 and S029)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K006L	Schaeffer & Fulton's Spore Stains - Kit (contains S028 and S029)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	К011	Malarial Parasite - Kit (contains S008 and S009)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K011L	Malarial Parasite - Kit (contains S008 and S009)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	К021	Fluorescent Stains - Kit for Mycobacteria (contains S042, S043 and S044)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K021L	Fluorescent Stains - Kit for Mycobacteria (contains S042, S043 and S044)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K021R	Fluorescent Stains Kit for Mycobacteria (conatins S054,S055,S056)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K021Y	Fluorescent Stains Kit for Mycobacteria (conatins S042Y,S043Y,S044Y)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	К049	Malarial Parasite - Kit (contains S008 and S009)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K061	HiFluo-Phenol Free Stain - kit for Mycobacteria [Kit contains 200ml each of Auramine – Rhodamine solution (Phenol free)-S082, Decolourizer-S099 (2 x200), Potassium Permanganate Solution- S083]	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K062	HiCold Stain TB - Kit for Mycobacteria [Kit contains 500ml each of Carbol Fuchsin Solution-S080, Decolourizer-S099, Counter Stain (Loeffler's Methylene Blue)-S081]	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K062S	HiCold Stain TB - Kit for Mycobacteria [Kit contains 100ml each of Carbol Fuchsin Solution-S080, Decolourizer-S099, Counter Stain (Loeffler's Methylene Blue) S081]	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	К063	Modified Neisser's Metachromatic Stains - Kit (1 minute staining)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R001	Barium Chloride Solution, 10% w/v	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R002	Benedict's Qualitative Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R003	Benedict's Quantitative Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R004	C.S.F. Diluting Fluid	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 76 of 130

BDA - Readymade Reagents in Liquid	R005	Ehrlich's Aldehyde Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R006	Folin & Wu's Alkaline Copper Solution	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R007	Folin & Wu's Phosphate, Molybdate Solution	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R008	Kovacs' Indole Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R009	a-Naphthylamine solution	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R010	Nessler's Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R011	Potassium Chromate, 5% w/v	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R012	Potassium Oxalate, 5% w/v	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R013	R.B.C. Diluting Fluid (Hayemis)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R014	Sodium Citrate, 3.8% w/v	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R015	Sulphanilic acid, 0.8%	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R016	W.B.C. Diluting Fluid	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R017	Nessler's Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R018	Fouchet's Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R019	E.D.T.A. (di-sodium) 5%	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R020	Sulphosalicylic Acid 3%	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R021	Topfer Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R022	o-Toluidine reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R023	R.B.C. Diluting Fluid (Grower's)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R024	o-Toluidine Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R026	Gordon-McLeod Reagent (Oxidase reagent)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R027	Gaby-Hadley Reagent A	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R028	Gaby-Hadley Reagent B	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R029	Barritt Reagent A (for VP test)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R030	Barritt Reagent B (for VP test)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R031	O'Meara Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R035	DMACA Reagent	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 77 of 130

BDA - Readymade Reagents in Liquid	R036	TDA Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R037	Fehling Solution No. 1	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R038	Fehling Solution No. 2	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R043	PYR Reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R044	lodine Solution	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R075	10X RBC Lysis Buffer Solution	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R083	Thrombocount reagent	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R084	HiDecal (mild decalcifying solution)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R085	HiDecal (strong decalcifying solution)	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R092	McFarland Standard Tube	Low risk	20/12/2012
BDA - Readymade Reagents in Liquid	R092A	Mcfarland standard 0.5	Low risk	22/04/2019
BDA - Readymade Reagents in Liquid	R092B	Mcfarland standard 1	Low risk	22/04/2019
BDA - Readymade Reagents in Liquid	R092C	Mcfarland standard 2	Low risk	22/04/2019
BDA - Readymade Reagents in Liquid	R092D	Mcfarland standard 3	Low risk	22/04/2019
BDA - Readymade Reagents in Liquid	R092E	Mcfarland standard 4	Low risk	22/04/2019
BDA - Readymade Reagents in Liquid	R092R	Test Tubes (McFarland Standard Tube)	Low risk	25/08/2016
BDA - Readymade Reagents in Liquid	R092S	McFarland Standard Set (0.5,1,2)	Low risk	04/07/2018
BDA - Readymade Reagents in Liquid	R097	Millons reagent	Low risk	28/04/2017
BDA- Readymade Stains in Liquid	S001	Albert's Stain A	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S002	Albert's Stain B	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S003	Borax Carmine (Grenacher's), Alcoholic Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S004	Borax Carmine (Grenacher's), Aqueous Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S005	Carbol Fuchsin (ZN,Strong)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S005D	Carbol Fuchsin (ZN,Strong)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S005M	Carbol Fuchsin (ZN,Strong)	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S006	Carbol Fuchsin (ZN, Dilute)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S007	Eosin, 2% w/v	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 78 of 130

BDA- Readymade Stains in Liquid	S008	Field's Stain A	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S009	Field's Stain B	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S010	Gentian Violet	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S011	Giemsa's Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S012	Gram's Crystal Violet	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S012D	Gram's Crystal Violet	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S012M	Gram's Crystal Violet	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S013	Gram's lodine	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S013D	Gram's lodine	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S013M	Gram's lodine	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S014	Haematoxylin (Delafield's)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S015	Lactophenol	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S016	Lactophenol Cotton Blue	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S017	Lactophenol Picric Acid	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S018	Leishman's Stain (Twin Pack)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S018S	Leishman's Stain Solution	Low risk	25/11/2017
BDA- Readymade Stains in Liquid	S019	Lugol's lodine	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S020	Malachite Green, 1% w/v	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S021	Methylene Blue (Aqueous)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S022	Methylene Blue (Loeffler's)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S022D	Methylene Blue (Loeffler's)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S022M	Methylene Blue (Loeffler's)	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S023	Neisser's Methylene Blue	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S024	Newman's Stain, Modified	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S025	Nigrosin Stain,10% w/v	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S026	Picric Acid (Saturated, Aqueous)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S027	Safranin, 0.5% w/v	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 79 of 130

BDA- Readymade Stains in Liquid	S027D	Safranin, 0.5% w/v	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S027M	Safranin, 0.5% w/v	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S028	Schaeffer & Fulton's Spore Stain A	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S029	Schaeffer & Fulton's Spore Stain B	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S030	Wright's Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S031	Mayer's Mucicarmine Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S032	Gram's Decolourizer	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S032D	Gram's Decolourizer	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S032M	Gram's Decolourizer	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S033	Acid Fast Decolourizer	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S033D	Acid Fast Decolourizer	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S033M	Acid Fast Decolourizer	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S034	Haematoxylin (Harris)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S035	Papanicolaou-OG-6	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S036	Papanicolaou-EA-36	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S037	Neutral Red Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S038	Basic Fuchsin 0.1% w/v	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S038D	Basic Fuchsin 0.1% w/v	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	S038M	Basic Fuchsin 0.1% w/v	Low risk	22/04/2019
BDA- Readymade Stains in Liquid	S039	May-Grunwald's Stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S041	FA Rhodamine Counterstain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S042	Phenolic auramine	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S042Y	Phenolic auramine O	Low risk	08/12/2017
BDA- Readymade Stains in Liquid	S043	Mycobacteria decolourizer	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S043Y	Mycobacteria decolourizer	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S044	Potassium permanganate	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S044Y	Potassium permanganate	Low risk	08/12/2017



Document ref.: DoC 2022 vs. 15

Page 80 of 130

BDA- Readymade Stains in Liquid	S047	M'Fadyean Stain (Polychrome Methylene Blue)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S054	Fluorochrome Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S055	Decolourising Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S056	Background Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S057	Grams lodine, Stabilized	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S058	Haematoxylin (Mayer)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S059	Haematoxylin (Ehrlich)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S062	Fixing solution, for fixing Haematological samples	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S066	Brilliant Cresyl Blue Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S067	Congo red (1% aqueous)Solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S068	Papanicolaou-EA-50	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S070	Schiff's fuchsin-sulphite reagent	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S073	Periodic Acid Solution (PAS)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S074	Schiff's Reagent	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S076	Haematoxylin (Gill No.3)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S102	Fixative, for fixing cytological or histological samples	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S109	Fixative (Buffered Formalin fixative) for fixing cytological or histological samples	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S118	Fixative, for rapid fixing of haematological samples	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S119	Fixative (BFA), for Rapid fixing of haematological samples	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S125	Romanowsky-Giemsa (RG) stain	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S126	Shorr's Stain solution	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	S127	Gabbett Counterstaining Solution	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S128	HiGrams Stain Crystal Violet	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S129	HiGrams Iodine	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S130	HiGrams Decolouriser	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S131	HiGrams Counter Stain	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S132	HiCarbol Fuchsin	Low risk	16/12/2017



Document ref.: DoC 2022 vs. 15

Page 81 of 130

BDA- Readymade Stains in Liquid	S133	HiAcid Fast Decolouriser	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S134	HiAcid Fast Counter Stain	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S135	Solution for Leishman's Stain L (Twin Pack)	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S136	Solution for Leishman's Stain R (Twin Pack)	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S137	Solution for Leishman's Stain HP (Twin Pack)	Low risk	16/12/2017
BDA- Readymade Stains in Liquid	S138	Gentian Violet 1 % Solution	Low risk	22/04/2019
BDA- Differentiation Discs	DD015	Bacitracin	Low risk	20/12/2012
BDA- Differentiation Discs	DD024	Bile Esculin	Low risk	20/12/2012
BDA- Differentiation Discs	DD040	DMACA Indole	Low risk	20/12/2012
BDA- Differentiation Discs	DD035	Hippurate hydrolysis	Low risk	20/12/2012
BDA- Differentiation Strips	DD034	Lead Acetate Paper strips	Low risk	20/12/2012
BDA- Differentiation Discs	DD041	Nitrate Discs	Low risk	20/12/2012
BDA- Differentiation Discs	DD042	Nitrate Reagent Discs	Low risk	20/12/2012
BDA- Differentiation Discs	DD008	ONPG	Low risk	20/12/2012
BDA- Differentiation Discs	DD009	Optochin	Low risk	20/12/2012
BDA- Differentiation Discs	DD009R	Optochin (5mcg)	Low risk	25/08/2016
BDA- Differentiation Discs	DD018	Oxidase	Low risk	20/12/2012
BDA- Differentiation Discs	DD020	X factor	Low risk	20/12/2012
BDA- Differentiation Discs	DD022	X+V Factor	Low risk	20/12/2012
BDA- Differentiation Discs	DD021	V Factor	Low risk	20/12/2012
BDA- Differentiation Discs	DD047	Vibrio 0129 Differential Disc (10 mcg)	Low risk	20/12/2012
BDA- Differentiation Discs	DD048	Vibrio 0129 Differential Disc (150 mcg)	Low risk	20/12/2012
BDA- Differentiation Discs	DD055	Bacitracin B	Low risk	25/08/2016
BDA- Differentiation Discs	DD056	Sodium Biselenite Disc	Low risk	04/07/2018
BDA- Differentiation Discs	DB001	Sodium Biselenite Bud	Low risk	04/07/2018



Page 82 of 130

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Antimicrobial Susceptibility Systems				
ASS- Sensitivity Discs (Multi Discs)	DE001	Dodeca Universal-I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE002	Dodeca G-I-Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE003	Dodeca G-I-Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE004	Dodeca UTI-I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE005	Dodeca UTI-II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE006	Dodeca UTI-III	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE007	Dodeca Universal-II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE008	Dodeca Universal-III	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE009	Dodeca G-II-Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE010	Dodeca G-II-Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE011	Dodeca UTI-IV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE012	Dodeca Universal-IV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE013	Dodeca Universal-V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE014	Dodeca Universal-VI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE015	Dodeca Universal-VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE016	Dodeca Universal III	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE017	Dodeca Universal-IX	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE018	Dodeca G-III-Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE019	Dodeca G-III-Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE020	Dodeca Pseudo-I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE021	Dodeca UTI-V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE022	Dodeca Universal X	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE023	Dodeca G-IV Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE024	Dodeca G-IV minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE025	Dodeca UTI-VI	Low risk	20/12/2012

ΙΜ	En	ΙΛ

Document ref.: DoC 2022 vs. 15

Page 83 of 130

ASS- Sensitivity	DE026	Dodeca Universal -XI	Low risk	20/12/2012
Discs (Multi Discs) ASS- Sensitivity				
Discs (Multi Discs)	DE027	Dodeca Universal -XII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE028	Dodeca Universal -XIII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE029	Dodeca G-V minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE030	Dodeca UTI-VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE031	Dodeca G-VI minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE032	Dodeca G-V Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE033	Dodeca G-VII Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE034	Dodeca UTI-VIII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE035	Dodeca Universal XIV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE036	Dodeca G-VI Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE037	Dodeca G-VIII Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE038	Dodeca G-VII Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE039	Dodeca G-IX Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE040	Dodeca UTI-IX	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE041	Dodeca Pseudo-II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE042	Dodeca Universal XV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE043	Dodeca G-X Minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE044	Dodeca - G-VIII Plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE045	Dodeca G-XI Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE046	Dodeca G-XII Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE047	Dodeca G-IX Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE048	Dodeca Staphylococci - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE049	Dodeca Staphylococci - 2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE050	Dodeca Enterococcus -1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE051	Dodeca Pseudomonas -1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE052	Dodeca Pseudomonas 2	Low risk	25/08/2016



Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 84 of 130

ASS- Sensitivity	DE053	Dodeca Enterobacteriaceae - 1	Low risk	20/12/2012
Discs (Multi Discs) ASS- Sensitivity Discs (Multi Discs)	DE054	Dodeca Enterobacteriaceae - 2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	DE700	Dodeca Staphylococci - 1	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE701	Dodeca Staphylococci - 2	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE702	Dodeca Enterococcus - 1	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE703	Dodeca Pseudomonas - 1	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE704	Dodeca Pseudomonas - 2	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE705	Dodeca Enterobacteriaceae - 1	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE706	Dodeca Enterobacteriaceae - 2	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE707	Dodeca Universal - 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE708	Dodeca UTI - 10	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE709	Dodeca G-Minus 13	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE710	Dodeca G-Plus 10	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE711	Dodeca G minus XIV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE712	Dodeca G minus XV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE713	Dodeca G minus 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE714	Dodeca G minus 17	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE715	Dodeca G minus 18	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE716	Dodeca G plus 11	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE717	Dodeca G plus 12	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE718	Dodeca G minus 19	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE719	Dodeca UTI 10	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE720	Dodeca UTI 11	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE721	Dodeca Universal 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE722	Dodeca Universal 17	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE723	Dodeca G Plus 13	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE724	Dodeca UTI-12	Low risk	25/08/2016

IM	ED	IA
	Ľ	

Document ref.: DoC 2022 vs. 15

S

Page 85 of 130

ASS- Sensitivity	DEZZE	Dedese Universal 10	Lauraial.	25/00/2016
Discs (Multi Discs)	DE725	Dodeca Universal-18	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE726	Dodeca UTI - 13	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE727	Dodeca G-minus 20	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE728	Dodeca UTI 14	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE729	Dodeca G-Plus 14	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE730	Dodeca G-Minus 21	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE731	Dodeca G-Minus 22	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE732	Dodeca Universal 19	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE733	Dodeca Universal 20	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE734	Dodeca Universal 21	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE735	Dodeca Universal 22	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE736	Dodeca G-Plus 15	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE737	Dodeca G-Minus 23	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE738	Dodeca G-Minus 24	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE739	Dodeca UTI 13	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE740	Dodeca G-Plus 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE741	Dodeca G-Minus 25	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE742	Dodeca Pseudomonas -3	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	DE743	Dodeca G-Minus 26	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE744	Dodeca UTI 15	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE745	Dodeca Pseudomonas -4	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE746	Dodeca G-Plus 17	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE747	Dodeca G-Minus 27	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE748	Dodeca UTI 16	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	DE749	Dodeca G-Plus 18	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE750	Dodeca G-Plus 19	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE751	Dodeca G-Minus 28	Low risk	10/11/2020

IM	ED	IA

Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 86 of 130

ASS- Sensitivity Discs (Multi Discs)	DE752	Dodeca G-Minus 29	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE753	Dodeca G-Plus 20	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE754	Dodeca G-Minus 30	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE755	Dodeca Pseudomonas -5	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE756	Dodeca G-Minus 31	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	DE757	Dodeca G-Plus 21	Low risk	10/11/2020
ASS- Ezy MIC Strips	EM001	Amikacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM002	Amoxycillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM003	Amoxyclav (2:1)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM004	Azithromycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM006	Aztreonam	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM008	Cefazolin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM009	Cefdinir	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM011	Cefpirome	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM012	Ceftazidime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM013	Ceftriaxone	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM016	Chloramphenicol	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM017	Ciprofloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM018	Clarithromycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM019	Clindamycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM020	Colistin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM020S	Colistin	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM021	Co-Trimoxazole (1:19)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM021S	Co-Trimoxazole (1:19)	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM022	Erythromycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM023	Fusidic Acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM024	Gatifloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM025	Gentamicin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM026	Kanamycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM027	Levofloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM029	Linezolid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM032	Minocycline	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM033	Moxifloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM035	Nalidixic acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM037	Nitrofurantoin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM038	Norfloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM039	Ofloxacin	Low risk	20/12/2012

M	ED	

Document ref.: DoC 2022 vs. 15

Page 87 of 130

ASS- Ezy MIC Strips	EM041	Piperacillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM042	Piperacillin/Tazobactam	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM043	Polymixin B	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM043	Pristinomycin (Quinupristin/Dalfopristin)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM045	Rifampicin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM045	Roxithromycin	Low risk	20/12/2012
ASS- EZY MIC Strips	EM040	Sparfloxacin		
			Low risk	20/12/2012
ASS- Ezy MIC Strips	EM048	Streptomycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM055	Teicoplanin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM055S	Teicoplanin	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM056	Tetracycline	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM057	Ticarcillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM058	Tobramycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM059	Trimethoprim	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM060	Vancomycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM060S	Vancomycin	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM061	Gentamicin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM062	Penicillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM063	Oxacillin - Vancomycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM064	Cefotaxime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM065	Oxacillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM066	Ceftriaxone	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM066S	Ceftriaxone	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM068	Ampicillin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM070	Cefepime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM071	Amphotericin-B	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM072	Fluconazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM073	Itraconazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM074	Ketoconazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM076	Gemifloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM077	Vancomycin -Cefoxitin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM078	Imipenem w&w/o EDTA	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM079A	Triple ESBL detection Strip	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM080	Meropenem	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM081A	ESBL & AmpC Detection Strip	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM082	Ciprofloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM083	Co-Trimoxazole (1:19)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM084	Penicillin	Low risk	20/12/2012
ASS- Ezy MIC Strips				
ASS- EZY IVITC SUTPS	EM085	Ertapenem	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 88 of 130

ASS- Ezy MIC Strips	EM087	Mupirocin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM087		Low risk	20/12/2012
	EM089		Low risk	
ASS- Ezy MIC Strips		Tigecycline		20/12/2012
ASS- Ezy MIC Strips	EM090	Doripenem	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM091	Faropenem	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM092	Meropenem with & without EDTA	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM093	Cefepime/Tazobactam (2:1)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM094	Cefoperazone/Sulbactam (2:1)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM095	Netilmicin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM097	Ceftriaxone/Sulbactam (2:1)	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM098	Ceftazidime / Ceftazidime + Clavulanic acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM099	Cefotaxime / Cefotaxime + Clavulanic acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM100	Cefotaxime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM101	Cefoxitin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM102	Cefuroxime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM103	Doxycycline	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM104	Imipenem	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM105	Cefotetan	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM106	Cephalothin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM107	Cefaclor	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM108	Fosfomycin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM109	Ampicillin/Sulbactam	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM110	Cefixime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM111	Vancomycin - Teicoplanin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM112	Cefoperazone	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM113	Cefonicid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM114	Cefmetazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM115	Enrofloxacin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM116	Cefepime / cefepime + Clavulanic acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM117	Ceftriaxone / Ceftriaxone + Clavulanic acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM118	Flucytosine	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM119	Caspofungin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM120	Posaconazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM121	Micafungin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM122	Anidulafungin	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM123	Ceftizoxime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM124	Mecillinam	Low risk	20/12/2012
ASS- Ezy MIC Strips				
	EM125	Ticarcillin/Clavulanic Acid	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM125 EM126	Ticarcillin/Clavulanic Acid Bacitracin	Low risk Low risk	20/12/2012

M	ED	ΙΛ

Document ref.: DoC 2022 vs. 15

Page 89 of 130

ASS- Ezy MIC Strips	EM128	Metronidazole	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM129	Cefpodoxime	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM130	Cefprozil	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM131	Sulbactam	Low risk	20/12/2012
ASS- Ezy MIC Strips	EM132	Improved ESBL Detection Ezy MIC Strip (Mix+/Mix)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM133	Improved AmpC Detection Ezy MIC Strip (Mix+/Mix)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM134	MBL Plus ESBL Detection Ezy MIC Strip (ESBL+/ESBL)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM135	MBL Plus AmpC Detection E27 MIC Strip (AmpC+/Amp)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM136	ESBL-AmpC Coexistence Detection Ezy MIC Kit	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM130	MBL-ESBL-AmpC Co-existence Detection Ezy MIC Kit	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM137	Cefpodoxime/Clavulanic Acid Ezy MIC Strip	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM138	Amoxyclav Ezy MIC Strip (AUG) (0.016-256 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM135	Ampicillin/Sulbactam Ezy MIC Strip (SAM) (4 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM140	Ertapenem/Ertapenem + Boronic acid Ezy MIC Strip (ETP+/ETP)	Low risk	25/08/2016
ASS- EZY MIC Strips				25/08/2016
, ,	EM142	Terbinafine Ezy MIC Strip(TRB) (0.002-32 mcg/ml)	Low risk	
ASS- Ezy MIC Strips	EM143	Griseofulvin EZY MIC Strip (GRI) (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM144	Clotrimazole EZY MIC Strip (CLO) (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM145	Terbinafine Ezy MIC Strip(TRB) (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM146	Miconazole EZY MIC Strip (MIC) (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM147	Flucloxacillin Ezy MIC Stripr (FLC) (0.016-256 mcg/ml)	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM148	Cefepime/Clavulanic acid Ezy MIC Stripr (FIC) (0.016-256 mcg/ml)	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM149	Ceftazidime /Tazobactum Ezy MIC Strip (CAT) (0.016-256 mcg/ml)	Low risk	04/07/2018
ASS- Ezy MIC Strips	EM150	Natamycin Ezy MIC Strip (NAT) (0.016-256 mcg/ml)	Low risk	22/04/2019
ASS- Ezy MIC Strips	EM151	Cefpirome/Sulbactam Ezy MIC™ Strip	Low risk	22/04/2019
ASS- Ezy MIC Strips	EM152	Ceftizoxime/Sulbactam Ezy MIC™ Strip	Low risk	10/11/2020
ASS- Ezy MIC Strips	EM153	Ceftazidime/Avibactam Ezy MIC [™] Strip	Low risk	10/11/2020
ASS- Ezy MIC Strips	EM154	Faropenem/Clavulanic acid Ezy MIC [™] strip (FAC)	Low risk	01/11/2020
ASS- Ezy MIC Strips	EM155	Cefuroxime/Clavulanic acid Ezy MIC [™] strip (CXC)	Low risk	01/11/2020
ASS- Ezy MIC Strips	EM701	Xylomonas Ezy MIC Strip (0.016-256mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM702	Arbekacin Ezy MIC Strip (ABK) (0.016-256 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM703	Garenoxacin EZY MIC Strip (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM705	Biapenem EZY MIC Strip (BPM) (0.002-32 mcg/ml)	Low risk	25/08/2016
ASS- Ezy MIC Strips	EM706	Reinvexin EZY MIC Strip (PB) (0.016-256 mcg/ml)	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	HX001	Hexa G-plus 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX002	Hexa G-plus 2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX003	Hexa G-plus 3	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX004	Hexa G-plus 4	Low risk	20/12/2012

ГЛ	IM	ED	
			i A

Document ref.: DoC 2022 vs. 15

Page 90 of 130

Discs (Multi Discs)HR005HExe G-plus 5Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX006Hexe G-minus 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX007Hexe G-minus 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX008Hexe G-minus 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX009Hexe G-minus 4Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX010Hexe G-minus 5Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX011Hexe Pseudo 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX012Hexe Pseudo 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX013Hexe Pseudo 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexe Pseudo 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexe ITI-1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexe Heemophilus 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX013Hexe Heemophilus 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexe Heemophilus 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX013Hexe Heemophilus 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexe Aneemophilus 3Low risk20/12/20 <th>ASS- Sensitivity</th> <th></th> <th></th> <th>I</th> <th></th>	ASS- Sensitivity			I	
Discs (Multi Discs) HX00b Head G-minus 1 Low risk ZU/12/20 ASS- Sensitivity Discs (Multi Discs) HX0097 Hexa G-minus 2 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX009 Hexa G-minus 3 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX009 Hexa G-minus 4 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX010 Hexa G-minus 5 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX011 Hexa G-minus 5 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX012 Hexa Pseudo 1 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX013 Hexa Pseudo 2 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX014 Hexa UTI-1 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX015 Hexa UTI-2 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX014 Hexa UTI-2 Low risk Z0/12/20 ASS- Sensitivity Discs (Multi Discs) HX017	Discs (Multi Discs)	HX005	Hexa G-plus 5	Low risk	20/12/2012
Discs (Multi Discs) HX00 ⁷ Hexa G-minus 2 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX008 Hexa G-minus 3 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX009 Hexa G-minus 4 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX010 Hexa G-minus 5 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX011 Hexa G-minus 5 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX012 Hexa Fseudo 1 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX013 Hexa Pseudo 2 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX014 Hexa Pseudo 3 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX014 Hexa Pseudo 3 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX014 Hexa TI-2 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX015 Hexa Haemophilus 1 Low risk 20/12/20 ASS-Sensitivity Discs (Multi Discs) HX017 <		HX006	Hexa G-minus 1	Low risk	20/12/2012
Discs (Multi Discs)FXX00SHexa G-minus 3Low riskZ/1/2/20ASS-sensitivity Discs (Multi Discs)HX010Hexa G-minus 4Low risk25/08/20ASS-sensitivity Discs (Multi Discs)HX011Hexa G-minus 5Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX011Hexa Pseudo 1Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX012Hexa Pseudo 2Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX013Hexa Pseudo 3Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 2Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX019Hexa Faemophilus 3Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX019Hexa Haemophilus 3Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX019Hexa Anaerobic 1Low risk20/12/20ASS-sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk20/12/20	,	HX007	Hexa G-minus 2	Low risk	20/12/2012
Discs (Multi Discs)HX009Hexa G-minus 4Low risk22/02/20ASS- Sensitivity Discs (Multi Discs)HX011Hexa G-minus 5Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX011Hexa Pseudo 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX012Hexa Pseudo 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX013Hexa Pseudo 3Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa UTI-2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 6Low risk20/12/20<		HX008	Hexa G-minus 3	Low risk	20/12/2012
Discs (Multi Discs)NADICHexa G-Jimita SLow risk20/12/00ASS-Sensitivity Discs (Multi Discs)HX012Hexa Pseudo 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX012Hexa Pseudo 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX013Hexa Pseudo 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexa Pseudo 3Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX018Hexa Pneumococci 1Low risk22/08/20ASS-Sensitivity Discs (Multi Discs)HX020Hexa Anaerobic 1Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX021Hexa G-plus 7Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk20/12/20ASS-Sensitivity Discs (Multi Discs)HX021Hexa G-plus 7Low risk20/12/20 <td< td=""><td></td><td>HX009</td><td>Hexa G-minus 4</td><td>Low risk</td><td>25/08/2016</td></td<>		HX009	Hexa G-minus 4	Low risk	25/08/2016
Discs (Multi Discs)HX011Hexa Pseudo 1LOW riskZ0/12/20ASS- Sensitivity Discs (Multi Discs)HX012Hexa Pseudo 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX013Hexa Pseudo 3Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk22/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 2Low risk22/02/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 6Low risk20/12/20 <td></td> <td>HX010</td> <td>Hexa G-minus 5</td> <td>Low risk</td> <td>20/12/2012</td>		HX010	Hexa G-minus 5	Low risk	20/12/2012
Discs (Multi Discs)HX012Hexa Pseudo 2Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX013Hexa Pseudo 3Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX016Hexa UTI-2Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 1Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 2Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX023Hexa G-plus 6Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX024Hexa G-plus 6Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX024Hexa G-plus 6Low risk2/012/20ASS-sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk2/012/20ASS-		HX011	Hexa Pseudo 1	Low risk	20/12/2012
Discs (Multi Discs)HX013Hexa Pseudo 3Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX014Hexa UTI-1Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk2.5/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Anaerobic 1Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 7Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 8Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk2.0/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 6Low risk<		HX012	Hexa Pseudo 2	Low risk	20/12/2012
Discs (Multi Discs)HX014Hexa UTI-1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX015Hexa UTI-2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Anerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-Minus 6Low risk25/08/20 <td></td> <td>HX013</td> <td>Hexa Pseudo 3</td> <td>Low risk</td> <td>20/12/2012</td>		HX013	Hexa Pseudo 3	Low risk	20/12/2012
Discs (Multi Discs)HX015Hexa OI1-2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-Minus 6Low risk25/08/20		HX014	Hexa UTI-1	Low risk	20/12/2012
Discs (Multi Discs)HX016Hexa Haemophilus 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-Minus 6Low risk		HX015	Hexa UTI-2	Low risk	20/12/2012
Discs (Multi Discs)HX017Hexa Haemophilus 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-Minus 6Low risk20/12/20	· · ·	HX016	Hexa Haemophilus 1	Low risk	25/08/2016
Discs (Multi Discs)HX018Hexa Haemophilus 3Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-plus 6Low risk20/12/20		HX017	Hexa Haemophilus 2	Low risk	20/12/2012
Discs (Multi Discs)HX019Hexa Pneumococci 1Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa G-Minus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk20/12/20		HX018	Hexa Haemophilus 3	Low risk	25/08/2016
Discs (Multi Discs)HX020Hexa Pneumococci 2Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa B-seudo 4Low risk20/12/20		HX019	Hexa Pneumococci 1	Low risk	25/08/2016
Discs (Multi Discs)HX021Hexa Anaerobic 1Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa Pseudo 4Low risk20/12/20		HX020	Hexa Pneumococci 2	Low risk	20/12/2012
Discs (Multi Discs)HX022Hexa G-plus 6Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa Pseudo 4Low risk20/12/20		HX021	Hexa Anaerobic 1	Low risk	20/12/2012
Discs (Multi Discs)HX023Hexa G-plus 7Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk25/08/20ASS- Sensitivity Discs (Multi Discs)HX026Hexa Resulto 4Low risk20/12/20		HX022	Hexa G-plus 6	Low risk	20/12/2012
Discs (Multi Discs)HX024Hexa G-plus 8Low risk20/12/20ASS- Sensitivity Discs (Multi Discs)HX025Hexa G-Minus 6Low risk25/08/20ASS- Sensitivity ASS- SensitivityHX026Hexa Pseudo 4Low risk20/12/20		HX023	Hexa G-plus 7	Low risk	20/12/2012
Discs (Multi Discs) HX025 Hexa G-Minus 6 Low risk 25/08/20 ASS- Sensitivity HX026 Hexa Pseudo 4 Low risk 20/12/20		HX024	Hexa G-plus 8	Low risk	20/12/2012
		HX025	Hexa G-Minus 6	Low risk	25/08/2016
		HX026	Hexa Pseudo 4	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) HX027 Hexa G-Plus 9 Low risk 20/12/20		HX027	Hexa G-Plus 9	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) HX028 Hexa G-minus 7 Low risk 20/12/20		HX028	Hexa G-minus 7	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) HX029 Hexa Pseudo 5 Low risk 20/12/20		НХ029	Hexa Pseudo 5	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) HX030 Hexa G-Minus 8 Low risk 20/12/20		HX030	Hexa G-Minus 8	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) HX031 Hexa G-Plus 10 Low risk 20/12/20		HX031	Hexa G-Plus 10	Low risk	20/12/2012

IM	

Document ref.: DoC 2022 vs. 15

Pa

Page 91 of 130

1	1		1	
ASS- Sensitivity Discs (Multi Discs)	HX032	Hexa Universal - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX033	Hexa UTI 3	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX034	Hexa G-plus11	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX035	Hexa G-minus 9	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX036	Hexa G-minus 29	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX037	Hexa UTI 4	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX038	Hexa Universal-2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	НХ039	Hexa G-plus 12	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX040	Hexa G-plus 13	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX041	Hexa Pneumococci - 3	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX042	Hexa Pneumococci-4	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX043	Hexa Pneumococci - 5	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX044	Hexa Pneumococci - 6	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX045	Hexa Pneumococci-7	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX046	Hexa Pneumococci-8	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX047	Hexa G-plus 25	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX048	Hexa G-plus 26	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX049	Hexa G-plus 27	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX050	Hexa Pseudo 6	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX051	Hexa Pseudo 7	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX052	Hexa Pseudo 8	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX053	Hexa Pseudo 9	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX054	Hexa Pseudo 10	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX055	Hexa Pseudo 11	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX056	Hexa G-minus 26	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX057	Hexa G-minus 27	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX058	Hexa G-minus 28	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 92 of 130

ASS- Sensitivity				
Discs (Multi Discs)	HX059	Hexa G-minus 10	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX060	Hexa G-minus 11	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX061	Hexa G-Minus 12	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX062	Hexa G-minus 13	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX063	Hexa G-minus 14	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX064	Hexa G-minus 15	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX065	Hexa G-Minus 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX066	Hexa G-minus 17	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX067	Hexa G-minus 18	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX068	Hexa G-minus 19	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX069	Hexa G-minus 20	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX070	Hexa G-minus 21	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX071	Hexa G-Minus 22	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX072	Hexa UTI 4 (Modified)	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX073	Hexa UTI 5	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX074	Hexa UTI 6	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX075	Hexa UTI 7	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX076	Hexa UTI 8	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX077	Hexa UTI 9	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX078	Hexa UTI 10	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX079	Hexa UTI 11	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX080	Hexa G-plus 14	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX081	Hexa G-plus 15	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX082	Hexa G-Plus 16	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX083	Hexa G-plus 17	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX084	Hexa Haemophilus 4	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	HX085	Hexa Haemophilus 5	Low risk	25/08/2016



Declaration of Conformity

Document ref.: DoC 2022 vs. 15

Microbiology Products

Page 93 of 130

1			
HX086	Hexa Haemophilus 6	Low risk	20/12/2012
HX087	Hexa Haemophilus 7	Low risk	20/12/2012
HX088	Hexa Haemophilus 8	Low risk	20/12/2012
HX089	Hexa Haemophilus 9	Low risk	20/12/2012
HX090	Hexa G-plus 18	Low risk	20/12/2012
HX091	Hexa G-plus 19	Low risk	20/12/2012
HX092	Hexa G-plus 20	Low risk	20/12/2012
HX093	Hexa G-plus 21	Low risk	20/12/2012
HX094	Hexa G-Plus 22	Low risk	25/08/2016
HX095	Hexa G-minus 23	Low risk	20/12/2012
HX096	Hexa G-minus 24	Low risk	20/12/2012
HX097	Hexa Universal-2	Low risk	25/08/2016
HX098	Hexa Universal-3	Low risk	25/08/2016
НХ099	Hexa UTI 12	Low risk	25/08/2016
HX100	Hexa G-Plus 23	Low risk	25/08/2016
HX101	Hexa G-plus 24	Low risk	20/12/2012
HX102	Hexa G-minus 25	Low risk	20/12/2012
HX103	Hexa Pseudo 12	Low risk	20/12/2012
HX104	Hexa Antimyco-01	Low risk	20/12/2012
HX700	Hexa G-Plus 25	Low risk	25/08/2016
HX701	Hexa G-Minus 26	Low risk	25/08/2016
HX703	Hexa Pseudo-13	Low risk	25/08/2016
HX704	Hexa G-Minus 27	Low risk	25/08/2016
HX705	Hexa Anaerobic 2	Low risk	25/08/2016
HX706	Hexa UTI 14	Low risk	25/08/2016
HX707	Hexa G-Plus 26	Low risk	25/08/2016
HX708	Hexa G-Minus 28	Low risk	25/08/2016
	IX087 IX088 IX089 IX090 IX091 IX092 IX093 IX094 IX095 IX096 IX097 IX098 IX099 IX096 IX097 IX098 IX099 IX100 IX101 IX102 IX103 IX104 IX700 IX701 IX703 IX704 IX705 IX706	Interface Interface IX087 Hexa Haemophilus 7 IX088 Hexa Haemophilus 8 IX089 Hexa Haemophilus 9 IX090 Hexa G-plus 18 IX091 Hexa G-plus 19 IX092 Hexa G-plus 20 IX093 Hexa G-plus 21 IX094 Hexa G-plus 22 IX095 Hexa G-minus 23 IX096 Hexa Iuniversal-2 IX097 Hexa Universal-3 IX099 Hexa G-plus 21 IX096 Hexa Iuniversal-3 IX097 Hexa Iuniversal-3 IX098 Hexa Universal-3 IX099 Hexa G-plus 24 IX100 Hexa G-plus 24 IX101 Hexa G-plus 24 IX102 Hexa G-plus 24 IX103 Hexa G-plus 24 IX101 Hexa G-plus 24 IX102 Hexa G-plus 24 IX103 Hexa G-plus 24 IX104 Hexa G-plus 25 IX103 Hexa G-plus 25 IX104 Hexa G-plus 26	IX087Hexa Haemophilus 7Low riskIX088Hexa Haemophilus 8Low riskIX089Hexa Haemophilus 9Low riskIX089Hexa G-plus 18Low riskIX091Hexa G-plus 19Low riskIX092Hexa G-plus 20Low riskIX093Hexa G-plus 21Low riskIX094Hexa G-plus 22Low riskIX095Hexa G-rinus 23Low riskIX097Hexa G-minus 24Low riskIX098Hexa Universal-2Low riskIX099Hexa Universal-3Low riskIX091Hexa G-plus 22Low riskIX095Hexa G-minus 24Low riskIX096Hexa G-minus 24Low riskIX097Hexa Universal-3Low riskIX098Hexa Universal-3Low riskIX099Hexa Universal-3Low riskIX101Hexa G-plus 23Low riskIX102Hexa G-plus 24Low riskIX103Hexa G-plus 25Low riskIX104Hexa G-plus 25Low riskIX105Hexa G-plus 25Low riskIX704Hexa G-Minus 26Low riskIX705Hexa G-Minus 27Low riskIX705Hexa Anaerobic 2Low riskIX706Hexa G-Plus 26Low riskIX707Hexa G-Plus 26Low riskIX704Hexa G-Plus 26Low riskIX705Hexa G-Plus 26Low riskIX704Hexa G-Minus 27Low riskIX705Hexa G-Plus 26Low risk<

IM	ED	IA
	Ľ	

Document ref.: DoC 2022 vs. 15

Page 94 of 130

ASS- Sensitivity Discs (Multi Discs)	HX709	Hexa Pseudo 14	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX710	Hexa UTI-15	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX711	Hexa G-Plus 27	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX712	Hexa Pseudo 15	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX713	Hexa Anaerobic-3	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX714	Hexa Combi 1	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX715	Hexa Universal 4	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX716	Hexa Universal 5	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX717	Hexa Combi 2	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX718	Hexa Combi 3	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX719	Hexa Combi 4	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX720	Hexa Combi 5	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX721	Hexa Combi 6	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX722	Hexa Combi 7	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	НХ723	Hexa Combi 8	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	HX724	Hexa Combi 9	Low risk	28/04/2017
ASS- Sensitivity Discs (Multi Discs)	HX725	Hexa Combi 10	Low risk	28/04/2017
ASS- Sensitivity Discs (Multi Discs)	HX726	Hexa Combi 11	Low risk	28/04/2017
ASS- Sensitivity Discs (Multi Discs)	IC001	Icosa Universal - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC002	Icosa G-I-Plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC003	Icosa G-I-Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC004	Icosa UTI - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC005	Icosa Pseudo - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC006	Icosa Universal - 2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC007	Icosa Pseudo - 2	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC008	Icosa G-II-Minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	IC701	Icosa Universal - 3	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 95 of 130

ASS- Sensitivity	IC702	lcosa Universal - 4	Low risk	25/08/2016
Discs (Multi Discs) ASS- Sensitivity				
Discs (Multi Discs)	IC703	Icosa Universal 5	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD001	Amikacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD002	Amoxycillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD003	Amoxyclav (Amoxycillin/ Clavulanic acid)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD004	Azithromycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD005	Azlocillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD006	Aztreonam	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD007	Carbenicillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD008	Cefazolin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD009	Cefdinir	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD010	Cefepime	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD011	Cefpirome	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD012	Ceftazidime	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD013	Ceftriaxone	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD014	Cefalexin (Cephalexin)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD015	Cefotaxime (Cephotaxime)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD016	Chloramphenicol	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD017	Ciprofloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD018	Clarithromycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD019	Clindamycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD020	Colistin (Methane Sulphonate)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD021	Co-Trimoxazole (Sulpha/Trimethoprim)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD022	Erythromycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD023	Fusidic Acid	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD024	Gatifloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD025	Gentamicin	Low risk	20/12/2012

M		Λ

Page 96 of 130

ASS-HiComb MIC Strips	MD026	Kanamycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD027	Levofloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD028	Lincomycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD029	Linezolid	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD030	Lomefloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD031	Methicillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD032	Minocycline	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD033	Moxifloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD034	Mupirocin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD035	Nalidixic Acid	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD036	Neomycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD037	Nitrofurantoin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD038	Norfloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD039	Ofloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD040	Pefloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD041	Piperacillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD042	Piperacillin/Tazobactam	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD043	Polymyxin-B	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD044	Pristinomycin (Quinupristin/Dalfopristin)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD045	Rifampicin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD046	Roxithromycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD047	Sparfloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD048	Streptomycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD049	Sulfasomidine	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD050	Sulphadiazine	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD051	Sulphafurazole (Sulfisoxazole)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD052	Sulphamethizole	Low risk	20/12/2012

M	
HН	

Document ref.: DoC 2022 vs. 15

roducts

Page 97 of 130

ASS-HiComb MIC Strips	MD053	Sulphamethoxypyridazine	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD054	Sulphaphenazole	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD055	Teicoplanin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD056	Tetracycline	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD057	Ticarcillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD058	Tobramycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD059	Trimethoprim	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD060	Vancomycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD061	Gentamicin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD062	Benzyl Penicillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD063	Vancomycin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD064	Cefotaxime (Cephotaxime)	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD065	Oxacillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD066	Ceftriaxone	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD067	Amikacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD068	Ampicillin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD069	Ceftazidime	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD070	Cefepime	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD071	Amphotericin B	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD072	Fluconazole	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD073	Itraconazole	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD074	Ketoconazole	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD076	Gemifloxacin	Low risk	20/12/2012
ASS-HiComb MIC Strips	MD701	Cefepime/Tazobactam	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD702	Ceftazidime/Tazobactum	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD704	Nadifloxacin	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD706	Cefoperazone/Tazobactam CST	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 98 of 130

ASS-HiComb MIC	I		I	l
Strips	MD707	Balofloxacin	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD708	Cefuroxime CXM	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD709	Cefpodaxime CPD	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD710	Cefpodaxime / Clavulanic acid (2:1)	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD711	Netilimicin NET	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD712	Cefixime CFM	Low risk	25/08/2016
ASS-HiComb MIC Strips	MD713	Pazufloxacin	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD001	G-I-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD001R	G-I-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD002	G-II-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD002R	G-II-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD003	G-III-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD0032R	Combi I	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD003R	G-III-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD004	G-IV-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD004R	G-IV-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD005	G-I-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD005R	G-I-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD006	G-II-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD006R	G-II-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD007	G-III-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD007R	G-III-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD008	Pseudo	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD008R	Pseudo	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD009	UTI-I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD009R	UTI-I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD010	UTI-II	Low risk	20/12/2012

IM	ED	IA

Page 99 of 130

ASS- Sensitivity Discs (Multi Discs)	OD010R	UTI-II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD011	G-X-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD011R	G-X-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD012	G-IX-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD012R	G-IX-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD014	G-IV-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD014R	G-IV-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD015	G-V-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD015R	G-V-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD016	UTI-IV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD016R	UTI-IV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD017	UTI-VI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD017R	UTI-VI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD018	UTI-VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD018R	UTI-VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD019	UTI-V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD019R	UTI-V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD020	Combi I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD020R	Combi I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD021	Combi II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD021R	Combi II	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD022	Combi III	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD022R	Combi III	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD023	Combi IV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD023R	Combi IV	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD024	Combi V	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD024R	Combi V	Low risk	25/08/2016

M	ED	

Page 100 of 130

			1	
ASS- Sensitivity Discs (Multi Discs)	OD025	Combi VI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD025R	Combi VI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD026	Combi VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD026R	Combi VII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD027	Combi VIII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD027R	Combi VIII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD028	Combi IX	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD028R	Combi IX	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD029	Combi X	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD029R	Combi X	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD030	Combi XI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD030R	Combi XI	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD031	Combi XII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD031R	Combi XII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD032	Combi XIII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD032R	Combi XIII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD033	G-V-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD033R	G-V-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD034	G-VI-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD034R	G-VI-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD035	UTI III	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD035R	UTI III	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD036	Pseudo I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD036R	Pseudo I	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD037	G-VII-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD037R	G-VII-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD038	G-VIII-plus	Low risk	20/12/2012

IM	EF	

Page 101 of 130

ASS- Sensitivity	OD038R	G-VIII-plus	Low risk	20/12/2012
Discs (Multi Discs) ASS- Sensitivity				
Discs (Multi Discs)	OD039	G-XI-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD039R	G-XI-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD040	UTI-VIII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD040R	UTI-VIII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD041	G-XII-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD041R	G-XII-plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD042	G-VI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD042R	G-VI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD043	G-VII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD043R	G-VII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD044	G-VIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD044R	G-VIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD045	G-IX-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD045R	G-IX-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD046	G-X-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD046R	G-X-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD047	G-XI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD047R	G-XI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD048	UTI-IX	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD048R	UTI-IX	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD049	G-XIII- plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD049R	G-XIII- plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD050	G-XIV- plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD050R	G-XIV- plus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD051	UTI-X	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD051R	UTI-X	Low risk	20/12/2012

IM		Λ

Page 102 of 130

ASS- Sensitivity				
Discs (Multi Discs)	OD052	UTI-XI	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD052R	UTI-XI	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD053	G-XII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD053R	G-XII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD054	UTI-XII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD054R	UTI-XII	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD055	G-XIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD055R	G-XIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD056	Combi 59	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD056R	Combi 59	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD057	G-XVIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD057R	G-XVIII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD058	G-XIX-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD058R	G-XIX-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD059	G-XX-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD059R	G-XX-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD060	G-XXI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD060R	G-XXI-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD061	G-XXII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD061R	G-XXII-minus	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD062	G-XXIII-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD062R	G-XXIII-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD063	Pseudo V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD063R	Pseudo V	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD064	Combi-XIV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD064R	Combi XIV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD065	UTI-XVII	Low risk	25/08/2016

IM	EN	ΙΛ

Page 103 of 130

ASS- Sensitivity			I	
Discs (Multi Discs)	OD065R	UTI-XVII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD066	Combi 82	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD066R	Combi 82	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD067	Combi 83	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD067R	Combi 83	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD202	Comb XXI	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD209	Combi 28	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD211	Combi 30	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD211R	Combi 30	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD212	Combi 31	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD215	Combi 34	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD215R	Combi 34	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD216	Combi 35	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD216R	Combi 35	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD220	Combi 39	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD221	Combi 40	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD223	G XIV minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD224	G XV plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD225	υτι χιΙΙ	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD226	Combi 41	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD227	UTI-XIV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD228	Pseudo II	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD229	G-XV-minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD230	G-XVI-plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD231	Combi -42	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD232	Combi 43	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD233	Combi 44	Low risk	25/08/2016

IM	EF	

Page 104 of 130

ASS- Sensitivity Discs (Multi Discs)	OD233R	Combi 44	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD234	Combi 45	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD234R	Combi 45	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD241	Combi 49	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD241R	Combi 49	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD243	G XVII minus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD244	G XIX plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD248	Combi-53	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD249	Combi-54	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD250	Pseudo - III for Pseudomonas	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD251	GXX plus	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD253	Combi 56	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD256	Combi 59	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD256R	Combi 59	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD257	Combi 60	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD257R	Combi 60	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD258	Combi 61	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD258R	Combi 61	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD259	Combi 62	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD259R	Combi 62	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD260	UTI-XIII	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD261	UTI-XIV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD262	UTI-E	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD263	UTI-XV	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD264	Pseudo II	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD265	Combi 63	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD266	Combi 64	Low risk	25/08/2016
Discs (Multi Discs) ASS- Sensitivity Discs (Multi Discs)	OD260 OD261 OD262 OD263 OD264 OD265	UTI-XIII UTI-XIV UTI-E UTI-XV Pseudo II Combi 63	Low risk Low risk Low risk Low risk Low risk Low risk	25/08/203 25/08/203 25/08/203 25/08/203 25/08/203 25/08/203

M	ED	

Page 105 of 130

ACC Constitution	I		I	
ASS- Sensitivity Discs (Multi Discs)	OD267	Combi 65	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD268	Combi 66	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD269	Combi 67	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD269R	Combi 67	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD270	Combi 68	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD270R	Combi 68	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD271	Combi 69	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD271R	Combi 69	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD272	Combi 70	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD272R	Combi 70	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD273	Combi 71	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD273R	Combi 71	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD274	Combi 72	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD274R	Combi 72	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD275	Combi 73	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD275R	Combi 73	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD275RS	Combi 60	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD275S	Combi 60	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD276	Combi 84	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD276R	Combi 84	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD277	Combi 77	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD277R	Combi 77	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD278	Combi 78	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD278R	Combi 78	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD279	Combi 79	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD279R	Combi 79	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD280	Combi 80	Low risk	20/12/2012
טוארא (ואועונו אוגנא)			I	

IM	

Page 106 of 130

Dates (Multi Dates) OD281 Combi 85 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD281 Combi 85 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD281 Combi 85 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD282 Combi 505 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD283 Combi 506 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD283 Combi 506 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD284 Combi 508 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD284 Combi 508 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD284 Combi 508 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD285 Combi 509 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD286 Combi 510 Low risk 20/12/2017 ASS - Sensitivity Discs (Multi Discs) OD287 Combi 51	ASS- Sensitivity	00000		l	20/10/2012
Discs (Multi Discs) DU281 Comits is Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD282 Combi 505 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD282 Combi 505 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD282 Combi 505 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 506 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD285 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD286 Combi 510 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD286 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD287 Combi 511 Low risk	Discs (Multi Discs)	OD280R	Combi 80	Low risk	20/12/2012
Discs DUUSING Comits is Comits is <thcomits is<="" th=""> <thcomits< td=""><td></td><td>OD281</td><td>Combi 85</td><td>Low risk</td><td>20/12/2012</td></thcomits<></thcomits>		OD281	Combi 85	Low risk	20/12/2012
Discs (Multi Discs) DU22 Combi 505 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD283 Combi 505 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD284 Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD285 Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD287 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD287 Combi 512 L		OD281R	Combi 85	Low risk	20/12/2012
Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD283 Combi 506 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD285 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD285 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD286 Combi 510 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD287 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD287 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD287 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) DD287 Combi 512		OD282	Combi 505	Low risk	20/12/2012
Discs (Multi Discs) OD283 Combi 506 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD284 Combi 506 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD284 Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD284 Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD285 Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286 Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288 Combi 512		OD282R	Combi 505	Low risk	20/12/2012
Discs (Multi Discs) DD283 M Combi 506 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD284 M Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD284 M Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD285 C Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD285 C Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288 Combi 512 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288 Combi 512 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288 Combi 513 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs)<		OD283	Combi 506	Low risk	20/12/2012
Discs (Multi Discs) 00284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00284 Combi 508 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00285 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00285 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00286 Combi 509 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00286 Combi 510 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00287 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00287 Combi 511 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00288 Combi 512 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00288 Combi 512 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00288 Combi 513 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) 00289 Combi 513		OD283R	Combi 506	Low risk	20/12/2012
Discs (Multi Discs) DD28R Combi 508 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28S Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 512 Low risk 25/08/2016 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 513 Low risk 25/08/2016 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 513 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD28R Combi 514		OD284	Combi 508	Low risk	20/12/2012
Discs (Multi Discs) DU28S Combi S09 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD285R Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD286 Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD286R Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) DD287R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288R Combi 512 Low risk 22/08/2016 ASS-Sensitivity Discs (Multi Discs) OD289R Combi 513 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD289R Combi 513 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD290R Combi 514 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD291R Combi 90		OD284R	Combi 508	Low risk	20/12/2012
Discs (Multi Discs) OD285R Combi 509 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286R Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD286R Combi 510 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287 Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD287R Combi 511 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288R Combi 512 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD288R Combi 512 Low risk 25/08/2016 ASS-Sensitivity Discs (Multi Discs) OD288R Combi 513 Low risk 25/08/2016 ASS-Sensitivity Discs (Multi Discs) OD289R Combi 513 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD290R Combi 514 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD290R Combi 514 Low risk 20/12/2012 ASS-Sensitivity Discs (Multi Discs) OD290R Combi 90		OD285	Combi 509	Low risk	20/12/2012
Discs (Multi Discs)OD286Combi S10Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287Combi 510Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287Combi 511Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287Combi 511Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287Combi 511Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD288Combi 512Low risk22/12/2012ASS- Sensitivity Discs (Multi Discs)OD288Combi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi		OD285R	Combi 509	Low risk	20/12/2012
Discs (Multi Discs)DD286RCombi S10Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287Combi 511Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287RCombi 511Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD288Combi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD288RCombi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD288RCombi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289RCombi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs		OD286	Combi 510	Low risk	20/12/2012
Discs (Multi Discs)OD287Combi S11Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD287RCombi S11Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD288Combi S12Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD288RCombi S12Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289Combi S13Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289RCombi S13Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi S13Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi S14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi S14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi S14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi S14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (M		OD286R	Combi 510	Low risk	20/12/2012
Discs (Multi Discs)OD287RCombi \$11Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD288Combi \$12Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD288RCombi \$12Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289Combi \$13Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi \$13Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi \$13Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi \$14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi \$14Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi \$90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi \$90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi \$90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD292Combi \$91Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi \$91Low risk20/12/2012ASS- Sensitivity D		OD287	Combi 511	Low risk	20/12/2012
Discs (Multi Discs)OD288Combi \$12Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD288Combi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD292Combi 91Low risk20/12/2012		OD287R	Combi 511	Low risk	20/12/2012
Discs (Multi Discs)OD288RCombi 512Low risk25/08/2016ASS- Sensitivity Discs (Multi Discs)OD289Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD289RCombi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD292Combi 91Low risk20/12/2012		OD288	Combi 512	Low risk	25/08/2016
Discs (Multi Discs)OD289Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 91Low risk20/12/2012	,	OD288R	Combi 512	Low risk	25/08/2016
Discs (Multi Discs)OD289RCombi 513Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290Combi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012		OD289	Combi 513	Low risk	20/12/2012
Discs (Multi Discs)OD290Combi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012		OD289R	Combi 513	Low risk	20/12/2012
Discs (Multi Discs)OD290RCombi 514Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291Combi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity Discs (Multi Discs)OD291RCombi 90Low risk20/12/2012ASS- Sensitivity 	,	OD290	Combi 514	Low risk	20/12/2012
Discs (Multi Discs) OD291 Combi 90 Low risk 20/12/2012 ASS- Sensitivity Discs (Multi Discs) OD291R Combi 90 Low risk 20/12/2012 ASS- Sensitivity OD292 Combi 91 Low risk 20/12/2012	,	OD290R	Combi 514	Low risk	20/12/2012
Discs (Multi Discs) OD291R Combi 90 Low risk 20/12/2012 ASS- Sensitivity OD292 Combi 91 Low risk 20/12/2012		OD291	Combi 90	Low risk	20/12/2012
(1)/2/2 = 1 (0)/2/2 = 1 (0)/2/2 = 1 (0)/2 =		OD291R	Combi 90	Low risk	20/12/2012
		OD292	Combi 91	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) OD292R Combi 91 Low risk 20/12/2012		OD292R	Combi 91	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) OD293 Combi 92 Low risk 20/12/2012		OD293	Combi 92	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs) OD293R Combi 92 Low risk 20/12/2012		OD293R	Combi 92	Low risk	20/12/2012

IM	ED	

Page 107 of 130

ASS- Sensitivity	00304	Correli 02	L avv viele	20/12/2012
Discs (Multi Discs) ASS- Sensitivity	OD294	Combi 93	Low risk	20/12/2012
Discs (Multi Discs)	OD294R	Combi 93	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD295	Combi 516	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD295R	Combi 516	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD296	Combi 517	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD296R	Combi 517	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD297	Combi 518	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD297R	Combi 518	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD298	Combi 94	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD298R	Combi 94	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD299	Combi 95	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD299R	Combi 95	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD300	Combi 96	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD300R	Combi 96	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD301	G minus-24	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD301R	G minus-24	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD302	G minus-25	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD302R	G minus-25	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD303	G Plus-15	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD303R	G Plus-15	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD304	G Plus-16	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD304R	G Plus-16	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD305	G Plus-17	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD305R	G Plus-17	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD306	UTI-18	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD306R	UTI-18	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD307	Pseudo VI	Low risk	20/12/2012

IM	EF	

Page 108 of 130

ASS- Sensitivity	OD307R	Pseudo VI	Low risk	20/12/2012
Discs (Multi Discs) ASS- Sensitivity Discs (Multi Discs)	OD308	Universal - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD308R	Universal - 1	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD309	G Plus-18	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD309R	G Plus-18	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD310	G minus-26	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD310R	G minus-26	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD311	G minus-27	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD311R	G minus-27	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD312	G Minus - 28	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD312R	G Minus - 28	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD313	G Minus - 29	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD313R	G Minus - 29	Low risk	20/12/2012
ASS- Sensitivity Discs (Multi Discs)	OD704	Combi 77	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD705	Combi 78	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD706	Combi 79	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD707	Combi 80	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD708	Combi 81	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD709	Combi 85	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD710	Combi 86	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD711	Combi 501	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD712	Combi 502	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD713	Combi 503	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD714	Combi 504	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD715	Combi 505	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD716	Combi 506	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD717	Octodiscs-A	Low risk	25/08/2016

IM	ED	IA
	Ľ	

Page 109 of 130

ASS- Sensitivity	I		I	
Discs (Multi Discs)	OD718	Octodiscs-B	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD719	Octodiscs-C	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD720	Octodiscs-D	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD721	Octodiscs-E	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD722	Octodiscs-F	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD723	Octodiscs-G	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD724	Combi 507	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD725	Combi 508	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD726	Combi 509	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD727	Combi 510	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD728	Combi 511	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD729	Combi 512	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD730	Combi 513	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD731	Combi 514	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD732	Combi 515	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD733	Combi 516	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD734	Combi 517	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD735	Combi 518	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD736R	Combi 519	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD737	Combi 520	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD737R	Combi 520	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD738	Combi 521	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD738R	Combi 521	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD739	Combi 522	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD739R	Combi 522	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD740	Combi 523	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD740R	Combi 523	Low risk	25/08/2016

IM	ED	ΙΛ

Page 110 of 130

ASS- Sensitivity			I	
Discs (Multi Discs)	OD741	Combi 524	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD741R	Combi 524	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD742	Combi 525	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD742R	Combi 525	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD743	Combi 526	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD743R	Combi 526	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD744	Combi 527	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD744R	Combi 527	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD745	Combi 528	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD745R	Combi 528	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD746	Combi 529	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD746R	Combi 529	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD747	Combi 530	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD747R	Combi 530	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD748	Combi 531	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD748R	Combi 531	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD749	Combi 532	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD749R	Combi 532	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD750	Combi 533	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD750R	Combi 533	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD751	Combi 534	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD751R	Combi 534	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD752	Combi 535	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD752R	Combi 535	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD753	Combi 536	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD753R	Combi 536	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD754	Combi 537	Low risk	25/08/2016

IM	EF	

Page 111 of 130

	I		I	
ASS- Sensitivity Discs (Multi Discs)	OD754R	Combi 537	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD755	Combi 538	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD755R	Combi 538	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD756	Combi 539	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD756R	Combi 539	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD757	Combi 540	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD757R	Combi 540	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD758	Combi 541	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD758R	Combi 541	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD759	Combi 542	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD759R	Combi 542	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD760	Combi 543	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD760R	Combi 543	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD761	Combi 544	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD761R	Combi 544	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD762	Combi 545	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD762R	Combi 545	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD763	Combi 546	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD763R	Combi 546	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD764	Combi 547	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD764R	Combi 547	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD765	Combi 548	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD765R	Combi 548	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD766	Combi 549	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD766R	Combi 549	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD767	Combi 550	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD767R	Combi 550	Low risk	25/08/2016

IM	ED	

Page 112 of 130

	I	l l	I	l
ASS- Sensitivity Discs (Multi Discs)	OD768	Combi 551	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD768R	Combi 551	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD769	Combi 552	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD769R	Combi 552	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD770	Combi 553	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD770R	Combi 553	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD771	Combi 554	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD771R	Combi 554	Low risk	25/08/2016
ASS- Sensitivity Discs (Multi Discs)	OD772	Combi 555	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD772R	Combi 555	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD773	Combi 556	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD773R	Combi 556	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD774	Combi 557	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD774R	Combi 557	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD775	Combi 558	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD775R	Combi 558	Low risk	16/12/2017
ASS- Sensitivity Discs (Multi Discs)	OD776	Combi 559	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD776R	Combi 559	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD777	Combi 560	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD777R	Combi 560	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD778	Combi 561	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD778R	Combi 561	Low risk	04/07/2018
ASS- Sensitivity Discs (Multi Discs)	OD779	Combi 562	Low risk	22/04/2019
ASS- Sensitivity Discs (Multi Discs)	OD779R	Combi 562	Low risk	22/04/2019
ASS- Sensitivity Discs (Multi Discs)	OD780	Combi 563	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD780R	Combi 563	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD781	Combi 564	Low risk	10/11/2020

IM	EF	

Page 113 of 130

ASS- Sensitivity			I	
Discs (Multi Discs)	OD781R	Combi 564	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD782	Combi 565	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD782R	Combi 565	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD783	Combi 566	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD783R	Combi 566	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD784	Combi 567	Low risk	10/11/2020
ASS- Sensitivity Discs (Multi Discs)	OD784R	Combi 567	Low risk	10/11/2020
ASS- Sensitivity Discs (Single Discs)	SD001	Amoxycillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD002	Ampicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD002A	Ampicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD003	Bacitracin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD004	Carbenicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD005	Cefaloridine (Cephaloridine)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD006	Chloramphenicol	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD006B	Chloramphenicol(2 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD007	Chlortetracycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD008	Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD009	Colistin (Methane Sulphonate)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD010	Co-Trimoxazole (Sulpha/Trimethoprim)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD012	Doxycycline Hydrochloride	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD013	Erythromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD014	Framycetin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD015	Furazolidone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD016	Gentamicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD017	Kanamycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD018	Lincomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD019	Methicillin	Low risk	20/12/2012

M	ED	

Document ref.: DoC 2022 vs. 15

Page 114 of 130

ASS- Sensitivity	SD020	Metronidazole	Low risk	20/12/2012
Discs (Single Discs) ASS- Sensitivity Discs (Single Discs)	SD021	Nalidixic Acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD022	Neomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD023	Nitrofurantoin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD023A	Nitrofurantoin	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD024	Nitrofurazone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD025	Nystatin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD026	Oleandomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD027	Oxytetracycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD028	Penicillin-G	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD029	Polymyxin-B	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD030	Rifampicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD031	Streptomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD032	Sulphafurazole (Sulfisoxazole)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD033	Sulphamethizole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD034	Sulphadiazine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD035	Amikacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD036	Sulphaphenazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD037	Tetracycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD038	Triple Sulphas	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD039	Trimethoprim	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD040	Cefotaxime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD040A	Cefotaxime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD041	Cefoxitin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD042	Furoxone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD043	Oxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD044	Tobramycin	Low risk	20/12/2012

M	ED	

Page 115 of 130

I		l	
SD045	Vancomycin	Low risk	20/12/2012
SD046	Netillin	Low risk	20/12/2012
SD047	Cefazolin	Low risk	20/12/2012
SD048	Cefalexin(Cephalexin)	Low risk	20/12/2012
SD049	Cycloserine	Low risk	25/08/2016
SD050	Cephalothin	Low risk	20/12/2012
SD051	Clindamycin	Low risk	20/12/2012
SD052	Dicloxacillin	Low risk	20/12/2012
SD053	Novobiocin	Low risk	20/12/2012
SD054	Spiramycin	Low risk	20/12/2012
SD055	Sulphamethoxypyridazine	Low risk	20/12/2012
SD056	Sulfasomidine	Low risk	20/12/2012
SD056A	Sulphamethoxazole	Low risk	25/08/2016
SD057	Norfloxacin	Low risk	20/12/2012
SD058	Co-Trimazine (Vet.)	Low risk	25/08/2016
SD059	Sisomicin	Low risk	20/12/2012
SD060	Ciprofloxacin	Low risk	20/12/2012
SD060A	Ciprofloxacin	Low risk	20/12/2012
SD061	Cefuroxime	Low risk	20/12/2012
SD062	Ceftazidime	Low risk	20/12/2012
SD062A	Ceftazidime	Low risk	20/12/2012
SD063	Amoxyclav (Amoxycillin/Clavulanic acid)	Low risk	20/12/2012
SD063A	Augmentine	Low risk	25/08/2016
SD064	Azlocillin	Low risk	20/12/2012
SD065	Ceftriaxone	Low risk	20/12/2012
SD066	Piperacillin	Low risk	20/12/2012
SD066A	Piperacillin	Low risk	20/12/2012
	SD047 SD048 SD049 SD050 SD051 SD052 SD053 SD054 SD055 SD056A SD057 SD058 SD059 SD060A SD060A SD060A SD061 SD062A SD062A SD062A SD063A SD063A SD063A SD065 SD065	Interfact of the second seco	Normalization Low risk SD046 NetIIIn Low risk SD047 Cefazelin Low risk SD048 Cefalexin(Cephalexin) Low risk SD049 Cycloserine Low risk SD050 Cephalothin Low risk SD051 Cindamycin Low risk SD052 Dicloxacillin Low risk SD053 Novobiocin Low risk SD054 Splamethoxypyridazine Low risk SD055 Sulphamethoxypyridazine Low risk SD056 Sulphamethoxazole Low risk SD057 Norfloxacin Low risk SD058 Ciprofloxacin Low risk SD059 Sisomicin Low risk SD050 Ciprofloxacin Low risk SD051 Ciprofloxacin Low risk SD052 Cefrazidime Low risk SD050 Cefrazidime Low risk SD051 Cefrazidime Low risk SD052 Cefrazidime Low risk



Document ref.: DoC 2022 vs. 15

Page 116 of 130

ASS- Sensitivity	SD067	Sterile Discs	Low risk	20/12/2012
Discs (Single Discs) ASS- Sensitivity Discs (Single Discs)	SD068	Methanamine Mandalate	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD069	Ofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD070	Pefloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD071	Co-Trimazine (Human)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD072	Cefoperazone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD073	Imipenem	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD074	Ticarcillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD075	Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD076	Amoxycillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD077	Ampicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD078	Amoxyclav	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD079	Cefaloridine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD080	Ciprofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD081	Chloramphenicol	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD082	Amikacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD083	Erythromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD084	Lincomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD085	Netillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD086	Nitrofurantoin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD087	Ofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD088	Oxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD089	Penicillin-G	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD090	Nitrofurantoin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD091	Streptomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD092	Sulphadiazine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD093	Trimethoprim	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 117 of 130

ASS- Sensitivity			I	
Discs (Single Discs)	SD094	Azlocillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD096	Rifampicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD097	Colistin (Methane Sulphonate)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD098	Lincomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD099	Metronidazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD101	Spiramycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD102	Penicillin-G (1.5 units)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD103	Nitrofurantoin NIT	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD104	Neomycin N	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD105	Bacitracin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD106	Polymyxin-B	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD107	Metronidazole	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD108	Colistin (Methane Sulphonate)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD109	Ceftriaxone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD110	Ceftizoxime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD111	Amphotericin-B	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD112	Ampicillin/Sulbactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD113	Ampicillin/Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD114	Fluconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD115	Clotrimazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD116	Cefadroxil (Cephadroxil)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD117	Bacitracin (0.1 units)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD118	Bacitracin (2 units)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD119	Bacitracin (1 unit)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD120	Doxycycline Hydrochloride	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD121	Novobiocin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD123	Tetracycline T	Low risk	25/08/2016

IM	ED	

Document ref.: DoC 2022 vs. 15

Page 118 of 130

ASS- Sensitivity			I	
Discs (Single Discs)	SD124	Azithromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD125	Lomefloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD126	Roxithromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD127	Rifampicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD128	Rifampicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD129	Amoxycillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD130	Cephaloridine	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD131	Chloramphenicol	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD132	Piperacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD133	Tetracycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD134	Tobramycin TB	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD135	Trimethoprim	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD136	Methicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD137	Methicillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD138	Erythromycin	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD139	Polymyxin-B	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD140	Floxidin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD141	Floxidin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD142	Ciprofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD143	Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD144	Penicillin-G	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD145	Penicillin-G	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD147	Tetracycline	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD148	Trimethoprim	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD149	Trimethoprim	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD150	Enrofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD152	Penicillin-G	Low risk	25/08/2016

Document ref.: DoC 2022 vs. 15

Page 119 of 130

ASS- Sensitivity Discs (Single Discs)	SD153	Chloramphenicol	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD154	Tobramycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD155	Vancomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD156	Enrofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD157	Cefaclor	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD158	Minocycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD159	Cephradine	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD160	Cefradine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD161	Trimethoprim	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD162	Sparfloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD163	Vancomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD164	Clindamycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD165	Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD166	Gentamicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD167	Penicillin-G	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD168	Ceftriaxone Ci	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD169	Fusidic Acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD170	Gentamicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD171	Fusidic Acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD174	Polymyxin-B Pb	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD175	Pipemidic Acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD176	Mecillinam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD177	Mecillinam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD178	Pristinomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD179	Fosfomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD180	Oxolinic Acid (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD181	Spectinomycin	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 120 of 130

ASS- Sensitivity			l	
Discs (Single Discs)	SD182	Virginamycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD184	Norfloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD185	Pipemidic Acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD186	Oxolinic Acid (2 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD187	Flumequine (2 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD188	Dibekacine (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD189	Oxolinic Acid (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD190	Flumequine (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD191	Kanamycin (1 mcg) (K1)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD192	Clarithromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD195	Gentamicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD196	Nitroxoline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD197	Furazolidone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD198	Flumequine	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD199	Tylosine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD200	Cefamandole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD201	Ticarcillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD203	Cefoperazone	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD204	Azithromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD205	Fosfomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD206	Lomefloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD207	Ceftazidime /Clavulanic acid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD209	Cefprozil	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD210	Piperacillin/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD211	Cefixime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD212	Aztreonam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD213	Teicoplanin	Low risk	20/12/2012

IM	

Page 121 of 130

ASS- Sensitivity	I		I	
Discs (Single Discs)	SD214	Isepamicin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD215	Linezolid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD216	Levofloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD217	Moxifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD218	Cefdinir	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD219	Cefepime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD220	Moxalactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD221	Itraconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD222	Erythromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD223	Kanamycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD224	Ketoconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD225	Mezlocillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD231	Cefoperazone :Sulbactum (30mcg:10mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD232	Fluconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD233	Amphotericin B	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD234	Cefepime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD235	Cefpirome	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD236	Streptomycin For detection of HLAR Strains.	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD237	Enoxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD238	Kit I for ESBL Identification, Cefotaxime (Cephotaxime) Kit contains 6 cartridges (6CT): 3CT of SD040 Cefotaxime (Cephotaxime) 30 mcg, 3CT of SD724 Cefotaxime (Cephotaxime)/Clavulanic acid 30/10 mcg	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD239	Kit II for ESBL Identification, Cefepime Kit contains 6 cartridges (6CT): 3CT of SD219 Cefepime 30 mcg, 3CT of SD234 Cefepime /Clavulanic acid 30/10 mcg	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD240	Kit III for ESBL Identification, Ceftazidime Kit contains 6 cartridges (6CT): 3CT of SD062 Ceftazidime 30 mcg, 3CT of SD207 Ceftazidime /Clavulanic acid 30/10 mcg	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD241	Kit IV for ESBL Identification, Cefpirome Kit contains 6 cartridges (6CT): 3CT of SD738 Cefpirome 30 mcg, 3CT of SD235 Cefpirome /Clavulanic acid 30/7.5 mcg	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD242	Kit V for ESBL identif	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD243	Amoxyclav (Amoxycillin / Clavulanicacid)	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 122 of 130

ASS- Sensitivity			l	
Discs (Single Discs)	SD244	Cefmetazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD245	Cinoxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD246	Nafcillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD247	Cefepime/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD248	Cefonicid	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD249	Cefotetan	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD250	Gemifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD251	Ceftriaxone/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD252	Ceftazidime/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD253	Cefoperazone/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD254	Cefoperazone/	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD255	Cefpodoxime/ Clavulanic acid	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD256	Ceftriaxone/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD257	Cefepime/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD258	Nadifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD259	Cefoperazone/Sulbactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD260	Lomefloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD261	Ceftriaxone/ Sulbactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD262	Cefepime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD263	Aztreonam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD264	Amoxycillin/	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD265	Imipenem/Cilastin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD266	Cefixime/	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD267	Prulifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD268	Prulifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD269	Ceftazidime/Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD270	Amphotericin B	Low risk	20/12/2012

M	ED	

Document ref.: DoC 2022 vs. 15

Page 123 of 130

ASS- Sensitivity	SD271	Nuctotio	Low rick	20/12/2012
Discs (Single Discs) ASS- Sensitivity	50271	Nystatin	Low risk	20/12/2012
Discs (Single Discs)	SD272	Miconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD273	Miconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD274	Ketoconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD275	Ketoconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD276	Itraconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD277	Voriconazole	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD278	Tigecycline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD279	Faropenem	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD280	Ertapenem	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD281	Amoxyclav	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD282	Imipenem-EDTA	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD283	Doripenem	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD284	Cloxacillin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD285	Cefoxitin-	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD286	Amoxycillin/Sulbactam	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD287	Ampicillin/Sulbactam	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD288	Cefotaxime CTX	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD289	Ceftriaxone CTR	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD290E	Ceftaroline	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD291E	Telithromycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD292E	Piperacillin / Tazobactam	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD293E	Mupirocin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD294E	Ceftibuten	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD295E	Cefotaxime CTX	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD296E	Linezolid LZ	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD297	Colistin Sulphate	Low risk	17/06/2021



Document ref.: DoC 2022 vs. 15

Page 124 of 130

ASS- Sensitivity				
Discs (Single Discs)	SD298	Caspofungin	Low risk	17/06/2021
ASS- Sensitivity Discs (Single Discs)	SD701	Carbenicilline	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD704	Cefradine	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD705	Amoxycillin (2 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD709	Novobiocin (5mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD712	Oleandomycin (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD715	Fluconazole (25 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD722	Penicillin-G (2mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD723	Ampicillin (20mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD724	Cefotaxime/Clavulanic acid (30/10 mcg)	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD725	Cefpodoxime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD726	Ceftazimide/Clavulinic (3/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD727	Meropenem	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD730	Metronidazole (50 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD731	Neomycin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD732	Novobiocin (5mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD736	Bacitracin B 0.05 units /disc	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD737	Gatifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD738	Cefpirome (Cfp) (30mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD740	Gatifloxacin	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD741	Cephotaxime/Sulbactam (30/15 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD744	Ofloxacin Of 30 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD745	Norfloxacin (30mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD746	Gentamicin (200mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD748	Mupirocin MU 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD751	Cefpodoxime/ Clavulanic acid (10/1 MCG)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD753	Gatifloxacin	Low risk	20/12/2012



Document ref.: DoC 2022 vs. 15

Page 125 of 130

ASS- Sensitivity Discs (Single Discs)	SD755	Ceftiofur (0.2mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD756	Ceftiaxone (30 mcg) / Sulbactam (15 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD761	Sparfloxacin Sc (10mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD764	Ceftriaxone/ Tazobactam (80/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD765	Gemifloxacin (GEM) 5mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD767	Ceftazidime-Tazobactam (CaT) (30/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD768	Cefoperazone-tazobactam (75/10mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD769	Cefoperazone-Sulbactam (Cfs) (75/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD770	Cefepime/Tazobactam (30/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD771	Cefpodoxime / Clavulanic acid (10/5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD773	Piperacillin / Sulbactam (100/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD774	Faropenem (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD775	Ceftriaxone (30 mcg) / Tazobactam (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD776	Cefepime (80 mcg) / Tazobactam (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD777	Nadifloxacin (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD779	Cefoperazone / Sulbactam (50 / 50 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD780	Lomefloxacin Lo (15 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD781	Cefixime/Clavulanic acid Cmc (200/125 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD782	Cefepime Cpm (50 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD783	Aztreonam Ao (50 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD784	Amoxycillin/Sulbactam Ams (30/15 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD785	Imipenem/Cilastatin Ic (10/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD786	Cefixime / Clavulanic acid Cmc (5/10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD787	Prulifloxacin Pr (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD788	Prulifloxacin Pr (5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD789	Ceftriaxone / Sulbactam (500/250 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD790	Ceftriaxone / Sulbactam (1000/500 mcg)	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 126 of 130

ASS- Sensitivity	60704			25 (00 /201 6
Discs (Single Discs)	SD791	Piperacillin + Tazobactam (80:10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD792	Pazufloxacin (PZ) (25 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD793	Cefditoren (10 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD794	Cefpodoxime/Clavulanic acid (10/6.25mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD795	Cefipime / Amikacin (30 / 7.5 mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD796	Cefepime / Sulbactam (30/15 mcg) CPS	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD797	Ceftazidime / Sulbactam (30/15 mcg) CAS	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD798	Ceftriaxone/Tobramycin (30/5.4 mcg) CTB	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD799	Ceftriaxone/Vancomycin (30/15 mcg) CVA	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD800	Cefpirome / Sulbactam (30/15 mcg) CRS	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD801	Cefaperazone/Sulbactum (70/35mcg)(CSB)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD802	Ceftazidime Tobramycin (30+3.6 mcg) CFT	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD803	Amoxycillin/Clavulanic acid AC 50/10 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD804	Cefpodoxime / Clavulanic acid (24:15mcg)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD805	Cefixime : Ofloxacin COF 5:5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD806	Balofloxacin BF 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD807	Tigecycline TGC 20 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD808	Ampicillin / Cloxacillin 128/128µg Ax	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD809	Amoxycillin/Cloxacillin 128/128µg ACX	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD810	Gentamicin GEN 128µg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD811	Enrofloxacin EX 8µg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD812	Ciprofloxacin CIP 8µg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD813	Tetracyclin TE 128µg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD814	Chloramphenicol C 8 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD815	Streptomycin/Penicillin SPN 128/128mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD816	Ceftazidime/Tobramycin CFT 30/10mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD816V	Ceftazidime/Tobramycin CFT (30:10)	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

ots

Page 127 of 130

ASS- Sensitivity Discs (Single Discs)	SD817	Cefepime / Amikacin CPA 30/10mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD818	Balofloxacin BF 10mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD819	Oxacillin Ox 10mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD820	Cefixime	Low risk	20/12/2012
ASS- Sensitivity Discs (Single Discs)	SD821	Cefpodoxim CPD 30mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD822	Garenoxacin GRN 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD823	Sitafloxacin STX 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD824	Tosufloxacin TOS 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD825	Biapenem BPM 10 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD826	Cefepime Amikacin 58.8:14.6.mcg CPA	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD827	Florfenikol FLO 30mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD828	Cefpodoxime:Levofloxacin 10:5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD829	Meropenem/Sulbactam MRS 10:5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD830V	Ceftriazone Vancomycin CVA (30:30)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD831	Ampicillin/Sulbactum (A/S) 20:10	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD832	Cefixime : Azithromycin CFA 5:15 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD833	Cefquinome CEQ 30mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD834	Ceftriaxone CTR 128 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD835	Sulphatrimethoprim STM 128/128 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD836	Erythromycin E 60 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD837	Kanmycin K 1000 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD838	Quninupristin/Dalfopristin RP 15/15 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD839	Levofloxacin/Cefpodoxime LEC 250 : 200 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD840	Ampicillin/Sulbactam A/S 20/12.5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD841	Garenoxacin GRN 1mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD842	Garenoxacin GRN 5mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD843	Mipenem (Meropenem) MIP 10 mcg	Low risk	25/08/2016



Document ref.: DoC 2022 vs. 15

Page 128 of 130

ASS- Sensitivity Discs (Single Discs)	SD844	Ranicef (Cefdinir) RNF 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD845	Clavamox (Amoxycillin / Clavulanic acid)	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD846	Ciprotab (Ciprofloxacin) CPT 5 mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD847	Ciprotab (Ciprofloxacin) CPT 10mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD848	Meropenem/Sulbactam MRS 2/200mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD849	Flucloxacillin FCO 30mcg	Low risk	25/08/2016
ASS- Sensitivity Discs (Single Discs)	SD850	Cefuroxime/Clavulanic acid CCV 30/7.5mcg	Low risk	28/04/2017
ASS- Sensitivity Discs (Single Discs)	SD851	Cefixime/Dicloxacillin CDC 5/12.5mcg	Low risk	28/04/2017
ASS- Sensitivity Discs (Single Discs)	SD852	Cefpodoxime / Clavulanic acid CCL 10/5mcg	Low risk	16/12/2017
ASS- Sensitivity Discs (Single Discs)	SD853	Nafithromycin NFT 15mcg	Low risk	30/10/2018
ASS- Sensitivity Discs (Single Discs)	SD854	Levonadifloxacin LND 10mcg	Low risk	30/10/2018
ASS- Sensitivity Discs (Single Discs)	SD855	Dicrysticin-S DCR 50mcg	Low risk	22/04/2019
ASS- Sensitivity Discs (Single Discs)	SD856	Garenoxacin GRN 10mcg	Low risk	22/04/2019
ASS- Sensitivity Discs (Single Discs)	SD857	Cefepime / sulbactam	Low risk	10/11/2020
ASS- Sensitivity Discs (Single Discs)	SD858	Cefotaxime / Sulbactam	Low risk	10/11/2020
ASS- Sensitivity Discs (Single Discs)	SD859	Ceftizoxime / Sulbactam	Low risk	10/11/2020
ASS- Sensitivity Discs (Single Discs)	SD860	Meropenem / EDTA	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM001	Amikacin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM002	Amoxicillin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM003	Amoxyclav HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM068	Ampicillin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM109	Ampicillin /Sulbactam HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM070	Cefepime HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM064	Cefotaxime HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM101	Cefoxitin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM012	Ceftazidime HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM066	Ceftriaxone HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM016	Chloramphenicol HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM017	Ciprofloxacin HiComb™ MIC Strip, Modified	Low risk	10/11/2020



Document ref.: DoC 2022 vs. 15

Page 129 of 130

1			1	
ASS-HiComb™ MIC Strip, Modified	MDM020	Colistin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM108	Fosfmycin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM025	Gentamicin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM080	Meropenem HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM065	Oxacillin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM084	Penicillin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM043	Polymyxin B HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM055	Teicoplanin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM056	Tetracycline HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM089	Tigecycline HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM059	Trimethoprim HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM060	Vancomycin HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM071	Amphotericin B HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM072	Fluconazole HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiComb™ MIC Strip, Modified	MDM086	Voriconazole HiComb™ MIC Strip, Modified	Low risk	10/11/2020
ASS-HiMIC™ Plate	МРК001	Amikacin HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP001,LQ314II,PW1378,R-MPK001)		
ASS-HiMIC™ Plate	MPK068	Ampicillin HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP068,LQ314II,PW1378,R-MPK068)		
ASS-HiMIC™ Plate	MPK109	Ampicillin/Sulbactam HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP109,LQ314II,PW1378,R-MPK109)		-, ,
ASS-HiMIC [™] Plate	MPK071	Amphotericin B HiMIC™ Plate Kit	Low risk	17/06/2021
Kit		(contains HMP071,LQ314I,PW1378,R-MPK071)		
ASS-HiMIC™ Plate	МРК070	Cefepime HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP070,LQ314I,PW1378,R-MPK070)		-0, 11, 2020
ASS-HiMIC™ Plate	MPK101	Cefoxitin HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP101,LQ314II,PW1378,R-MPK101)	2011 HJK	10/ 11/ 2020
ASS-HiMIC™ Plate	МРК012	Ceftazidime HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP012,LQ314II,PW1378,R-MPK012)		10/11/2020
ASS-HiMIC™ Plate	МРК016	Chloramphenicol HiMIC™ Plate Kit	Low risk	10/11/2020
Kit		(contains HMP016,LQ314II,PW1378,R-MPK016)		10/11/2020
ASS-HiMIC™ Plate		Ciprofloxacin HiMIC™ Plate Kit	Low risk	10/11/2020
Kit	MPK017	(contains HMP017,LQ314II,PW1378,R-MPK017)	Low risk	10/11/2020
ASS-HiMIC™ Plate	MDK010	Clindamycin HiMIC™ Plate Kit	Levy siels	10/11/2022
Kit	MPK019	(contains HMP019,LQ314II,PW1378,R-MPK019)	Low risk	10/11/2020
ASS-HiMIC [™] Plate	ΜΡΚΟΣΟ	Colistin HiMIC™ Plate Kit	low rick	10/11/2020
Kit	МРКО2О	(contains HMP020,LQ314II,PW1378,R-MPK020)	Low risk	10/11/2020

Declaration of Conformity	Document ref.: DoC 2022 vs. 15
Microbiology Products	Page 130 of 130

ASS-HiMIC™ Plate Kit MPK085		Ertapenem HiMIC™ Plate Kit		10/11/2020
	МРК085	(contains HMP085,LQ314II,PW1378,R-MPK085)	Low risk	
ASS-HiMIC [™] Plate MPK025 Kit	Gentamicin HiMIC™ Plate Kit	Less Sel		
	IMIPK025	(contains HMP025,LQ314II,PW1378,R-MPK025)	Low risk	10/11/2020
ASS-HiMIC™ Plate Kit	MPK104	lmipenem HiMIC™ Plate Kit	Low risk	10/11/2020
		(contains HMP104,LQ314II,PW1378,R-MPK104)	LOW HSK	
ASS-HiMIC™ Plate Kit	MPK156	Isavuconazole HiMIC [™] Plate Kit	Low risk	17/06/2021
		(contains HMP156,LQ314I,PW1378,R-MPK156)		
ASS-HiMIC [™] Plate MPK0 Kit	МРК073	Itraconazole HiMIC™ Plate Kit	Low risk	17/06/2021
		(contains HMP073,LQ314I,PW1378,R-MPK073)		
ASS-HiMIC [™] Plate Kit MPK080		Meropenem HiMIC™ Plate Kit	Low risk	10/11/2020
	IVIP KUOU	(contains HMP080,LQ314I,PW1378,R-MPK080)	LOW TISK	
ASS-HiMIC™ Plate	MPK084	Penicillin HiMIC™ Plate Kit	Low risk	10/11/2020
Kit	IVIF NU04	(contains HMP084,LQ314II,PW1378,R-MPK084)	LOW HISK	
ASS-HiMIC [™] Plate MPI Kit	МРК042	Piperacillin/Tazobactam HiMIC™ Plate Kit	Low risk	10/11/2020
		(contains HMP042,LQ314I,PW1378,R-MPK042)		
Kit	МРКО43	Polymyxin B HiMIC™ Plate Kit	Low risk	10/11/2020
		(contains HMP043,LQ314II,PW1378,R-MPK043)		
ASS-HiMIC [™] Plate Kit MPK120	MPK120	Posaconazole HiMIC [™] Plate Kit	Low risk	17/06/2021
		(contains HMP120,LQ314II,PW1378,R-MPK120)		
ASS-HiMIC™ Plate Kit	МРК055	Teicoplanin HiMIC™ Plate Kit	Low risk	10/11/2020
NIL		(contains HMP055,LQ314II,PW1378,R-MPK055)		
ASS-HiMIC™ Plate Kit	МРК089	Tigecycline HiMIC™ Plate Kit	Low risk	10/11/2020
		(contains HMP089,LQ314II,PW1378,R-MPK089)		
ASS-HiMIC™ Plate Kit	МРК060	Vancomycin HiMIC™ Plate Kit	Low risk	10/11/2020
	МРК086	(contains HMP060,LQ314II,PW1378,R-MPK060) Variconazole HiMIC [™] Plate Kit		
		(contains HMP086,LQ314II,PW1378,R-MPK086)	Low risk	17/06/2021



CERTIFICATE

Quality Austria Certification GmbH awards this qualityaustria certificate to the following organisation:

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM

Medical devices - Quality management systems -

complying with the requirements of standard

Requirements for regulatory purposes

Date of initial issue: 28 February 2022

Quality Austri Certification GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry)

For accreditation registration details please refer to the applicable decisions or recognition documents

Quality Austria is the Austrian member of IQNet (International Certification Network)

Dok. Nr. FO_24_028

b9848bfe-d23d-4edf-91e0-8d0d63d0b1ae HiMedia Laboratories Pvt. Ltd.

Plot No. C40, Road - 21Y, WAGLE Industrial Estate, Thane (West) - 400604 Maharashtra, India

Design, Development & Manufacturing of Biosciences Products for application in Microbiology, Cell Biology & Molecular Biology Products.

The validity of the qualityaustria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

The current validity of the certificate is documented exclusively on the Internet under

http://www.gualityaustria.com/en/cert

Quality Austria Certification GmbH, AT-1010 Vienna, Zelinkagasse 10/3

Mag. Christoph Mondl CEO

Mag. Dr. Werner Paar CEO

Ing. Christoph Baumgartner, MSc, MBA Authorised representative, management Customer Service Center



MEMBER OF

IQNET

Vienna, 10 March 2025

Registration No.: M-00391/0

Valid until: 27 February 2028

ISO 13485:2016



CERTIFICATE

Quality Austria Certification GmbH awards this qualityaustria certificate to the following organisation:

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

HIMEDIA

Quality Austria Certification GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry)

For accreditation registration details please refer to the applicable decisions or recognition documents

Quality Austria is the Austrian member of IQNet (International Certification Network)

Dok. Nr. FO_24_028

ffcf93e2-26e1-4a0d-9e33 43e35e833781

HiMedia Laboratories Pvt. Ltd.

Plot No. C40, Road - 21Y, WAGLE Industrial Estate, Thane (West) - 400604 Maharashtra, India

Design, Development & Marnufacturing of Microbiology, Cell Biology, Plant Tissue Culture & Molecular Biology Products and Trading of Allied Plastic-wares, Lab Aid Instrument and Consumables (Sterile Disposable Petri Dishes, Sterile Swabs, Sterile Loops and Spreaders)

The validity of the qualityaustria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Registration No.: Q-27302/0 Date of initial issue: 28 February 2022 Valid until: 27 February 2028



💽 qualityaustria

MEMBER OF

IQNET

Vienna, 10 March 2025

ISO 9001:2015

Quality Austria Certification GmbH, AT-1010 Vienna, Zelinkagasse 10/3

CEO

Mag. Christoph Mondl

Mag. Dr. Werner Paar CEO

Ing. Christoph Baumgartner, MSc, MBA Authorised representative, management Customer Service Center

The current validity of the certificate is documented exclusively on the Internet under http://www.gualityaustria.com/en/cert



Technical Data

Kovac's Reagent Strip

DD019

Kovac's Reagent Strips are used to detect indole producing bacteria.

Directions

Indole production by organisms is observed by inserting the Kovac's reagent strip between the plug and inner wall of the tube, above the inoculated Peptone Water (M028) and incubating at 35-37°C for 18-24 hours.

Preparation of Kovac's reagent

Kovac's reagent is prepared by dissolving 10 gm of p-dimethyl aminobenzaldehyde in 150 ml of isoamyl alcohol and then slowly adding 50 ml of concentrated hydrochloric acid.

Principle And Interpretation

The various enzymes involved in the degradation of tryptophan to indole are collectively called as tryptophanase, a general term used to denote the complete system of enzymes (2). The presence of indole is detected by the Kovac's reagent strip which turns pink in the presence of indole.

Kovac's Reagent Strips are sterile filter paper strips impregnated with Kovac's reagent. Peptone is used in the preparation of Peptone Water because of its high tryptophan content. When tryptophan is degraded by bacteria, indole is produced. Tryptone Water (M463) can also be used to detect indole production in the identification of members of coliform group (1).

Quality Control

Appearance

Filter paper strips of 70 mm x 5 mm.

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours by inserting Kovac's Reagent Strips between the plug and inner wall of tube, above the inoculated Peptone Water (M028).

Organism	Growth	Indole
Escherichia coli ATCC 25922	luxuriant	positive reaction, pink colour at the lower portion
Enterobacter aerogenes ATCC 13048	luxuriant	of the strip. negative reaction, no colour change.

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1.Eaton A.D, Clesceri L.S., Greenberg. A.E, Rice E. W.(Eds) 2005, Standard Methods for the Examination of Water and wastewater, 21st ed., APHA, Washington DC.

2. MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd ed., Philadelphia: Lippincott. Williams and Wilkins.

Disclaimer :

Revision : 1 / 2011

(6

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. A-516, Swastik Disha Business Park, Via Vadhani Ind. Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com



Technical Data

Bile Esculin Discs

DD024

Bile Esculin Discs are used for detection of esculin hydrolysis in the presence of bile, for differentiating Group D streptococci from other Streptococcal groups.

Directions

Esculin impregnated disc is placed on the seeded Bile Esculin Agar Base (M340) plate and is incubated at 35-37°C for 18-24 hours.

Principle And Interpretation

Group D streptococci hydrolyze esculin to esculetin and dextrose. Esculetin reacts with an iron salt such as ferric citrate to form a blackish brown coloured complex (4).

Rochaix found that esculin hydrolysis is an important criteria in the identification of enterococci (1). Meyer and Schonfeld (2) observed that when bile was added to esculin medium, around 60% enterococci were able to grow and split the esculin while other streptococci could not. When a comparative study was performed by Facklam and Moody (3) for presumptive identification of Group D streptococci, they found the bile esculin test as a reliable means of identifying Group D streptococci and differentiating them from other streptococci groups.

Quality Control

Appearance

Plain filter paper discs of 6mm diameter

Cultural response

Cultural response observed by placing Bile Esculin disc (DD024) on seeded Bile Esculin Agar Base(M340) plate, incubated at 35-37°C for 18-24 hours.

Organism	Growth	Esculin hydrolysis
Enterococcus faecalis ATC 29212	C luxuriant	positive: blackening of media around the disc.
Streptococcus agalactiae ATCC 13813	luxuriant	negative: no blackening
Listeria monocytogenes ATCC 19118	luxuriant	positive: blackening of media around the disc.
Streptococcus pyogenes ATCC 19615	luxuriant	negative: no blackening

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1. Rochaix, 1924, C. R. Soc. Biol., 90:771.

2. Meyer and Schonfeld, 1926, Zentralbl. Bacteriol. Parasitenkd. Infectionskr. Hyg. Abt. I Orig., 99:402.

3. Facklam and Moody, 1970, Appl. Microbiol., 20:245.

4. MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd ed., Philadelphia: Lippincott. Williams and Wilkins.

Revision : 1 / 2011

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. A-516, Swastik Disha Business Park, Via Vadhani Ind. Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com

CE



Technical Data

Spore Strips (Steam Sterilization Monitor Strips)

DD032

Steam Sterilization Monitor Strips are used for evaluating sterilization process. These indicators which are specified by the U.S. military specification MIL-S- 36586 are GMP requirements of U.S. FDA.

Directions

Place indicators in the areas of the pack or load least accessible to steam. Places such as the geometrical center, and the upper and lower regions of both front and rear of the load to be sterilized are considered suitable areas for placement of these indicators. A standard procedure should be established for the routine evaluation of each sterilizer. On completion of the sterilization cycle, remove the indicators from the test loads and deliver them to the laboratory for testing. All sterility tests should be performed in a clean dust free transfer area, preferably under positive air pressure, using rigid aseptic technique throughout the test procedure.

Using sterile scissors, cut open one end of the envelope. Thereafter remove the indicator with sterile tweezers and aseptically transfer it to a tube of sterile Soyabean Casein Digest Medium w/ Yeast Extract and Ferric pyrophosphate (M207) or Soyabean Casein Digest Medium (M011). Incubate the tubes for seven days at 55 - 60°C. Observe the tubes daily. If turbidity develops, failure of the sterilization process is indicated.

Precautions

The spore strips or broth cultures of *Bacillus stearothermophilus* must be autoclaved at 121°C for at least 30 minutes prior to discarding.

Each spore strip is individually packaged in a steam-permeable envelope.

Principle And Interpretation

Bacillus stearothermophilus is a thermophilic bacteria which can grow at 65°C and above. The spores are highly heat resistant and are used to monitor autoclave performance (1).

Sterilisation is the freeing of an article from all living organisms including viable spores(1). Sterilization quality control can only be achieved through the use of calibrated biological indicators (endospores). These indicators consist of *Bacillus stearothermophilus* spores impregnated on chromatography paper strips, individually placed into envelopes. Number of spores present per strip : 10⁶. These organisms are difficult to destroy because they are more resistant to heat than other vegetative bacteria and viruses. Therefore, if they are destroyed during sterilization, it is assumed that all other life forms are also destroyed. This test is considered the most sensitive check of the autoclaves efficiency.

Precautions :

The spore strips or broth cultures of *Bacillus stearothermophilus* must be autoclaved at 121°C for at least 30 minutes prior to discarding.

Each spore strip is individually packaged in a steam-permeable envelope.

Quality Control

Appearance

Filter paper strip impregnated with spores of standard culture of B.stearothermophilus

Number of spores

1000000 spores/strip

Cultural response

Sterility checking of the autoclave was carried out using Spore strip. After autoclaving, strip was inoculated in 100ml of st. Soyabean Casein Digest Medium(M011) and incubated at 55°C upto 7 days. An unexposed spore strip was also inoculated separately in 100ml M011

Growth	Unexposed	Exposed Spor	e Positive	Negative
	Spore Strip	Strip	control	control
Growth in M011	Luxuriant	No growth	Luxuriant	No growth

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1.Mackie and McCartney, 1996, Practical Medical Microbiology, 14th ed., Vol. 2, Collee J. G., Fraser A. G., Marmion B, P., Simmons A (Eds.), Churchill Livingstone, Edinburgh.

Revision : 1 / 2011

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. A-516, Swastik Disha Business Park, Via Vadhani Ind. Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com



Ciprofloxacin Ezy MICTM Strip (CIP) (0.002 - 32 mcg/ml)

EM017

Antimicrobial Susceptibility Testing For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Ciprofloxacin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002 to 32 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC[™] strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MIC[™] strip exhibits several advantages over existing plastic strip.

- 1. Ezy MICTM strip is made up of porous paper material unlike plastic non-porous material
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC[™] strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
- 5. Once placed, Ezy MICTM strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

METHOD AND USE OF EZY MIC[™] STRIPS

• Type of specimen

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

• <u>Clinical specimen collection, handling and processing</u>

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1,3).

• <u>Guidelines for preparation of the medium</u>

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to $45-50^{\circ}$ C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

• <u>Preparation of Inoculum</u>

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm). Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland. This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

Test Procedure

- 1. Prepare plates with suitable make of Mueller Hinton Agar (M173) for rapidly growing aerobic organisms as mentioned above. For *Haemophilus* spp, Haemophilus Test Agar Base (M1259) with added supplement (FD117) and for *Neisseria gonorrhoeae*, GC Agar Base (M434) with 1% defined growth supplement (FD025) is recommended.
- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate pre-spread with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MIC[™] strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- 3. For bacteriostatic drugs such Ciprofloxacin, Chloramphenicol, Tetracycline, Azithromycin, Fluconazole, Linezolid and Trimethoprim/ sulphamethoxazole, read MICs at 80% inhibition for homogenously sensitive strains such as QC control strains.
- 4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Ciprofloxacin showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MIC[™] Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MIC[™] Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strip is at room temperature.
- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL

Interpretation

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	Incubation	Inter	pretative Cri	teria
		<u><</u> S	Ι	<u>></u> R
Enterobacterales (Excluding Salmonella spp), Shigella spp.	35-37°C for 18 hrs.	0.25	0.5	1
Acinetobacter spp, Enterococcus spp, Staphylococcus spp, other non-enterobacterales	35-37°C for 18 hrs.	1	2	4
P.aeruginosa	35-37°C for 18 hrs.	0.5	1	2
Salmonella spp.	35-37°C for 18 hrs.	0.06	0.12-0.5	1
Haemophilus spp	$35^{\circ}C \pm 2^{\circ}C$ at 5% CO ₂ for 20-24 hours	1	-	-
N. gonorrhoeae	$35^{\circ}C \pm 2^{\circ}C$ at 5% CO ₂ for 20-24 hours	0.06	0.12-0.5	1
N. meningitidis	$35^{\circ}C \pm 2^{\circ}C$ at 5% CO ₂ for 20-24 hours	0.03	0.06	0.12

Quality Control

Quality control of Ezy MIC[™] Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.

 Table 2: Following are the reference MIC values (mcg/ml) range for Ciprofloxacin.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
S. aureus ATCC 29213	Mueller Hinton Agar	35-37°C for 18 hrs.	0.12- 0.25 -0.5
E. faecalis ATCC 29212	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25 - 0.5 - 1.0 - 2.0
<i>E. coli</i> ATCC 25922	Mueller Hinton Agar	35-37°C for 18 hrs.	0.004 - 0.008 - 0.016
P. aeruginosa ATCC 27853	Mueller Hinton Agar	35-37°C for 18 hrs.	0.12 - 0.25 - 0.5 -1.0
H. influenzae ATCC 49247	Haemophilus Test Agar	$35^{\circ}C \pm 2^{\circ}C$ at 5% CO ₂ for	0.004 - 0.008- 0.016-0.03
		20-24 hours	
N. gonorrhoeae ATCC 49226	GC Agar Base (M434) with 1% defined growth supplement (FD025)	35-37°C for 24 – 48 hrs at 5% CO ₂	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC[™] strips container at 2-8°C, for prolonged use store below -20°C.
- 2. Use before expiry date on the label.
- 3. Ezy MICTM Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MICTM Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Limitation of Test

Ezy MICTM Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

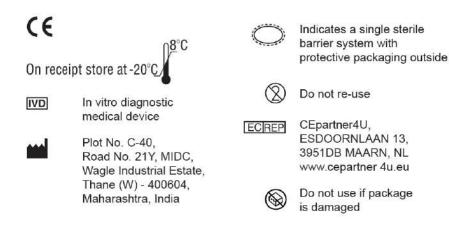
- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- 3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

- 1) Ciprofloxacin Ezy MICTM strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Colistin Ezy MIC[™] Strip (CL) (0.016-256 mcg/ml)

EM020

Antimicrobial Susceptibility Testing For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Colistin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.016mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC[™] strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MIC[™] strip exhibits several advantages over existing plastic strip.

- 1. Ezy MICTM strip is made up of porous paper material unlike plastic non-porous material.
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antimicrobial agent is evenly distributed on either side of the Ezy MICTM strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
- 5. Once placed, Ezy MIC[™] strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

METHOD AND USE OF EZY MIC[™] STRIPS

• <u>Type of specimen</u>

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

<u>Clinical specimen collection, handling and processing</u>

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1,3).

• <u>Guidelines for preparation of the medium</u>

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

Preparation of Inoculum

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for 2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm).

Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old nonselective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland. This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, *Bacteroides* spp, streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

<u>Test Procedure</u>

1. Prepare plates with suitable make of Mueller Hinton Agar for rapidly growing aerobic organisms as mentioned above.

- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate pre-spread with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MICTM strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- For bactericidal drugs such as Colistin, Amikacin, Vancomycin, Gentamicin, β-lactams class of drugs always read the MIC at the point of complete inhibition of all growth, including hazes, microcolonies and isolated colonies. If necessary, use magnifying glass.
- 4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Colistin showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MIC[™] Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MIC[™] Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strips is at room temperature.
- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL :

Interpretation:

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	Incubation	Inte	Interpretative Criteria (mcg/ml)	
		<u>< S</u>	Ι	<u>></u> R
Other non-Enterobacterales	35-37°C for 18 hrs.	2	4	8
Enterobacterales, Acinetobacter spp., P.aeruginosa,	35-37°C for 18 hrs.	-	<u>≤</u> 2	4

Quality control:

Quality control of Ezy MIC[™] Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on a suitable medium incubated appropriately.

Following are the reference MIC values (mcg/ml) range for Colistin.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
E.coli ATCC 25922 ^a	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25 - 0.5 - 1.0 - 2.0
P. aeruginosa ATCC 27853	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25 - 0.5 - 1.0 - 2.0
<i>E. coli</i> NCTC 13846	Mueller Hinton Agar	35-37°C for 18 hrs.	2.0 - 4.0 - 8.0

^a: Quality Control Limit deleted in CLSI 2024.

In-house Quality Control for Resistant Clinical Isolates :

Organism	Medium used	Incubation	MIC values obtained by repeated Microbroth dilution (mcg/ml)	MIC values obtained by Ezy MIC TM Strip (mcg/ml)
Col-Res Clinical	Mueller Hinton	35-37°C for 18 hrs.	32	32, 32, 24, 32,
Isolate 1	Agar		(Range: 16.0 -32.0-64.0)	24
Col-Res Clinical	Mueller Hinton	35-37°C for 18 hrs.	16	16, 16, 8, 8, 12
Isolate 2	Agar		(Range: 8.0 - 16.0 - 32.0)	
Col-Res Clinical	Mueller Hinton	35-37°C for 18 hrs.	8	8, 8, 8, 4, 4
Isolate 3	Agar		(Range: 4.0 - 8.0 - 16.0)	

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC[™] strips container at 2-8°C, for prolonged use store below -20°C.
- 2. Use before expiry date on the label.
- 3. Ezy MIC Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MICTM Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Limitation of Test

Ezy MICTM Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

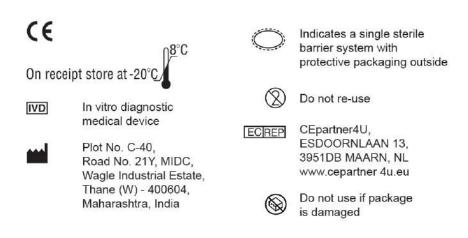
- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- Jorgensen, J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

- 1) Colistin Ezy MICTM strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

€

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Vancomycin Ezy MIC[™] Strip (VAN) (0.016-256 mcg/ml)

EM060

Antimicrobial Susceptibility Testing For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Vancomycin in a concentration gradient manner, capable of showing MICs in the range of 0.016mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction

Ezy MICTM strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MICTM strip exhibits several advantages over existing plastic strip.

- 1. Ezy MIC[™] strip is made up of porous paper material unlike plastic non-porous material
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC[™] strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
- 5. Once placed, Ezy MICTM strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

CLSI RECOMMENDATION FOR VANCOMYCIN SENSITIVITY TEST

High molecular weight antibiotics such as Vancomycin, polymyxin B and colistin do not diffuse in concentration gradient manner while diffusing through the agar medium when the disc susceptibility test is employed. The Antimicrobial Susceptibility Testing using disc diffusion test does not differentiate vancomycin-susceptible isolates of *S.aureus* from Vancomycin intermediate isolates, nor does the test differentiates among Vancomycin–susceptible, intermediate, and resistant isolates of coagulase-negative staphylococci, all of which may give similar size zones of inhibition.

CLSI therefore recommends that MIC test should be performed to determine the susceptibility of all isolates of staphylococci to Vancomycin.¹

Usefulness of Vancomycin Ezy MICTM strip

 Besides obtaining accurate MIC values for Gram- positive cultures, VISA (Vancomycin Intermediate Staphylococcus aureus) can be detected when isolated colonies appear within the zone of inhibition of Vancomycin particularly when 1.0 McFarland inoculum is used and MIC is read on full 48 hrs incubation. The sensitivity of the method can be further enhanced for better detection of VISA/ VRSA (Vancomycin Resistant Staphylococcus aureus / hVISA (Hetro Vancomycin Intermediate Staphylococcus aureus) using BHI agar with higher inoculum and 48 hr incubation.

METHOD AND USE OF EZY MICTM STRIPS

• <u>Type of specimen</u>

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

<u>Clinical specimen collection, handling and processing</u>

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

• <u>Guidelines for preparation of the medium</u>

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

• <u>Preparation of Inoculum</u>

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm yields $10^5 - 10^6$ cells/ml).

Also direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24 hour old nonselective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland .This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, and streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

<u>Test Procedure</u>

- 1. Prepare plates with suitable make of Mueller Hinton Agar for rapidly growing aerobic organisms as mentioned above. For fastidious organisms such as Streptococci, Mueller Hinton Agar supplemented with 5% sterile, defibrinated blood is recommended.
- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MIC[™] strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- For bactericidal drugs such Vancomycin, Gentamicin, Amikacin, and members of β-lactams class of drugs, always read the MIC at the point of completion inhibition of all growth, including hazes, microcolonies and isolated colonies. If necessary, use magnifying glass.
- 4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Vancomycin showing reading of 0.75 mcg/ml should be rounded up to next concentration i.e. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as ≥ the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MICTM Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MIC[™] Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strips is at room temperature.
- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL:

Interpretation

Table 1: Use following interpretive criteria for susceptibility categorization as per CLSI.

When testing	Incubation	Interpretative Criteria		riteria
		<u>< S</u>	Ι	<u>> R</u>
Staphylococcus aureus	35-37°C for 18 hrs.	2	4-8	16
<i>Enterococcus</i> spp., <i>Staphylococcus</i> spp <i>other than S. aureus</i>	35-37°C for 18 hrs.	4	8-16	32
<i>S. pneumoniae, Streptococcus</i> spp. Beta haemolytic group, <i>Streptococcus</i> spp. Viridans group	35-37°C for 20-24 hrs at 5% CO ₂	1	-	-

Quality control

Quality control of Ezy MIC[™] Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.

Table 2: Following are the reference MIC values (mcg/ml) range for Vancomycin.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
S. aureus ATCC 29213	Mueller Hinton Agar	35-37°C for 18 hrs.	0.5 - 1.0 - 2.0
E. faecalis ATCC 29212	Mueller Hinton Agar	35-37°C for 18 hrs.	1.0 - 2.0 - 4.0
S. pneumoniae ATCC 49619	Mueller Hinton Agar w/ 5% Sheep Blood	35-37°C for 20-24 hrs at 5% CO ₂	0.12 - 0.25 - 0.5

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC[™] strips container at 2-8°C, for prolonged use store below -20°C.
- 2. Use before expiry date on the label.
- 3. Ezy MICTM Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MICTM Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MICTM Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

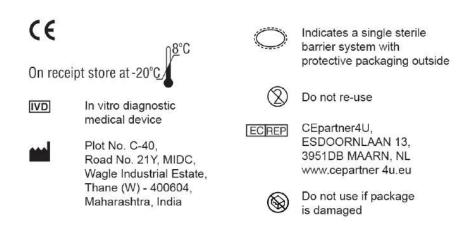
- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- 3. Jorgensen, J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

- 1) Vancomycin Ezy MIC[™] strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Penicillin Ezy MICTM Strip (PEN) (0.016-256 mcg/ml) EM062

Antimicrobial Susceptibility Testing For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Penicillin on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.016 mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction:

Ezy MICTM strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MIC[™] strip exhibits several advantages over existing plastic strip.

- 1. Ezy MICTM strip is made up of porous paper material unlike plastic non-porous material.
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antimicrobial agent is evenly distributed on either side of the Ezy MIC[™] strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar is employed.
- 5. Once placed, Ezy MIC[™] strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.

METHOD AND USE OF EZY MIC[™] STRIPS

• Type of specimen

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1,3).

<u>Clinical specimen collection, handling and processing</u>

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1,3).

Guidelines for preparation of the medium

Prepare the medium of choice from dehydrated powder according to the directions specified on the label. Cool the sterilized molten medium to $45-50^{\circ}$ C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow it to solidify. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

• <u>Preparation of Inoculum</u>

Use only pure cultures. Confirm by Gram-staining before starting susceptibility test. Transfer 4-5 similar colonies with a wire, needle or loop to 5 ml Tryptone Soya Broth (M011) and incubate at 35-37°C for2-8 hours until light to moderate turbidity develops. Compare the inoculum turbidity with that of standard 0.5 McFarland. Alternatively, the inoculum can be standardized by other appropriate optical method (0.08 - 0.13 OD turbid suspension at 620 nm). Also, direct colony suspension method can be used. Prepare a direct colony suspension, from 18-24-hour old non-selective media agar plate in broth or saline. Adjust the turbidity to that of standard 0.5 McFarland. This method is recommended for testing fastidious organisms like *Haemophilus* spp., *Neisseria* spp, streptococci and for testing staphylococci for potential Methicillin or Oxacillin resistance.

<u>Test Procedure</u>

- 1. Prepare plates with suitable make of Mueller Hinton Agar for rapidly growing aerobic organisms as mentioned above. For fastidious organisms such as Streptococci, Mueller Hinton Agar is supplemented with 5% sterile, defibrinated blood and for *Neisseria gonorrhoeae*, GC Agar Base (M434) with 1% defined growth supplement (FD025) is recommended.
- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking.
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self-sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MICTM strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- 3. For bactericidal drugs such as Penicillin and other members of β-lactams class of drugs, Amikacin, Vancomycin, Gentamicin, always read the MIC at the point of complete inhibition of all growth, including hazes, microcolonies and isolated colonies. If necessary, use magnifying glass.
- 4. Isolated colonies, microcolonies and hazes appearing in the zone of inhibition are indicative of hetero nature of the culture having resistant subpopulation in it. In such cases, consider reading for MIC determination at a point on the scale above which no resistant colonies are observed close to MIC strip (within 1-3 mm distance from the strip).
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two-fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Penicillin showing reading of 0.75 mcg/ml should be rounded up to next concentration ie. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MICTM Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MIC[™] Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strips is at room temperature.
- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL:

Interpretation:

Table 1: Use following interpretive criteria for susceptibility categorization.

When testing	Incubation	Inte	Interpretive Criteria		
		<u><</u> S	Ι	<u>></u> R	
Staphylococcus spp	35-37°C for 18 hrs.	0.12	-	0.25	
Enterococcus spp	35-37°C for 18 hrs.	8	-	16	
S.pneumoniae (Non Meningitis)	35-37°C for 20-24hrs with 5% CO ₂	2	4	8	
S.pneumoniae (Meningitis)	35-37°C for 20-24hrs with 5% CO ₂	0.06	-	0.12	
<i>Streptococcus</i> spp. Beta haemolytic group	35-37°C for 20-24hrs with 5% CO ₂	0.12	-	-	
<i>Streptococcus</i> spp. Viridans group	35-37°C for 20-24hrs with 5% CO ₂	0.12	0.25-2	4	
N. gonorrhoeae, S. pneumoniae (oral)	35-37°C for 20-24hrs with 5% CO ₂	0.06	0.12-1	2	
N. meningitidis	35-37°C for 20-24hrs with 5% CO ₂	0.06	0.12-0.25	0.5	
Anaerobes	35-37°C for 20-24hrs	0.5	1	2	

Quality control

Quality control of Ezy MICTM Strip is carried out by testing the strips with standard ATCC cultures recommended by CLSI on suitable medium incubated appropriately.

Table 2: Following are the reference MIC values (mcg/ml) range for Penicillin

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
S. aureus ATCC 29213	Mueller Hinton Agar	35-37°C for 18 hrs.	0.25 - 0.5 - 1.0 - 2.0
E. faecalis ATCC 29212	Mueller Hinton Agar	35-37°C for 18 hrs.	1.0 - 2.0 - 4.0
S. pneumoniae ATCC 49619	Mueller Hinton Agar w/ 5% Sheep Blood	35-37°C for 20- 24hrs at 5% CO ₂	0.25 - 0.5 - 1.0
N. gonorrhoeae ATCC 49226	GC Agar Base (M434) with 1% defined growth supplement (FD025)	35-37°C for 20- 24hrs at 5% CO ₂	0.25 - 0.5 - 1.0

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC[™] strips container at -20°C or below.
- 2. Use before expiry date on the label.
- 3. Ezy MICTM Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MICTM Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Limitation of Test

Ezy MICTM Strips provides *in vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

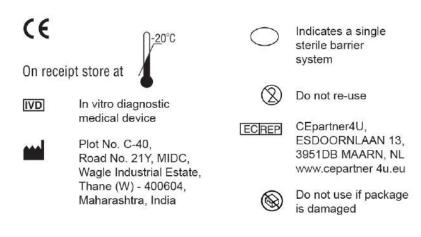
- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- 3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Performance Standards of Antimicrobial Susceptibility Testing; 34th Edition. M100-Ed34, Vol.44, No.5, Jan-2024.

Packing:

Each Pack contains following material packed in sealed glass vial with a desiccator capsule.

- 1) Penicillin Ezy MIC[™] strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Fluconazole Ezy MIC[™] Strip (FLC) (0.016-256 mcg/ml)

EM072

Antimicrobial Susceptibility Testing For *In Vitro* Diagnostic use

It is a unique MIC determination paper strip which is coated with Fluconazole on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.016mcg/ml to 256 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC[™] strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MICTM strip exhibits several advantages over existing plastic strip.

- 1. Ezy MIC[™] strip is made up of porous paper material unlike plastic non-porous material
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antifungal agent is evenly distributed on either side of the Ezy MIC[™] strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar or Mueller Hinton Agar, 2% glucose with methylene blue is employed.
- 5. Once placed, Ezy MIC[™] strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
- 7. The strips give reproducible MIC values that are equivalent to the standard reference MIC obtained by Broth dilution performed as per guidelines with less efforts.

METHOD AND USE OF EZY MIC[™] STRIPS

• Type of specimen

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

• Clinical specimen collection, handling and processing

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

• Guidelines for preparation of the medium

Prepare Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) from dehydrated powder according to the directions specified on the label. Alternately, prepare Mueller Hinton Agar with added 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (this could be added pre or post sterilization). Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow solidifying. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

<u>Preparation of Inoculum</u>

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at $35 \pm 2^{\circ}$ C. Colonies are suspended in 5ml of sterile 0.85% Saline. 2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10⁶ - 5 x 10⁶ cells /ml (i.e. 0.5 McFarland standard).

<u>Test Procedure</u>

- 1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye i.e. Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) as mentioned above
- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 15 minutes with lid in place.
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MIC[™] strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- 3. Examine each plate after 20 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniform and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation
- 4. Isolated colonies, pinpoint microcolonies and hazes may appear within the zone of inhibition frequently and they should be ignored. In such cases, consider reading for MIC determination at a point on the scale at which prominent reduction of growth is seen.
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Fluconazole showing reading of 0.75 mcg/ml should be rounded up to next concentration ie. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MICTM Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MIC[™] Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strip is at room temperature.
- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

INTERPRETATION & QUALITY CONTROL:

Interpretation:

Table 1: Use following interpretive criteria for susceptibility categorization.

When testing	Incubation	Inter	Interpretative Criteria	
		<u>< S</u>	S-DD*	<u>> R</u>
Candida albicans	35-37°C for 24 -48 hrs	2	4	8
Candida glabrata	35-37°C for 24 -48 hrs	-	<u><</u> 32	64
Candida parapsilosis	35-37°C for 24 -48 hrs	2	4	8
Candida tropicalis	35-37°C for 24 -48 hrs	2	4	8

* S-DD - Susceptible - Dose Dependent.

#: Isolates of *C. krusei* are assumed to be intrinsically resistant to Fluconazole. The results of Fluconazole susceptibility testing should not be interpreted using this criterion for this species.

Quality control

Quality control of Ezy MIC[™] Strip is carried out by testing the strips with standard ATCC Cultures recommended by CLSI on suitable medium incubated appropriately.

Organism	Medium used	Incubation	Std. Quality Control limits (mcg/ml)
C.albicans ATCC 90028	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 -0.5 - 1.0
C.albicans ATCC 24433	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 -0.5 - 1.0
C.tropicalis ATCC 750	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	1.0 - 2.0- 4.0
C.parapsilosis ATCC 90018	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	0.25 - 0.5 - 1.0
C.parapsilosis ATCC 22019*	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	1.0 - 2.0 - 4.0 - 8.0
C.krusei ATCC 6258	Mueller Hinton Agar, 2% glucose with methylene blue	35-37°C for 24 - 48 hrs	16.0 - 32.0 - 64.0

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MICTM strip container at 2-8°C, for prolonged use store below -20°C.
- 2. Use before expiry date on the label.
- 3. Ezy MICTM Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MIC[™] Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MICTM Strips provides *In vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into

consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

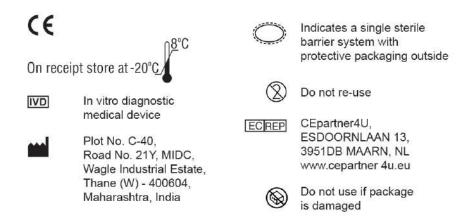
- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume
- 5. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Forth Edition. Vol.37 No.13, November-2017 CLSI document M27-Ed4.
- 6. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. Vol.32 No.17, December 2012 CLSI document M27-S4.
- 7. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement. Vol.28 No.15, December 2007 CLSI document M27-S3.
- 8. Performance Standards of Antifungal Susceptibility Testing of Yeast; Second Edition. M61-E02, Vol.40, No.9, Jan-2020.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

- 1) Fluconazole Ezy MIC[™] strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Clotrimazole Ezy MICTM Strip (CLO) (0.002-32 mcg/ml) EM144

Antimicrobial Susceptibility Testing For In Vitro Diagnostic use

It is a unique MIC determination paper strip which is coated with Clotrimazole on a single paper strip in a concentration gradient manner, capable of showing MICs in the range of 0.002 mcg/ml to 32 mcg/ml, on testing against the test organism.

Introduction:

Ezy MIC[™] strip is useful for quantitative determination of susceptibility of bacteria to antibacterial agents. The system comprises of a predefined quantitative gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in mcg/ml of different antimicrobial agents against microorganisms as tested on appropriate agar media, following overnight incubation.

Ezy MICTM Strip FEATURES AND ADVANTAGES

Ezy MIC[™] strip exhibits several advantages over existing plastic strip.

- 1. Ezy MIC[™] strip is made up of porous paper material unlike plastic non-porous material
- 2. Ezy MICTM strip has MIC values printed on both sides identically.
- 3. The antifungal agent is evenly distributed on either side of the Ezy MIC[™] strip and hence it can be placed by any side on the agar surface.
- 4. For Ezy MIC[™] strips, MIC values can be read without opening the lid of the plate as most commonly translucent medium such as Mueller Hinton Agar or Mueller Hinton Agar, 2% glucose with methylene blue is employed.
- 5. Once placed, Ezy MICTM strip is adsorbed within 60 seconds and firmly adheres to the agar surface.
- 6. Unlike the plastic material, it does not form air bubbles underneath and hence there is no need to press the strip once placed.
- 7. The strips give reproducible MIC values that are equivalent to the standard reference MIC obtained by Broth dilution performed as per guidelines with less efforts.

METHOD AND USE OF EZY MICTM STRIPS

• <u>Type of specimen</u>

Pure cultures should be derived from specimens obtained from patients prior to the initiation of antimicrobial therapy. Specimens can be of bacterial or fungal isolates derived from blood, urine, faeces, pus, CSF etc. Direct specimens should not be employed in this test. Refer procedure, which includes preparation of inoculum (1, 3).

<u>Clinical specimen collection, handling and processing</u>

Follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding (1, 3).

Guidelines for preparation of the medium

Prepare Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) from dehydrated powder according to the directions specified on the label. Alternately, prepare Mueller Hinton Agar with added 2% Glucose + 0.5 mcg/ml Methylene Blue Dye (this could be added pre or post sterilization). Cool the sterilized molten medium to 45-50°C and pour in sterile, dry Petri plates on a leveled surface, to a depth of 4 ± 0.2 mm and allow solidifying. Few droplets appearing on the surface of the medium following cooling do not matter. Hence, once poured, Petri plates containing media should not be dried on laminar flow and can be used immediately for swabbing.

• <u>Preparation of Inoculum</u>

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar (M063) and incubated at $35 \pm 2^{\circ}$ C. Colonies are suspended in 5ml of sterile 0.85% Saline. 2. Vortex the resulting suspension and adjust the turbidity to yield 1 x 10⁶ - 5 x 10⁶ cells /ml (i.e. 0.5 McFarland standard).

<u>Test Procedure</u>

- 1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye i.e. Mueller Hinton Agar, Modified (as per CLSI for antifungal) (M1825) as mentioned above.
- 2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 15 minutes with lid in place.
- 3. Remove Ezy MIC[™] strip container from cold and keep it at room temperature for 15 minutes before opening.
- 4. Remove one applicator from the self sealing bag stored at room temperature.
- 5. Hold the applicator in the middle and gently press its broader sticky side on the centre of Ezy MIC[™] strip.
- 6. Lift the applicator along with attached Ezy MIC[™] strip.
- 7. Place the strip at a desired position on agar plate swabbed with test culture. Gently turn the applicator clockwise with fingers. With this action, the applicator will detach from the strip.
- 8. DO NOT PRESS EZY MIC[™] STRIP. Within 60 seconds, Ezy MIC[™] strip will be adsorbed and will firmly adhere to the agar surface.
- 9. Ezy MICTM strip should not be repositioned or adjusted once placed.
- 10. Transfer plates in the incubator under appropriate conditions.

MIC Reading:

- 1. Read the plates only when sufficient growth is seen.
- 2. Read the MIC where the ellipse intersects the MIC scale on the strip.
- 3. Examine each plate after 20 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniform and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation
- 4. Isolated colonies, pinpoint microcolonies and hazes may appear within the zone of inhibition frequently and they should be ignored. In such cases, consider reading for MIC determination at a point on the scale at which prominent reduction of growth is seen.
- 5. Since Ezy MIC[™] strip has continuous gradient, MIC values "in-between" two fold dilutions can be obtained.
- 6. Always round up these values to the next two-fold dilution before categorization. For example: Clotrimazole showing reading of 0.75 mcg/ml should be rounded up to next concentration ie. 1.0 mcg/ml.
- 7. If the ellipse intersects the strip in between 2 dilutions, read the MIC as the value which is nearest to the intersection.
- 8. When growth occurs along the entire strip, report the MIC as \geq the highest values on the MIC strip. When the inhibition ellipse is below the strip (does not intersect the strip), report the MIC < the lowest value on the MIC scale.

Warning and Precautions:

- 1. Ezy MICTM Strip is intended for *In vitro* diagnostic use only.
- 2. Although based on simple procedure, Ezy MIC[™] Strip should only be used by at least semi-trained personnel.
- 3. This strip is intended only for agar diffusion method and not for broth dilution method.
- 4. Ezy MICTM Strip should be used strictly according to procedures described herein.
- 5. Performance of Ezy MICTM Strips depends on use of proper inoculum and control cultures, recommended test medium and proper storage temperature.
- 6. Follow aseptic techniques and precautions against microbiological hazards should be used when handling bacterial or fungal specimen throughout the testing procedure.
- 7. Before using Ezy MIC[™] Strips, ensure that the strip is at room temperature.

- 8. When applying strips be steady. Do not move the strip once in contact with agar surface, since the antibiotic instantaneously diffuse on contact with agar.
- 9. Place the unused strips back to recommended temperature.

QUALITY CONTROL

Quality control of Ezy MICTM Strip is carried out by testing the strips with standard ATCC cultures.

Organism	Medium Used	Incubation	Std. Quality Control limits (mcg/ml)
C.parapsilosis ATCC 22019	Mueller Hinton Agar, Modified (as per CLSI for antifungal)	35-37°C for 24 - 48 hrs.	0.016 - 0.03 - 0.06
C. krusei ATCC 6258	(M1825) Or		0.016 - 0.03 - 0.06
C. albicans ATCC 10231	Mueller Hinton Agar + 2% Glucose + 0.5 mcg/ml		0.06 - 0.125 - 0.25
	Methylene Blue		

*Not as per CLSI

Storage & Shelf Life:

- 1. Once the consignment is received, store applicators at Room Temperature and Ezy MIC[™] strips container at 2-8°C, for prolonged use store below -20°C.
- 2. Use before expiry date on the label.
- 3. Ezy MICTM Strip left over from opened package must be kept dry.
- 4. Moisture should be prevented from penetrating into or forming within the package or storage container.
- 5. Check whether the batch number and expiry date are marked on the storage container.
- 6. Product performance is best within stated expiry period if correctly stored and handled.

Disposal:

After use, Ezy MICTM Strips and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2, 3).

Limitation of Test

Ezy MICTM Strips provides *in vitro* MIC values, which provides only a possible insinuation of pathogens potential in *In vivo* susceptibility. These values can be considered as a guide to therapy selection only after taking into consideration several other factors; and must be the sole decision and responsibility of the physician along with the clinical experience in treating the infection. These tests are comparable to the standards as per the given specifications and set of experiment standards as far as possible. Please refer to CLSI standards for detailed limitation of susceptibility test on the clinical use of an antibiotic in various therapeutic conditions.

References:

- 1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 1, Section 2.
- 2. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition, Vol. 3, Section 15.
- Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 4. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guidelines-Second edition Vol.29 No.17, August- 2009 CLSI document M44-A2. For more details refer to this volume
- 5. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Edition. Vol.28 No.14, April- 2008 CLSI document M27-S3.
- 6. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. Vol.32 No.17, December 2012 CLSI document M27-S4.

HiMedia Laboratories

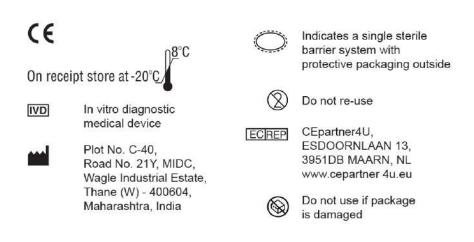
7. Theill, L., Dudiuk, C., Morano, S., Gamarra, S., Nardin, M. E., Mendez, E and Garcia-Effron, E. (2016) Prevalence and antifungal susceptibility of *Candida albicans* and its related species *Candida dubliniensis* and *Candida africana* isolated from vulvovaginal samples in a hospital of Argentina. **48:1**, 43-49.

Packing:

Each Pack contains following material packed in air-tight plastic container with a desiccator capsule.

- 1) Clotrimazole Ezy MIC[™] strips (10/30/60/90/120/150 Strips per pack)
- 2) Applicator sticks
- 3) Package insert

Revision: 05/2024



Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory,diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, INDIA. Customer care No.: +91-22-6147 1919 / 6116 9797 / 6903 4800 Email: techhelp@himedialabs.com Website: www.himedialabs.com



HiIndicatorTM pH papers

LA310, LA312, LA315, LA318, LA321, LA323, LA334, LA335.

The convenience of using HiIndicator papers for the rapid determination of pH values has led to many applications in laboratories and industry. These pH papers are made with special indicator dyes that change color at specified pH value.

Somewhat uneven colour of the strips is of no consequence. The colour obtained on use is indicative of the correct pH.

Product Name	Product Code	Description	pH Range
	LA310	HiIndicator pH paper	2.00 - 10.50
HiIndicator TM pH papers.	LA312	HiIndicator pH paper	3.50 - 6.00
pii papers.	LA315	HiIndicator pH paper	3.80 - 5.30
	LA318	HiIndicator pH paper	5.00 - 7.50
	LA321	HiIndicator pH paper	6.50 - 9.00
	LA323	HiIndicator pH paper	8.00 - 10.50
	LA334	HiIndicator pH paper	2.00 - 4.50
	LA335	HiIndicator pH paper	1.00 - 14.00

Application : Analytical chemistry, biology & various laboratories and industries etc.

Direction for use : Tear off strip of indicator paper and insert it for a few seconds into the solution to be tested. With highly viscous or stained liquids and with suspensions, drip the substance onto the indicator paper. Compare the wet paper with the colour scale. For papers where liquids are dripped, compare the reverse side. Possible discolouration of the dry new papers may be caused by their high sensitivity. This does not impair the efficacy of the Indicator papers for pH determinations.

The so-called indicator error may occur with very weakly buffered or unbuffered solution and can be compensated for up to a point in the following manner. : - The strip can be made to adhere to the inner wall of the a test tube, which can then filled to the upper edge of the paper with the fluid to be tested. After 1/2 to 1 minute, the colour of the paper may be compared with the scale through the glass of test tube.

Product Features:

- ➢ Instant pH readings.
- > Accurate for a wide range of routine pH testing.
- Convenient and portable for field use.
- Pack Size : 1 pack-200 Nos.

Disclaimer :

CE

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. A-516,Swastik Disha Business Park,Via Vadhani Ind. Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Nutrient Agar

Technical Data

M001

Intended use

Nutrient Agar is used as a general purpose medium for the cultivation of less fastidious microorganisms, can be enriched with blood or other biological fluids.

Composition**

Ingredients	g / L
Peptone	5.000
Sodium chloride	5.000
HM peptone B [#]	1.500
Yeast extract	1.500
Agar	15.000
Final pH (at 25°C)	7.4±0.2
**Formula adjusted, standardized to suit performance parameters	

- Equivalent to Beef extract

- Equivalent to Beef extract

Directions

Suspend 28.0 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. If desired ,the medium can be enriched with 5-10% blood or other biological fluids. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Nutrient media are basic culture media used for maintaining microorganisms, cultivating fastidious organisms by enriching with serum or blood and are also used for purity checking prior to biochemical or serological testing (1,2). Nutrient Agar is ideal for demonstration and teaching purposes where a more prolonged survival of cultures at ambient temperature is often required without risk of overgrowth that can occur with more nutritious substrate. This relatively simple formula has been retained and is still widely used in the microbiological examination of variety of materials and is also recommended by standard methods. It is one of the several non-selective media useful in routine cultivation of microorganisms (3,4). It can be used for the cultivation and enumeration of bacteria which are not particularly fastidious. Addition of different biological fluids such as horse or sheep blood, serum, egg yolk etc. makes it suitable for the cultivation of related fastidious organisms. Peptone, HM peptone B and yeast extract provide the necessary nitrogen compounds, carbon, vitamins and also some trace ingredients necessary for the growth of bacteria. Sodium chloride maintains the osmotic equilibrium of the medium.

Type of specimen

Clinical samples - faeces, urine ; Food and dairy samples; Water samples

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (5,6). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (3,4,7). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (8). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 2.8% w/v aqueous solution at 25°C. pH : 7.4±0.2

pН

7.20-7.60

Cultural Response

Productivity : Cultural characteristics observed after an incubation at 35-37°C for 18-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Productivity			
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	good-luxuriant	>=70%
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	good-luxuriant	>=70%
Salmonella Typhi ATCC 6539	50-100	good-luxuriant	>=70%
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	good-luxuriant	>=70%
Streptococcus pyogenes ATCC 19615	50-100	good-luxuriant	>=70%
Salmonella Enteritidis ATCC 13076 (00030*)	50-100	good-luxuriant	>=70%
Salmonella Typhimurium ATCC 14028 (00031*)	50-100	good-luxuriant	>=70%
Yersinia enterocolitica ATCC 9610 (00038*)	50-100	good-luxuriant	>=70%
Yersinia enterocolitica ATCC 23715 (00160*)	50-100	good-luxuriant	>=70%

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1.Lapage S., Shelton J. and Mitchell T., 1970, Methods in Microbiology', Norris J. and Ribbons D., (Eds.), Vol. 3A, Academic Press, London.

2.MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd Ed., Lippincott, Williams and Wilkins, Baltimore.

3.American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.

4.Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.

5. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

6.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

7.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

8.Lipps WC, Braun-Howland EB, Baxter TE, eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

Revision : 07/2024



Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMediaTM publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMediaTM Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Corporate Office : Plot No.C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) - 400604, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Technical Data

Soyabean Casein Digest Medium (Tryptone Soya Broth)

M011

Intended Use:

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms and recommended for sterility testing of moulds and lower bacteria.

Composition**

Ingredients	g / L
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Dextrose (Glucose)	2.500
Dipotassium hydrogen phosphate	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 30.0 grams in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Mix well and dispense in tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Note: If any fibres are observed in the solution, it is recommended to filter the solution through a 0.22 micron filter to eliminate the possibility of presence of fibres.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium (1,2,3). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (4). The combination of Tryptone and soya peptone makes the medium nutritious by providing nitrogenous, carbonaceous substances, amino acids and long chain peptides for the growth of microorganisms. Dextrose/glucose serve as the carbohydrate source and dibasic potassium phosphate buffer the medium. Sodium chloride maintains the osmotic balance of the medium.

Type of specimen

Pharmaceutical samples, Clinical samples - urine, pus, wound samples.

Specimen Collection and Handling

For clinical samples, follow appropriate techniques for handling specimens as per established guidelines (5,6). For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic Use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

- 1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
- 2. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

Reaction

pH of 3.0% w/v aqueous solution at 25°C (after sterilization). pH : 7.3±0.2

pН

7.10-7.50

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5days for fungal) Growth promotion is carried out as per USP/ EP/BP/JP/IP.

Organism	Inoculum	Growth	Incubation	Incubation
Organism	(CFU)	Growth	temperature	period
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
^Pseudomonas paraeruginosa ATCC 9027 (00026*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
** Bacillus spizizenii ATCC 6633 (00003*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>\$ Kokuria rhizophila</i> ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	20 -25 °C	<=5 d
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
Sterility Testing- Growth promotion+Validation				
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50 -100	luxuriant	20 -25 °C	<=3 d
# Aspergillus brasiliensis ATCC 16404 (00053*)	50 -100	luxuriant	20 -25 °C	<=5 d
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	30 -35 °C	<=5 d
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	luxuriant	20 -25 °C	<=3 d
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	20 -25 °C	<=3 d

Please refer disclaimer Overleaf.

^Pseudomonas paraeruginosa ATCC 9027 (00026*)	50 -100	luxuriant	20 -25 °C	<=3 d
** Bacillus spizizenii ATCC 6633 (00003*)	50 -100	luxuriant	20 -25 °C	<=3 d
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	20 -25 °C	<=3 d
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	20 -25 °C	<=3 d
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>\$ Kokuria rhizophila</i> ATCC 9341	50 -100	luxuriant	20 -25 °C	<=3 d

Key: (*) Corresponding WDCM numbers ^ Formerly known as Pseudomonas aeruginosa

Formerly known as Aspergillus niger

**Formerly known as Bacillus subtilis subsp. spizizenii \$ Formerly known as Micrococcus luteus

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

Reference

1.Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India

2.MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams & Wilkins, Baltimore, M.d.

3. The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.

4.Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.

5. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

6.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.



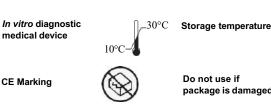
HiMedia Laboratories Pvt. Limited. Plot No.C-40, Road No.21Y. MIDC, Wagle Industrial Area, Thane (W) -400604, MS, India



CEpartner4U, Esdoornlaan 13, 3951DB Maarn, NL www.cepartner4u.eu



IVD



Revision : 05/2024

package is damaged

Disclaimer:

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMediaTM publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMediaTM Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Corporate Office : Plot No.C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) - 400604, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Technical Data

EMB Agar, Levine

M022

Intended Use:

Recommended for the isolation, enumeration and differentiation of members of *Enterobacteriaceae* from clinical and non clinical samples.

Composition**	
Ingredients	g / L
Peptone	10.000
Dipotassium hydrogen phosphate	2.000
Lactose	10.000
Eosin - Y	0.400
Methylene blue	0.065
Agar	15.000
Final pH (at 25°C)	7.1±0.2
**Formula adjusted, standardized to suit performance parameters	

Directions

Suspend 37.46 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. **AVOID OVERHEATING**. Cool to 50°C and shake the medium in order to oxidize the methylene blue (i.e. restore its blue colour) and to suspend the precipitate, which is an essential part of the medium.

Precaution : Store the medium away from light to avoid photo-oxidation.

Principle And Interpretation

Levine EMB Agar was developed by Levine (1,2) and is used for the differentiation of *Escherichia coli* and *Klebsiella* aerogenes and also for the rapid identification of *Candida albicans*. This medium is recommended for the detection, enumeration and differentiation of members of the coliform group by American Public Health Association (3,4,5). Weld (6,7) proposed the use of Levine EMB Agar, with added Chlortetracycline hydrochloride, for the rapid identification of

Candida albicans in clinical specimens. A positive identification of *Candida albicans* can be made after 24-48 hours incubation at 35-37°C in 10% carbon dioxide atmosphere, from specimens such as faeces, oral and vaginal secretions and nail or skin scraping etc. However, the typical appearance is variable.

Eosin Y and methylene blue make the medium slightly selective and inhibit certain gram-positive bacteria. These dyes serve as differential indicators in response to the fermentation of carbohydrates. This helps to differentiate between lactose-fermenters and non-fermenters in EMB Agar, Levine. The ratio of eosin-methylene blue is adjusted to approximately 6:1. Coliforms produce purplish black colonies due to uptake of methylene blue-eosin dye complex, when the pH drops. The dye complex is absorbed into the colony. Non-fermenters probably raise the pH of surrounding medium by oxidative de-amination of protein, which solubilizes the methylene blue-eosin complex resulting in formation of colourless colonies . Peptone serves as source of carbon, nitrogen, long chain amino acids, vitamins and other essential growth nutrients. Lactose serves as the source of energy by being the fermentable carbohydrate. Eosin-Y and methylene blue serve as differential indicators. Phosphate buffers the medium.

The test sample can be directly streaked on the medium plates. Inoculated plates should be incubated, protected from light. However standard procedures should be followed to obtain isolated colonies. A non-selective medium should be inoculated in conjunction with EMB Agar. Confirmatory tests should be further carried out for identification of isolated colonies.

Type of specimen

Clinical samples - urine, faeces, oral and vaginal secretions and nail or skin scraping, Foodstuffs; Water samples.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9). For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (5,10). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (3). After use, contaminated materials must be sterilized by autoclaving before discarding.

Please refer disclaimer Overleaf.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

- 1. A non-selective medium should be inoculated in conjunction with EMB Agar.
- 2. Confirmatory tests should be further carried out for identification of isolated colonies.
- 3. Some strains of Salmonella and Shigella species do not grow in the presence of eosin and methylene blue.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light pink to purple homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Reddish purple coloured, opalescent gel with greenish cast and finely dispersed precipitate forms in Petri plates **Reaction**

Reaction of 3.75% w/v aqueous solution at 25°C. pH : 7.1±0.2

pН

6.90-7.30

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony	
Candida albicans ATCC 10231 (00054*)	50-100	luxuriant (incubated in 10% carbon dioxide)	>=50%	colourless	
# Klebsiella aerogenes ATCC 13048 (00175*)	50-100	good	40-50%	pink-red	
Escherichia coli ATCC 25922 (00013*)	50-100	luxuriant	>=50%	blue-black with metallic sheen	
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	50-100	none-poor	<=10%	colourless	
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	luxuriant	>=50%	colourless	
Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)	50-100	none-poor	<=10%	colourless	
^Pseudomonas paraeruginosa ATCC 9027 (00026*)	50-100	luxuriant	>=50%	colourless	
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50-100	luxuriant	>=50%	colourless	
Saccharomyces cerevisiae ATCC 9763	50-100	none-poor	<=10%	cream	
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00058*)	50-100	none-poor	<=10%	colourless	
Escherichia coli ATCC 8739 (00012*)	50-100	luxuriant	>=50%	blue-black with green metallic sheen	

Key : (*) Corresponding WDCM numbers.

(#) Formerly known as Enterobacter aerogenes ^ Formerly known as Pseudomonas aeruginosa

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Levine M., 1918, J. Infect. Dis., 23:43.

2. Levine M., 1921, Bull. 62, Iowa State College Engr. Exp. Station.

3. Lipps WC, Braun-Howland EB, Baxter TE, eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

4. Marshall R. (Ed.), 1992, Standard Methods for the Examination of Dairy, Products, 16th ed., APHA Inc., New York.

5. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.

6. Weld J. T., 1952, Arch. Dermat. Syph., 66:691.

7. Weld J. T., 1953, Arch. Dermat. Syph., 67(5):433.

8. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

9. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

10. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.

Revision : 06/2024



Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMediaTM publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMediaTM Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Corporate Office : Plot No.C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) - 400604, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com





Slanetz and Bartley Medium

Intended Use

Recommended for detection and enumeration of faecal Streptococci by membrane filtration technique.

Composition**

Ingredients	Gms / Litre
Tryptose	20.000
Yeast extract	5.000
Dextrose (Glucose)	2.000
Disodium hydrogen phosphate	4.000
Sodium azide	0.400
2,3,5-Triphenyl tetrazolium chloride	0.100
Agar	15.000
Final pH (at 25°C)	7.2 ± 0.2
**Formula adjusted, standardized to suit performance parameters	

Directions

Suspend 46.5 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Slanetz and Bartley Medium was originally devised by Slanetz and Bartley (9) for the detection and enumeration of Enterococci by membrane filtration technique. It can be also used as a direct plating medium (2,7). The medium is highly selective for Enterococci.

Tryptose and yeast extract in the medium provide the necessary nitrogen, carbon, vitamins and minerals required for the growth of organisms. Sodium azide has inhibitory effect on gram-negative organisms. Triphenyl Tetrazolium Chloride is reduced to the insoluble formazan inside the bacterial cell forming dark red-coloured colonies. When the medium is incubated at higher temperature (44-45°C), all red or maroon colonies can be considered as presumptive Enterococci (6,10). The Department of Health (3) has recommended this medium to be used for enumeration of Enterococci in water supplies. Water is filtered through a membrane filter which is then placed on the surface of the Slanetz and Bartley Medium plates and incubated at 35°C for 4 hours and then at 44-45°C for 44-48 hours. Red or maroon colonies are counted as Enterococci. The preliminary incubation at 35°C helps for the recovery of stressed organisms. Not all the species reduce TTC, hence pale colonies also should be considered.

Food samples are homogenized and so diluted with physiological saline to give 15-150 colonies on each Petri plate. Homogenates or dilutions are spread on agar surface and incubated at 35°C for 48 hours. Pink or dark red colonies with a narrow whitish border are counted (7).

Type of specimen

Food; Water samples

Specimen Collection and Handling:

For food samples, follow appropriate techniques for sample collection and processing as per guidelines (8). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards(1). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Further biochemical testing is required for identification of species.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 4.65% w/v aqueous solution at 25°C. pH : 7.2±0.2

pН

7.00-7.40

Cultural Response

Cultural characteristics observed after an incubation at 44-45°C for 44-48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
Enterococcus faecalis ATCC 29212 (00087*)	C 50-100	good-luxuriant	>=50%	red or maroon
Escherichia coli ATCC 25922 (00013*)	>=10 ⁴	inhibited	0%	

Key: (*) Corresponding WDCM numbers

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Use before expiry date on the label.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

- 1. Baird R.B., Eaton A.D., and Rice E.W., (Eds.), 2015, Standard Methods for the Examination of Water and Wastewater, 23rd ed., APHA, Washington, D.C.
- 2. Burkwall M.K. and Hartman P.A., 1964, Appl. Microbiol., 12:18.
- 3. Department of Health and Social Security, 1982, Report 71, HMSO, London.
- 4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
- 6. Mead G.C., 1966, Proc. Soc. Wat. Treat. Exam., 15:207.
- 7. Nordic Committee on Food Analysis, 1968, Leaflet 68.
- 8. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
- 9. Slanetz L. W. and Bartley C.H., 1957, J. Bact., 74:591.
- 10. Taylor E.W. and Burman N.P., 1964, J. Appl. Bact., 27:294.

Revision : 03 / 2019

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Reg.office : 23, Vadhani Ind.Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6116 9797 Corporate office : A-516,Swastik Disha Business Park,Via Vadhani Ind. Est., LBS Marg, Mumbai-400086, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com



Technical Data

HiCrome[™] UTI Agar

M1353

Intended use

Recommended for presumptive identification and confirmation of microorganisms mainly causing urinary tract infections, can also be used for testing water, food, environmental and other clinical samples.

Composition**	
Ingredients	g / L
Peptone, special	15.000
Chromogenic mixture	2.450
Agar	15.000
Final pH (at 25°C)	6.8 ± 0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 32.45 gram in 1000 ml purified /distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Urinary tract infections are bacterial infections affecting parts of urinary tract. The common symptoms of urinary tract infection are urgency and frequency of micturition, with associated discomfort or pain. The common condition is cystitis, due to infection of the bladder with a uropathogenic bacterium, which most frequently is *Escherichia coli*, but sometimes *Staphylococcus saprophyticus* or especially in hospital-acquired infections, *Klebsiella* species, *Proteus mirabilis*, other coliforms, *Pseudomonas aeruginosa* or *Enterococcus faecalis* (1). HiCromeTM UTI Agar is formulated on basis of work carried out by Pezzlo (2) Wilkie et al (3), Friedman et al (4), Murray et al (5), Soriano and Ponte (6) and Merlino et al (7). These media are recommended for the detection of various microorganisms. It facilitates and expedites the identification of some gram-negative bacteria and some gram-positive bacteria on the basis of different contrasted colony colours produced by reactions of genus or species specific enzymes with two chromogenic substrates. The chromogenic substrates are specifically cleaved by enzymes produced by *Enterococcus* species, *E.coli* and coliforms. Presence of amino acids like phenylalanine and tryptophan from peptones helps for detection of tryptophan deaminase activity, indicating the presence of *Proteus* species, *Morganella* species and *Providencia* species.

One of the chromogenic substrate is cleaved by β -glucosidase possessed by Enterococci resulting in formation of blue colonies. *E.coli* produce pink colonies due to the enzyme β -D-galactosidase that cleaves the other chromogenic substrate. Further confirmation of *E.coli* can be done by performing the indole test. Coliforms produce purple coloured colonies due to cleavage of both the chromogenic substrate. Colonies of *Proteus, Morganella* and *Providencia* species appear brown because of tryptophan deaminase activity. Peptone special provides nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other essential growth nutrients. This medium can be made selective by supplementation with antibiotics for detecting microorganisms associated with hospital borne infections.

Type of specimen

Clinical samples : urine, faeces, etc.; Food samples, Water samples.

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (8,9).

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (10,11). For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards (12). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

In Vitro diagnostic use. For professional use only. Read the label before opening the container. Wear protective gloves/ protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Since it is an enzyme-substrate based reaction, the intensity of colour may vary with isolates.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel **Colour and Clarity of prepared medium**

Light amber coloured, clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 3.24% w/v aqueous solution at 25°C. pH : 6.8±0.2

pН

6.60-7.20

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 16-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
Escherichia coli ATCC 25922 (00013*)	50-100	luxuriant	>=70%	Purple to magenta
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	50-100	luxuriant	>=70%	blue-green (small)
Klebsiella pneumoniae ATCC 13883 (00097*)	50-100	luxuriant	>=70%	blue to purple, mucoid
Proteus mirabilis ATCC 12453	50-100	luxuriant	>=70%	light brown
Pseudomonas aeruginosa ATCC 27853 (00025*)	50-100	luxuriant	>=70%	colourless (greenish pigment may be observed)
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC	50-100	luxuriant	>=70%	golden yellow

25923 (00034*)

Key: *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 15-25°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (8,9).

Reference

1. Collee J. G., Fraser A. G., Marmion B. P., Simmons A., (Eds.), Mackie and McCartney, Practical Medical Microbiology, 1996, 14th Edition, Churchill Livingstone.

- 2. Pezzlo M., 1998, Clin. Microbiol. Rev., 1:268-280.
- 3. Wilkie M. E., Almond M. K., Marsh F. P., 1992, British Medical Journal 305:1137-1141.
- 4. Friedman M. P. et al, 1991, J. Clin. Microbiol., 29:2385-2389.

5. Murray P., Traynor P. Hopson D., 1992, J. Clin. Microbiol., 30:1600-1601.

6. Soriano F., Ponte C., 1992, J. Clin. Microbiol., 30:3033-3034.

7. Merlino et al, 1995, Abstr. Austr. Microbiol. 16(4):17-3.

8. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

9. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

10. Salfinger Y., and Tortorello M.L., 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.

11. Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.

12. Lipps WC, Braun-Howland EB, Baxter TE, eds. Standard methods for the Examination of Water and Wastewater, 24th ed. Washington DC:APHA Press; 2023.

Revision : 07/2024



Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMediaTM publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMediaTM Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HiMedia Laboratories Pvt. Ltd. Corporate Office : Plot No.C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane (W) - 400604, India. Customer care No.: 022-6147 1919 Email: techhelp@himedialabs.com Website: www.himedialabs.com





SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD) TEL. +39 049 9903866 R.A. FAX +39 049 9903867 C.F./P.I./N.REG.IMP. PADOVA 03573950288 REA PD-320123 - CAP.SOC. 20.700,00€ E-MAIL INFO@SYNTESYS.IT PEC POSTA@PEC.SYNTESYS.IT

AUTHORIZATION LETTER

We, Syntesys S.R.L. having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign Sanmedico SRL having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This letter is valid till 31.12.2025

Teolo, 13.09.2024

Rinaldo Ruggero CEO and Legal Representative SYNTESYS S.R.L.



8 ITA Microbiologia e batteriologia EN Microbiology and bacteriology

ANSE PER INOCULAZIONE **INOCULATION LOOPS**

318286 Sterile polystyrene inoculating loops 1 µl (bags 20 pcs) Conf. / Case

318288

Sterile polystyrene inoculating loops 10 µl (bags 20 pcs)



ASTE A "L" OPEN "L" SHAPED SPREADER

- 318290 Aste a "L" angolo 100° sterili in confezione singola Sterile polystyrene open "L" shaped spreader individually wrapped
- Aste a "L" angolo 100° sterili in confezione da 5 pezzi *Sterile polystyrene open "L" shaped spreader in packs of 5pcs* 318289

1.000 pz/pcs

1.000 pz/pcs





SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD) TEL. +39 049 9903866 R.A. FAX +39 049 9903867 C.F./P.I./N.REG.IMP. PADOVA 03573950288 REA PD-320123 - CAP.SOC. 20.700,000 E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT PEC POSTA@PEC.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA' Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta: The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.r.l.

indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/declares under his own responsability that the product:

Denominazione/Description	Anse sterili in polistirolo : loops 1 ul (bags of 20 pcs)		rile polystyrene inoculating
Lotto/ <i>Lot</i> Codice/ <i>Code</i>	225035 318286	Data di scadenza/Expiry	05.2027
Materiale/Material	Polistirolo/ Polystyrene		
Confezione/Pack	8.000 pezzi/8.000 pcs.		

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.

Data 05.07.2022

SYNTESYS S.R.L.
II Legale Rappresentante
Rinaldo Ruggero
1-000
C



SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD) TEL. •39 049 9903866 R.A. FAX •39 049 9903867 C.F./P.I./N.REG.IMP. PADOVA 03573950288 REA PD-320123 - CAP.SOC. 20.700,00€ E-MAIL INFO@SYNTESYS.IT PEC POSTA@PEC.SYNTESYS.IT



	TECHNICAL SHEET	
Page 1	Rev. 07	Date 08/02/2023
	PRODUCT CODE: 318280	
	Description:	5
STERILE POLYSTYRENE IN		
	Specifications and Dimensions:	
Needle Lenght: 30 mm	Total Lenght: 195 mm	Ring Volume: 1 mcl
	Microbiological Status:	
	Sterile	
	Packaging:	
Single	Under Package	Package
Transparent bags containing	Transparent bags containing	Box of 8.000 pcs.
20 pcs.	1.000 pcs.	(0,027 m ³ - 7,5 kg)
	Intended use:	
	ng of samples of microbiological culture	
The product is air	med at professional in biomedical labora	itories for analysis.
	Quality System applied:	
 -UNI EN ISO 9001:2015 "Quality Manage of 05/06/2022. -UNI CEI EN ISO 13485:2016 "Medical de certificate nr.7111/3 issued by ICIM S.p 	evices:Quality Management System: Rec	
	POLYSTYRENE	
	Method of disposal:	
Before use	is considered non-hazardous waste: EW	/C 18 01 07
	nicals other than those mentioned in 18	
After use, are con	sidered potentially infectious medical wa	aste EWC 18 01 03
	I disposed of, subject to special requiren	
	Regulatory standards:	
CE Marked: CE mark and issuing the	Declaration of Conformity as a result of	the technical dossier in accordance of
EEC Directive 98/79 (D.Lgs. n. 332/20	000) and to the competent authority to e	ensure that the manufacturing process
	e requirements of quality assurance of p	





Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD) Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 9001:2015

 Issued on:
 2022-06-05

 First issued on:
 2013-06-05

 Expires on:
 2025-06-04

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-83562

Alex Stoichitoiu President of IQNET

Mario Romersi President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia ICS Bosnia and Herzegovina Inspecta Sertifiointi Oy Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland NYCE-SIGE México PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TSE Turkey YUQS Serbia

CISQ is a member of



The International Certification Network www.ignet-certification.com



CERTIFICATO N. CERTIFICATE No.

6574/3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.R.L.

Sede e Unità Operativa

Via G. Galilei, 10/1-2-3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto. Unità Operative

Via G. Galilei, 16/1 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * Via San Benedetto, 48/A - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * Via G. Galilei, 3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * * *Magazzino.*

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 29 - 14

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento. Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico. The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il nº telefonico +39 02 725341 o indirizzo e-mail info@icim.it. For timely and updated information about any changes in the certification status referred to in this certificate,

please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE FIRST ISSUE 05/06/2013

EMISSIONE CORRENTE CURRENT ISSUE 05/06/2022

Vincenzo Delacqua Rappresentante Direzione / Management Representative ICIM S.p.A. Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI) www.icim.it

122

DATA DI SCADENZA EXPIRING DATE 04/06/2025

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ Is the Italian Federation of management system Certification Bodies.



SGQ Nº 004 A



Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD) Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 13485:2016

 Issued on:
 2022-06-05

 First issued on:
 2014-06-21

 Expires on:
 2025-06-04

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-93779

Alex Stoichitoiu President of IQNET

Mario Romersi President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia ICS Bosnia and Herzegovina Inspecta Sertifiointi Oy Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland NYCE-SIGE México PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TSE Turkey YUQS Serbia

CISQ is a member of



The International Certification Network www.ignet-certification.com



CERTIFICATO n. CERTIFICATE No.

7111/3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.R.L.

Sede e Unità Operativa

Via G. Galilei, 10/1-2-3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Unità Operative

Via G. Galilei, 16/1 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * Via San Benedetto, 48/A - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * Via G. Galilei, 3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia * * *Magazzino.*

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.

Refer to the documentation of the Quality Management System for details of application to reference standard requirements. Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico. The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme. Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it. For timela and undatedi informazioni any changes in the variadore to reference di to in this certificato.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE FIRST ISSUE 21/06/2014 EMISSIONE CORRENTE CURRENT ISSUE DATA DI SCADENZA EXPIRING DATE 04/06/2025



Rappresentante Direzione / Management Representative ICIM S.p.A. Piazza Don Enrico:Mapelli, 75 – 20099 Sesto San Giovanni (MI)

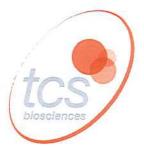
www.icim.it

122



SGQ Nº 004 A

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Pederation of management system Certification Bodies. accuracy and quality as a science



Authorisation to Distribute

TCS Biosciences Limited, having registered offices in Botolph Claydon, Buckingham MK18 2LR, England, confirms that:

SanMedico SRL, 88/1 Petricani Str, Office 10, MS-2059, mun Chisinau, Republic of Moldova

Is authorised to promote and sell the TCS Biosciences range of products in the Republic of Moldova on a non-exclusive basis.

SanMedico SRL is also authorised to participate in tenders, to submit quotations and to deliver these products within the territory of Republic of Moldova.

This letter of authorisation is valid for 1 year from the date of issue but can be terminated by either party provided that a notice period of 3 months is given.

This authorisation may be extended by 1 year, by mutual agreement between TCS Biosciences Limited and San Medico SRL Limited

Signed Name: Lesley Ayres

Date: 12th September 2024

Title: Key Account Manager



TCS Biosciences Ltd

Botolph Claydon Buckingham MK18 2LR United Kingdom t +44 (0) 1296 714222 f +44 (0) 1296 714806 e sales@tcsgroup.co.uk i www.tcsbiosciences.co.uk

Registered in England No. 2172900 Vat No. GB 729 8545 85







Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TCS Biosciences Limited Botolph Claydon Buckingham MK18 2LR United Kingdom

Holds Certificate Number:

FS 28907

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Original Registration Date: 1994-08-11 Latest Revision Date: 2024-12-13



Matt Page, Senior Vice President, EMEA Assurance

Effective Date: 2025-01-27 Expiry Date: 2028-01-26

Page: 1 of 1

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.





Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

TCS Biosciences Ltd Botolph Claydon Buckingham Buckinghamshire MK18 2LR United Kingdom

Holds Certificate Number:

MD 800713

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of freeze-dried microorganisms for Microbiology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-25 Latest Revision Date: 2025-02-25





Effective Date: 2025-02-25 Expiry Date: 2028-02-24

Page: 1 of 2

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 800713

Location

TCS Biosciences Ltd Botolph Claydon Buckingham Buckinghamshire MK18 2LR United Kingdom

TCS Biosciences Ltd (Park Leys) Botolph Claydon Buckingham Buckinghamshire MK18 2LR United Kingdom **Registered Activities**

QC testing and distribution of freeze-dried microorganisms for Microbiology.

Design, development and manufacture of freeze-dried microorganisms for Microbiology.



Original Registration Date: 2025-02-25 Latest Revision Date: 2025-02-25 Effective Date: 2025-02-25 Expiry Date: 2028-02-24

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

1	-	/		
biosc	20	-	S	
iences	in			
10		9		
	-	-		

SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA account number 0000009546 that the following CE marked products:

General microbial isolate identification control IVD	GMDN Term
63319	GMDN Code
Selectrol – All MM codes	TCS product code and description

diagnostic medical devices. conform to the relevant provisions of the In-vitro Diagnostic Medical Devices Directive 98/79/EC and The Medical Devices Regulations 2002 (SI 2002 No.618) and The Medical Devices (Amendment) Regulations 2003 (SI 2003 No.1697) for in-vitro

This declaration is made on the basis of meeting the requirements of Annexes I and III of the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and continued maintenance of an approved Quality Management System meeting the requirements of ISO 9001, as certified by BSi, certificate number FS 28907.

Signed by:	Signed by: Sue Bow	Date:_	Date: <u>September 2020</u>
Vame: Position:	Sue Brown Quality Assurance & Regulatory Affairs Manager	lager	
Signed by:	lynda reabon	Date:	September 2020
Vame: Position:	Lynda Preston Managing Director		
Manu TCS	<u>Manufacturer</u> TCS Biosciences Ltd		EC Authorised Representative TCS Biosciences Europe B.V.
Botol UK	Botolph Claydon Buckingham MK18 2LR UK		Provincialeweg 6 9864 PD Kornhorn The Netherlands

ANNEX TO SELF DECLARATION OF CONFORMITY - SELECTROL (Dated 30.04.2016)

List of product codes and descriptions – August 2018

Product	Description
MM01-10	Enterobacter cloacae 10 Disc
MM02-10	Escherichia coli 10 Disc
MM02-25	Escherichia coli 25 Disc
MM04-10	Klebsiella pneumoniae 10 Disc
MM04-25	Klebsiella pneumoniae 25 Disc
MM05-5	Neisseria gonorrhoeae 5 Disc
MM07-10	Shigella sonnei 10 Disc
MM08-10	Legionella pneumophila serogroup 1 10d
MM09-10	Proteus vulgaris 10 Disc
MM09-25	Proteus vulgaris 25 Disc
MM10-10	Pseudomonas aeruginosa 10 Disc
MM10-10	Pseudomonas aeruginosa 10 Disc
MM10-25	Pseudomonas aeruginosa 25 Disc
MM100-10	Haemophilus influenzae 10 Disc
MM11-10	Salmonella Typhimurium 10 Disc
MM11-25	Salmonella Typhimurium 25 Disc
MM12-10	Serratia marcescens 10 Disc
MM13-10	Staphylococcus aureus 10 Disc
MM13-10	Staphylococcus aureus 10 Disc
MM13-25	Staphylococcus aureus 25 Disc
MM14-10	Staphylococcus aureus 10 Disc
MM14-25	Staphylococcus aureus 25 Disc
MM15-10	Staphylococcus epidermidis 10 Disc
MM15-10	Staphylococcus epidermidis 10 Disc
MM15-25	Staphylococcus epidermidis 25 Disc
MM16-10	Streptococcus agalactiae 10 Disc
MM17-10	Enterococcus faecalis 10 Disc
MM17-25	Enterococcus faecalis 25 Disc
MM18-10	Enterococcus faecalis 10 Disc
MM18-10	Enterococcus faecalis 10 Disc
MM18-25	Enterococcus faecalis 25 Disc
MM19-10	Streptococcus pneumoniae 10 Disc
MM20-10	Streptococcus pyogenes 10 Disc
MM20-25	Streptococcus pyogenes 25 Disc
MM21-10	Bacillus cereus 10 Disc
MM24-10	Escherichia coli 10 Disc
MM24-25	Escherichia coli 25 Disc
MM26-10	Enterobacter aerogenes 10 Disc
MM26-25	Enterobacter aerogenes 25 Disc

Product	Description
MM27-10	Citrobacter freundii 10 Disc
MM28-10	Candida albicans 10 Disc
MM28-25	Candida albicans 25 Disc
MM29-10	Bacillus subtilis 10 Disc
MM29-25	Bacillus subtilis 25 Disc
MM30-10	Staphylococcus aureus 10 Disc
MM30-25	Staphylococcus aureus 25 Disc
MM31-10	Clostridium sporogenes 10 Disc
MM33-10	Escherichia coli 10 Disc
MM33-25	Escherichia coli 25 Disc
MM34-10	Escherichia coli (mcr-1) 10 Disc
MM35-10	Enterococcus hirae 10 Disc
MM36-10	Campylobacter jejuni 10 Disc
MM37-10	Haemophilus influenzae 10 Disc
MM38-10	Escherichia coli 10 Disc
MM38-25	Escherichia coli 25 Disc
MM40-25	Pseudomonas aeruginosa 25 Disc
MM41-10	Pseudomonas aeruginosa 10 Disc
MM42-10	Candida albicans 10 Disc
MM42-25	Candida albicans 25 Disc
MM43-10	Proteus mirabilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM45-10	Clostridium perfringens 10 Disc
MM45-10	Clostridium perfringens 10 Disc
MM46-10	Staphylococcus aureus 10 Disc
MM46-10	Staphylococcus aureus 10 Disc
MM46-25	Staphylococcus aureus 25 Disc
MM47-10	Listeria monocytogenes 10 Disc
MM48-10	Listeria monocytogenes 10 Disc
MM48-25	Listeria monocytogenes 25 Disc
MM50-10	Saccharomyces cerevisiae 10 Disc
MM51-10	Enterobacter cloacae 10 Disc
MM52-10	Enterococcus faecalis 10 Disc
MM53-10	Candida krusei 10 Disc
MM54-10	Candida parapsilosis 10 Disc
MM55-10	Klebsiella pneumoniae 10 disc
MM56-10	Klebsiella pneumoniae 10 Disc
M M5 7-10	Escherichia coli 10 Disc
MM58-10	Klebsiella pneumoniae 10 Disc
MM59-10	Klebsiella pneumoniae 10 Disc
MM60-10	Streptococcus dysgalactiae 10 Disc
MM62-10	Salmonella Enteritidis 10 Disc

Product	Description	
MM63-10	Escherichia coli 10 Disc	
MM64-10	Staphylococcus aureus 10 Disc	
MM65-10	Pseudomonas aeruginosa 10 Disc	
MM68-10	Proteus mirabilis 10 Disc	
MM70-10	Burkholderia cepacia 10 Disc	
MM73-10	Saccharomyces cerevisiae 10 Disc	
MM73-25	Saccharomyces cerevisiae 25 Disc	
MM75-10	Escherichia coli 10 Disc	
MM76-10	Lactobacillus brevis 10 Disc	
MM77-10	Listeria monocytogenes 10 Disc	
MM80-10	Yersinia enterocolitica 10 Disc	
MM80-25	Yersinia enterocolitica 25 Disc	
MM81-10	Haemophilus influenzae 10 Disc	
MM82-10	Campylobacter jejuni 10 Disc	
MM83-10	Klebsiella pneumoniae 10 Disc	
MM84-10	Salmonella Nottingham 10 Disc	
MM85-10	Staphylococcus aureus 10 Disc	
MM86-10	Bacillus cereus 10 Disc	
MM86-25	Bacillus cereus 25 Disc	
MM87-10	Listeria monocytogenes 10 Disc	
MM88-10	Klebsiella aerogenes 10 Dis	
MM89-10	Salmonella Poona 10 Disc	
MM89-25	Salmonella Poona 25 Disc	
MM91-10	Staphylococcus aureus 10 Disc	
MM91-10	Staphylococcus aureus 10 Disc	
MM92-10	Listeria innocua 10 Disc	
MM93-10	Escherichia coli 0157 non-toxigenic 10d	
MM93-25	Escherichia coli 0157 non-toxigenic 25D	
MM94-10	Aspergillus brasiliensis 10 Disc	
MM95-10	Streptococcus pneumoniae 10 Disc	
MM97-10	Rhodococcus equi 10 Disc	
MM99-10	Legionella anisa 10 Disc	
MM99-10	Legionella anisa 10 Disc	

Signed by: Dre Brow

Date: 21.08.2018

Name: Position: Sue Brown Regulatory Affairs Manager

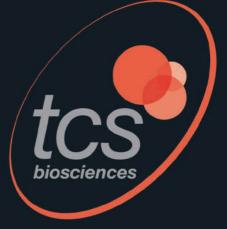
Signed by: R NU

Name: Position:

Lynda Preston Managing Director

Date: 21.08.2018

accuracy and quality as a science









Selectrol®: Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as EUCAST, CLSI and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC[®] and NCPF[®]) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol[®] disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol[®] discs are guaranteed to contain at least 10⁶ organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol[®] batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol[®] can be accessed via our website. The reporting of Selectrol[®] test results via the website comes under our UKAS accreditation.

Selectrol[®] cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.



Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC[®] strains are listed for reference only. ATCC[®] is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF[®]: National Collection of Pathogenic Fungi. NCPF[®] is a registered trademark of Public Health England.

NCTC[®]: National Collection of Type Cultures. NCTC[®] is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections



SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly Aspergillus niger):

MM94 – NCPF[®] 2275 / ATCC[®] 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

Bacillus cereus:

MM21 – NCTC[®] 10320 / ATCC[®] 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 - NCTC[®] 7464 / ATCC[®] 10876 - PHE recommended media and ID test control organism.

Bacillus subtilis (Bacillus subtilis subsp. spizizenii):

MM29 - NCTC[®] 10400 / ATCC[®] 6633 / WDCM 00003 - used in antibiotic assays (fully sensitive), PHE recommended media and ID test control organism.



Bacteroides fragilis:

MM44 – NCTC[®] 9343 / ATCC[®] 25285 – type strain, PHE recommended strain for media and sensitivity test control.

Campylobacter jejuni (Campylobacter jejuni subsp. jejuni):

MM82 - NCTC[®] 11322 / ATCC[®] 29428 / WDCM 00156 - PHE recommended strain for media control.

MM36 - NCTC® 11351 / ATCC® 33560 - EUCAST recommended strain for susceptibility testing.

Candida albicans:

MM28 - NCPF[®] 3255 / ATCC[®] 2091 / WDCM 00055 - sensitivity control / industrial use.

MM42 – NCPF[®] 3179 / ATCC[®] 10231 / WDCM 00054 – pharmaceutical / media testing / PHE recommended strain for media control.

CRE ≡ 'Carbapenem Resistant Enterobacteriaceae' / CPE ≡ 'Carbapenemase Producing Enterobacteriaceae'

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem² such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 Klebsiella pneumoniae - NCTC® 13440 - produces a Class B VIM-1 Carbapenemase.

MM56 Klebsiella pneumoniae - NCTC® 13443 - produces a Class B NDM-1 Carbapenemase.

MM58 Klebsiella pneumoniae – NCTC[®] 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 Klebsiella pneumoniae - NCTC® 13442 - produces a Class D OXA-48 Carbapenemase.

MM57 Escherichia coli - NCTC® 13476 - produces a Class B IMP Carbapenemase.

MM33 Escherichia coli - NCTC® 10418 / ATCC® 10536 - recommended by PHE as a negative control for CRE testing.



Citrobacter freundii:

MM27 - NCTC® 9750 / ATCC® 8090 - type strain.

Clostridium perfringens:

MM45 – NCTC[®] 8237 / ATCC[®] 13124 / WDCM 00007 – type strain. PHE recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which <u>does not</u> produce the lethal epsilon toxin of potential interest to bioterrorists.

Clostridium sporogenes:

MM31 – NCTC[®] 532 / ATCC[®] 19404 / WDCM 00008 – used for media control. PHE recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

Enterobacter aerogenes:

MM26 - NCTC® 10006 / ATCC® 13048 / WDCM 00175 - type strain; used in water, paint and adhesive testing.

Enterobacter cloacae:

MM01 - NCTC® 13380 / ATCC® 23355 / WDCM 00082 - disinfectant control, media testing.

MM51- NCTC[®] 13406 - PHE recommended strain for QC of AmpC (de-repressed) detection.

Enterococcus faecalis:

MM52 – NCTC[®] 13379 / ATCC[®] 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows highlevel resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC[®] 775 / ATCC[®] 19433 / WDCM 00009 – used in water industry and QC. PHE recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC[®] 12697 / ATCC[®] 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. PHE recommended positive control strain for aesculin test. CLSI, EUCAST recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.





Enterococcus hirae:

MM35 – NCTC[®] 13383 / ATCC[®] 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alphahaemolytic on sheep blood agar.

Escherichia coli strains:

MM02 – NCTC[®] 12241 / ATCC[®] 25922 / WDCM 00013 – EUCAST, CLSI, PHE recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 - NCTC[®] 13476 - CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC[®] 10418 / ATCC[®] 10536 – (PHE recommended alternative to NCTC 12241) fully sensitive control strain. PHE recommended positive control for indole test, ONPG test, negative control for oxidase test, PHE recommended negative control for CRE and ESBL testing.

MM24 – NCTC[®] 11954 / ATCC[®] 35218 – beta-lactamase positive strain. CLSI recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC[®] 9001 / ATCC[®] 11775 / WDCM 00090 – used in water / chemical industry. PHE recommended strain for media QC.

MM93 – NCTC[®] 12900 / ATCC[®] 700728 / WDCM 00014 – O157 strain (non-toxigenic). PHE recommended strain for media QC.

MM63 - NCTC® 11560 - beta-lactamase positive strain.

MM38 – NCTC[®] 12923 / ATCC[®] 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC[®] 13846 – Possesses the plasmid-mediated mcr-1 colistin resistance mechanism gene and is recommended by PHE and EUCAST as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.



Haemophilus influenzae strains:

MM81 - NCTC[®] 12699 / ATCC[®] 49247 – is a 'BLNAR' strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. PHE, CLSI recommended QC strain for susceptibility testing media.

MM98 – NCTC[®] 11931 – a fully sensitive strain. PHE recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC[®] 8468 / ATCC[®] 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

MM37 - NCTC® 12975 / ATCC® 49766 - recommended by EUCAST.

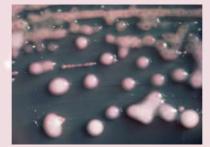


Klebsiella strains:

MM04 *Klebsiella pneumoniae* – NCTC[®] 9633 / ATCC[®] 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC[®] 13368 / ATCC[®] 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 Klebsiella pneumoniae – NCTC[®] 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 Klebsiella pneumoniae - NCTC® 13443 - CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 Klebsiella pneumoniae – NCTC[®] 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 Klebsiella pneumoniae - NCTC® 13442 - CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes (Raoultella planticola)* – NCTC[®] 9528 – used in water / pharmaceutical industry. PHE recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.



Lactobacillus brevis:

MM76 - NCTC[®] 13386 / ATCC[®] 8287 - used in food industry.

Legionella pneumophila serogroup 1:

MM08 – NCTC[®] 11192 / ATCC[®] 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

Listeria innocua:

MM92 - NCTC[®] 11288 / ATCC[®] 33090 / WDCM 00017 - type strain. Non-pathogenic.

Listeria monocytogenes:

MM87 – NCTC[®] 11994 / WDCM 00019 – type strain, PHE recommended positive control strain for Listeria detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC[®] 7973 / ATCC[®] 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC[®] 13372 / ATCC[®] 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

Neisseria gonorrhoeae:

 $MM96 - NCTC^{\circ}$ 12700 / ATCC $^{\circ}$ 49226 - has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. PHE recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO₂ is helpful in growth.

MM05 – NCTC[®] 8375 / ATCC[®] 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. PHE recommended strain for media QC.

Proteus mirabilis:

MM43 – NCTC[®] 13376 / ATCC[®] 14153 – pharmaceutical / disinfectant / media control. MM68 – NCTC[®] 10975 – media control. PHE recommended control for motility test.



Proteus vulgaris:

MM09 – NCTC[®] 4175 / ATCC[®] 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

Pseudomonas aeruginosa strains:

MM10 – NCTC[®] 12903 / ATCC[®] 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 - NCTC® 10662 / ATCC® 25668 / WDCM 00114 - is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC[®] 12924 / ATCC[®] 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC[®] 13359 / ATCC[®] 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

Rhodococcus equi:

MM97 - NCTC[®] 1621 / ATCC[®] 6939 / WDCM 00028 - type strain.

Saccharomyces cerevisiae:

MM73 – NCPF[®] 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 - used for QC of culture media and for antifungal susceptibility testing.

Salmonella serotypes:

MM11 Salmonella Typhimurium – NCTC[®] 12023 / ATCC[®] 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 Salmonella Poona - NCTC[®] 4840 - (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 Salmonella Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

Serratia marcescens:

MM12 – NCTC[®] 13382 / ATCC[®] 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.



Staphylococcus aureus:

(A) Fully sensitive:

MM85 – NCTC[®] 6571 / ATCC[®] 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of Staph aureus strains. Sensitive to penicillin and cefoxitin / methicillin / oxacillin. PHE recommended coagulase, DNAse and catalase positive control.

MM13 – NCTC[®] 12981 / ATCC[®] 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all antistaphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC[®] 12973 / ATCC[®] 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. EUCAST, CLSI strain. Sensitive to cefoxitin / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC[®] 7447 / ATCC[®] 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Cefoxitin / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and betalactamase negative.

(C) MRSA (cefoxitin / methicillin / oxacillin resistant):

MM91 – NCTC[®] 13373 / ATCC[®] 43300 / WDCM 00211 (MRSA) – Possesses mecA gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level cefoxitin /oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of cefoxitin – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for cefoxitin.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully cefoxitin / oxacillin / methicillin sensitive strain (such as MM13). CLSI recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC[®] 12493 / WDCM 00212 (MRSA) – possesses mecA gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level cefoxitin / methicillin / oxacillin resistance. EUCAST recommended strain. Instances have been reported where loss of the mecA gene has occurred during storage.

D) Other:

MM46 – NCTC[®] 10788 / ATCC[®] 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.





Staphylococcus epidermidis:

MM15 - NCTC® 13360 / ATCC® 12228 / WDCM 00036 - used for media control / antibiotic assay. Colonies are small and betahaemolytic.

Streptococcus agalactiae: (Beta-haemolytic Streptococcus group B)

MM16 - NCTC® 8181 / ATCC® 13813 - type strain, used for QC. PHE recommended negative control for aesculin test.

Streptococcus pneumoniae strains:

MM95 – NCTC[®] 12977 / ATCC[®] 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. PHE recommended positive control for bile solubility test. CLSI, EUCAST recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC[®] 12695 / ATCC[®] 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.



Streptococcus pyogenes:

MM20 – NCTC[®] 12696 / ATCC[®] 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic. PHE recommended blood agar control.

Vibrio parahaemolyticus:

MM06 – NCTC[®] 10885 / WDCM 00185 – used for QC of media and ID testing. PHE recommended strain used mainly in the food industry.

Yersinia enterocolitica:

MM80 - NCTC[®] 12982 / ATCC[®] 9610 / WDCM 00038 - type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

- European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.
- 2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).
- 3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).



How to use Selectrol®

Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.



Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies





Place disc in a small volume of a suitable broth medium such as brain-heart infusion



Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium

Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests



Out-of-specification results

Laboratories use Selectrol[®] for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly check standard operating procedures
- There is an instrumentation error check calibration, mechanical functioning, etc
- There is a problem with the consumables out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.





Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol[®] disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)

- Assume the count in the broth to be 10⁸ organisms per ml ------ (A)
- Mix and transfer 100 μl of (A) to 100 ml of saline or 1/4 strength Ringer's solution -- (B)
- Mix and transfer 100 μl of (B) to 10 ml of saline or 1/4 strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10⁸ organisms per ml
- (B) contains 10⁵ organisms per ml
- (C) contains 10³ organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol[®] organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.





Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol[®] strain MM33) mentioned above is designated WDCM 00033.

Staphylococcus aureus WDCM 00033

AHU 1142; ATCC[™] 6538P; BCRC 10451; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; NCTC 7447; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Every effort has been made to ensure the accuracy of the information in this document, however TCS makes no warranties, expressed or implied, regarding errors or omissions and assumes no legal liability or responsibility for loss or damage resulting from the use of information contained within.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
Aspergillus brasiliensis	NCPF [®] 2275 / ATCC [®] 16404	MM94	00053
Bacillus cereus	NCTC [®] 10320 / ATCC [®] 9634	MM21	00001
Bacillus cereus	NCTC [®] 7464 / ATCC [®] 10876	MM86	
Bacillus subtilis	NCTC [®] 10400 / ATCC [®] 6633	MM29	00003
Bacteroides fragilis	NCTC [®] 9343 / ATCC [®] 25285	MM44	
Campylobacter jejuni	NCTC [®] 11351 / ATCC [®] 33560	MM36	
Campylobacter jejuni	NCTC [®] 11322 / ATCC [®] 29428	MM82	00156
Candida albicans	NCPF [®] 3255 / ATCC [®] 2091	MM28	00055
Candida albicans	NCPF [®] 3179 / ATCC [®] 10231	MM42	00054
Citrobacter freundii	NCTC [®] 9750 / ATCC [®] 8090	MM27	
Clostridium perfringens	NCTC [®] 8237 / ATCC [®] 13124	MM45	00007
Clostridium sporogenes	NCTC [®] 532 / ATCC [®] 19404	MM31	00008
Enterobacter aerogenes	NCTC [®] 10006 / ATCC [®] 13048	MM26	00175
Enterobacter cloacae	NCTC [®] 13380 / ATCC [®] 23355	MM01	00082
Enterobacter cloacae	NCTC [®] 13406	MM51	
Enterococcus faecalis	NCTC [®] 775 / ATCC [®] 19433	MM17	00009
Enterococcus faecalis	NCTC [®] 12697 / ATCC [®] 29212	MM18	00087
Enterococcus faecalis	NCTC [®] 13379 / ATCC [®] 51299	MM52	00085
Enterococcus hirae	NCTC [®] 13383 /ATCC [®] 10541	MM35	00011
Escherichia coli	NCTC [®] 12241 / ATCC [®] 25922	MM02	00013
Escherichia coli	NCTC [®] 11954 / ATCC [®] 35218	MM24	
Escherichia coli	NCTC [°] 10418 / ATCC [°] 10536	MM33	
Escherichia coli	NCTC [®] 12923 / ATCC [®] 8739	MM38	00012
Escherichia coli	NCTC [®] 11560	MM63	
Escherichia coli	NCTC [®] 9001 / ATCC [®] 11775	MM75	00090
Escherichia coli CRE	NCTC [®] 13476	MM57	
Escherichia coli (mcr-1)	NCTC [®] 13846	MM34	
Escherichia coli O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93	00014
Haemophilus influenzae	NCTC [®] 8468 / ATCC [®] 9334	MM100	
Haemophilus influenzae	NCTC [®] 12975 / ATCC [®] 49766	MM37	
Haemophilus influenzae	NCTC [®] 12699 / ATCC [®] 49247	MM81	
Haemophilus influenzae	NCTC [®] 11931	MM98	
Klebsiella aerogenes	NCTC [®] 9528	MM88	
Klebsiella pneumoniae	NCTC [®] 9633 / ATCC [®] 13883	MM04	00097
Klebsiella pneumoniae	NCTC [®] 13368 / ATCC [®] 700603	MM83	
Klebsiella pneumoniae CRE	NCTC [®] 13440	MM55	
Klebsiella pneumoniae CRE	NCTC [®] 13443	MM56	
Klebsiella pneumoniae CRE	NCTC [®] 13438	MM58	

Selectrol Strain Index

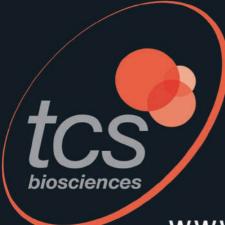
Strain Name	Designation	Code	WDCM
Klebsiella pneumoniae CRE	NCTC [®] 13442	MM59	
Lactobacillus brevis	NCTC [®] 13386 / ATCC [®] 8287	MM76	
Legionella pneumophila serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08	00107
Listeria innocua	NCTC [®] 11288 / ATCC [®] 33090	MM92	00017
Listeria monocytogenes	NCTC [®] 7973 / ATCC [®] 35152	MM48	00109
Listeria monocytogenes	NCTC [®] 133 <mark>72 ATCC[®] 7644</mark>	MM77	
Listeria monocytogenes	NCTC [®] 11994	MM87	00019
Neisseria gonorrhoeae	NCTC [®] 8375 / ATCC [®] 19424	MM05	
Neisseria gonorrhoeae	NCTC [®] 12700 / ATCC [®] 49226	MM96	
Proteus mirabilis	NCTC [®] 13376 / ATCC [®] 14153	MM43	
Proteus mirabilis	NCTC [®] 10975	MM68	
P <mark>roteus</mark> vulgaris	NCTC [®] 4175 / ATCC [®] 13315	MM09	
P <mark>seudomon</mark> as aeruginosa	NCTC [®] 12903 / ATCC [®] 27853	MM10	00025
Pseudomonas aeruginosa	NCTC [®] 12924 / ATCC [®] 9027	MM40	00026
Pseudomonas aeruginosa	NCTC [®] 13359 / ATCC [®] 15442	MM41	
Pseudomonas aeruginosa	NCTC [®] 10662 / ATCC [®] 25668	MM65	00114
Rhodococcus equi	NCTC [®] 1621 / ATCC [®] 6939	MM97	00028
Saccharomyces cerevisiae	NCTC [®] 10716/ ATCC [®] 9763	MM50	00058
Saccharomyces cerevisiae	NCPF [®] 3178	MM73	1
Salmonella Nottingham	NCTC [®] 7832	MM84	
Salmonella Poona	NCTC [®] 4840	MM89	
Salmonella Typhimurium	NCTC [®] 12023/ ATCC [®] 14028	MM11	00031
Serratia marcescens	NCTC [®] 13382 / ATCC [®] 8100	MM12	
Staphylococcus aureus	NCTC [®] 12981 / ATCC [®] 25923	MM13	00034
Staphylococcus aureus	NCTC [®] 12973 / ATCC [®] 29213	MM14	00131
Staphylococcus aureus	NCTC [®] 7447 / ATCC [®] 6538P	MM30	00033
Staphylococcus aureus	NCTC [®] 10788 / ATCC [®] 6538	MM46	00032
Staphylococcus aureus	NCTC [®] 6571 / ATCC [®] 9144	MM85	00035
Staphylococcus aureus (MRSA)	NCTC [®] 12493	MM64	00212
Staphylococcus aureus (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91	00211
Staphylococcus epidermidis	NCTC [®] 13360 / ATCC [®] 12228	MM15	00036
Streptococcus agalactiae	NCTC [®] 8181 / ATCC [®] 13813	MM16	
Streptococcus pneumoniae	NCTC [®] 12695 /ATCC [®] 6303	MM19	
Streptococcus pneumoniae	NCTC [®] 12977 /ATCC [®] 49619	MM95	
Streptococcus pyogenes	NCTC [®] 12696 /ATCC [®] 19615	MM20	
Vibrio parahaemolyticus	NCTC [®] 10885	MM06	00185
Yersinia enterocolitica	NCTC [®] 12982 / ATCC [®] 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	Bacillus cereus	NCTC [®] 10320 / ATCC [®] 9634	MM21
00003	Bacillus subtilis	NCTC [®] 10400 / ATCC [®] 6633	MM29
00007	Clostridium perfringens	NCTC [®] 8237 / ATCC [®] 13124	MM45
00008	Clostridium sporogenes	NCTC [®] 532 / ATCC [®] 19404	MM31
00009	Enterococcus faecalis	NCTC [®] 775 / ATCC [®] 19433	MM17
00011	Enterococcus hirae	NCTC [®] 13383 /ATCC [®] 10541	MM35
00012	Escherichia coli	NCTC [®] 12923 / ATCC [®] 8739	MM38
00013	Escherichia coli	NCTC [®] 12241 / ATCC [®] 25922	MM02
00014	Escherichia coli O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93
00017	Listeria innocua	NCTC [®] 11288 / ATCC [®] 33090	MM92
00019	Listeria monocytogenes	NCTC [®] 11994	MM87
00025	Pseudomonas aeruginosa	NCTC [®] 12903 / ATCC [®] 27853	MM10
00026	Pseudomonas aeruginosa	NCTC [®] 12924 / ATCC [®] 9027	MM40
00028	Rhodococcus equi	NCTC [®] 1621 / ATCC [®] 6939	MM97
00031	Salmonella Typhimurium	NCTC [®] 12023/ ATCC [®] 14028	MM11
00032	Staphylococcus aureus	NCTC [®] 10788 / ATCC [®] 6538	MM46
00033	Staphylococcus aureus	NCTC [®] 7447 / ATCC [®] 6538P	MM30
00034	Staphylococcus aureus	NCTC [®] 12981 / ATCC [®] 25923	MM13
00035	Staphylococcus aureus	NCTC [®] 6571 / ATCC [®] 9144	MM85
00036	Staphylococcus epidermidis	NCTC [®] 13360 / ATCC [®] 12228	MM15
00038	Yersinia enterocolitica	NCTC [®] 12982 / ATCC [®] 9610	MM80
00053	Aspergillus brasiliensis	NCPF [®] 2275 / ATCC [®] 16404	MM94
00054	Candida albicans	NCPF [®] 3179 / ATCC [®] 10231	MM42
00055	Candida albicans	NCPF [®] 3255 / ATCC [®] 2091	MM28
00058	Saccharomyces cerevisiae	NCTC [®] 10716/ ATCC [®] 9763	MM50
00082	Enterobacter cloacae	NCTC [®] 13380 / ATCC [®] 23355	MM01
00085	Enterococcus faecalis	NCTC [®] 13379 / ATCC [®] 51299	MM52
00087	Enterococcus faecalis	NCTC [®] 12697 / ATCC [®] 29212	MM18
00090	Escherichia coli	NCTC [®] 9001 / ATCC [®] 11775	MM75
00097	Klebsiella pneumoniae	NCTC [®] 9633 / ATCC [®] 13883	MM04
00107	Legionella pneumophila serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08
00109	Listeria monocytogenes	NCTC [®] 7973 / ATCC [®] 35152	MM48
00114	Pseudomonas aeruginosa	NCTC [®] 10662 / ATCC [®] 25668	MM65
00131	Staphylococcus aureus	NCTC [®] 12973 / ATCC [®] 29213	MM14
00156	Campylobacter jejuni	NCTC [®] 11322 / ATCC [®] 29428	MM82
00175	Enterobacter aerogenes	NCTC [®] 10006 / ATCC [®] 13048	MM26
00185	Vibrio parahaemolyticus	NCTC [®] 10885	MM06
00211	Staphylococcus aureus (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91
00212	Staphylococcus aureus (MRSA)	NCTC [®] 12493	MM64

Notes





www.tcsbiosciences.co.uk

TCS Biosciences Ltd Botolph Claydon, Buckingham, MK18 2LR, United Kingdom t: +44 (0) 1296 714222, f: +44 (0) 1296 714806, e: sales@tcsgroup.co.uk