Certificate

mdc medical device certification GmbH

certifies that

VECTOR BEST

AO Vector-Best
Research and Production Area
Building 36,Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

with the locations listed in the attachment

for the scope

Design and development, production and distribution of medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1213100019 date 2020-06-02

Location	Scope
AO Vector-Best Arbuzova str. 1/1, 630117 Novosibirsk Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best Pasechnaya str, 3, 630117 Novosibirsk Russian Federation	design and development, production of medical devices for in vitro diagnostics

medical device certification mdc

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 107677 0001 Rev. 01

Holder of Certificate: **AO Vector-Best**
Research and Production area, building 36
630559 Koltsovo (Novosibirsk Region)
RUSSIAN FEDERATION

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 107677 0001 Rev. 01

Report No.: 713183967_B

Valid from: 2021-01-01
Valid until: 2021-12-31

Date, 2020-12-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 107677 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

AO Vector-Best
Research and Production area, building 36, 630559 Koltsovo (Novosibirsk Region), RUSSIAN FEDERATION

See Scope of Certificate

AO Vector-Best
Arbuzova str 1/1, 630117 Novosibirsk, RUSSIAN FEDERATION

See Scope of Certificate

AO Vector-Best
Pasechnaya str 3, 630117 Novosibirsk, RUSSIAN FEDERATION

See Scope of Certificate

./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

Bioron GmbH
Address: Rheinhorststr. 18, D-67071 Ludwigshafen, Germany, tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2017/10/16

Акционерное общество «Вектор-Бест» ВЕКТОР БЕСТ Новосибирская область, р.п. Кольцово ОГРН 1025404347550

Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the quantitative and qualitative determination of IgG to measles virus in blood serum (plasma)	D-1356
3.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to nuclear antigen of Epstein-Barr virus in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to early antigens of Epstein-Barr virus in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	VectoMumps-IgM	Enzyme immunoassay kit for the detection of IgM to mumps virus in blood serum (plasma)	D-2604
11.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
12.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
13.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
14.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
15.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
16.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma)	D-3356
17.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma)	D-3452
18.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgA to tissue transglutaminase in blood serum (plasma)	D-3758
19.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
20.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 1 concentration in blood serum	D-3762
21.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 2 concentration in blood serum	D-3764

22.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to Hantavirus in blood serum (plasma)	D-4902
23.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to Hantavirus in blood serum (plasma)	D-4904
24.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile Virus in blood serum (plasma)	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile Virus in blood serum (plasma)	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile Virus in blood serum (plasma)	D-5154

Ministero della Salute
DGFDM
0043588-P-26/10/2011

96082548

Ministero dell'Economia e delle Finanze MARCA DA BOLLO €14,62 QUATTORDICI/62
Agenzia Entrate
00011148 00008968 WD8AIQQ1
QD468407 29/06/2011 08:42:26
0001-00009 E3A3A5A456EF68C3
IDENTIFICATIVO : 01092857617099
0 1 09 285761 709 9

Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE E DELL'ORDINAMENTO DEL SERVIZIO SANITARIO NAZIONALE
DIREZIONE GENERALE DEI DISPOSITIVI MEDICI, DEL SERVIZIO FARMACEUTICO E DELLA SICUREZZA DELLE CURE
UFFICIO IV ex DGFDM – DIAGNOSTICI IN VITRO

I.5.l.c.2/IV/2011/37

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza del 29/09/2011 presentata dalla ditta Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;
VISTI gli atti d'ufficio;
HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical-devices;*
HAVING REGARD *to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD to *the request dated 29/09/2011 submitted by the company* Dia.Pro Diagnostic Bioprobes Srl con with legal site in Via Columella, 31 – 20128 Milano – C.F. and P.Iva 11924660159;
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004:*
HAVING REGARD to *the official deeds;*

SI ATTESTA
IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, ha prodotto e marcato CE, come dispositivo medico- diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il prodotto:
that the Company Dia.Pro Diagnostic Bioprobes Srl located in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, manufactured and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

DP-9 DIA.BLOOD INSTRUMENT

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.

Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione nei paesi extra UE.

The above mentioned product, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and to export to non-European countries

IL DIRETTORE DELL'UFFICIO IV
(Dott.ssa Giovanna Nisticò)

IC/CM

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

ENAC CERTIFICACIÓN Nº 39/C-SG055

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número

grants the certificate no.

2013 11 0039 EN

según la norma

in accordance with the standard

UNE-EN ISO 13485:2018
(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios

Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa / *to the company*

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ *Headquarters and manufacturing facility*

Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

Para las siguientes actividades / *For the following activities:*

Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.

Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.

Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.

Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.

Modificaciones de alcance: Ver Anexo I / *see Annex I*

Fecha de validez/ *Date of validity:* **Desde/** *From:* **8-03-2019** **Hasta/***To:* **17-12-2021**

Certificación inicial/ *Initial certification date:* **27-11-2013**

Renovación / *Renewal of certification date:* **8-03-2019**

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

13485 CERTIFICADO Revisión 17/12/2018

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: https://sede.aemps.gob.es

Localizador: L P D T J L 5 2 D F

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ENAC
CERTIFICACIÓN
Nº 39/C-SG055

ANEXO I / *ANNEX I*

CERTIFICADO UNE-EN ISO 13485:2018/ *UNE-EN ISO 13485:2018 CERTIFICATE*

Modificaciones del alcance / *Scope modifications:*

Fecha/*Date*	**Descripción de la modificación**/ *Modification description*
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico *Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques).* *Change in the level of detail of the technological scope description.*
8-03-2019	Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro". *Extension of technological scope:* *Immunochemistry and Microbiology* *Instruments and software for "in vitro" diagnostic* *Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic*

Madrid, 08 de marzo de 2019
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 08/03/2019
Puede comprobar la autenticidad del documento en la sede de la AEMPS: https://sede.aemps.gob.es
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Fax: (+34) 91.822.52.89

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**Chlamydia Trachomatis IgA** CODE: **CTA.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

Dia.Pro
*Dia*gnostic
Bio*Pro*bes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**Chlamydia Trachomatis IgG** CODE: **CTG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: B86E8DZ586

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas /** *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II /** *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HCV Ab ELISA cualitativo / *ELISA qualitative*

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: B86E8DZ586

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: GJEC8290C8

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas /** *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II /** *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HDV Ab ELISA cualitativo / *ELISA qualitative*

- DAB.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity*.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: GJEC8290C8

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ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
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Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas /** *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II /** *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HBs Ag one Version ULTRA ELISA cualitativo / *ELISA qualitative*

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity*.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

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28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L82-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-22 3L82-42	53301	Glucose	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: _____

Full Name: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: 26-FEB-2018

Digitally signed by Ceaicovschi Tudor
Date: 2020.11.03 14:19:09 EET
Reason: MoldSign Signature
Location: Moldova

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 26-FEB-2018

Date Issued: 26-FEB-2018

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Applicable

Effective (Date or Lot Number): 26-FEB-2018

Abbott

Declaration of Conformity

Certificate Identification: 6L45
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6L45-21	53229	Total Bilirubin	Self-declared
6l45-41	53229	Total Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 28-June-2019

Signature: Mark Littlefield

Full Name: **Mark Littlefield**

Position: **Associate Director, Regulatory Affairs**

Date of Approval: 28-JUN-2019

Date Issued: 28-JUN-2019

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: October 12, 2018

Effective (Date or Lot Number): 28-JUN-2019

Abbott

Declaration of Conformity

Certificate Identification: 8G63
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8G63-21	53236	Direct Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature: 
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: September 3, 2015
Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 1E66

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E66-04	41830	Bilirubin Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: September 28, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

Declaration of Conformity

Certificate Identification: 7D56
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-21	52925	Alanine Aminotransferase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D81
Legal Manufacturer's Name: Abbott Laboratories Diagnostic Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D81-21	52954	Aspartate Aminotransferase	**Self-declared**

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 15-Oct-2018

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 15-OCT-2018

Date Issued: 15-OCT-2018

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 08-SEP-2017

Effective (Date or Lot Number): 15-OCT-2018

ABBOTT

Declaration of Conformity

Certificate Identification: 7D65
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D65-21 7D65-41	53030	Gamma-Glutamyl Transferase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D58
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D58-21	52941	Amylase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification: 7D80
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D80-31	53114	Lipase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature: 
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: November 17, 2014
Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 7D75
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D75-21 7D75-31	53590	Urea Nitrogen	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 3L81

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L81-22; 3L81-32; 3L81-41	53251	Creatinine	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: July 16, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 3P39

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P39-21; 3P39-41	53583	Uric Acid	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 7D73
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D73-21	53989	Total Protein	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D53
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D53-23	53599	Albumin BCG	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D55
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D55-21 7D55-31	52929	Alkaline Phosphatase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 6, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification: 7D56
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-21	52925	Alanine Aminotransferase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D62
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D62-21	53362	Cholesterol	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 9-3-2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D74
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D74-21	53462	Triglyceride	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: 9-3-2015
Effective (Date or Lot Number): 8-SEP-2017

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

ABBOTT

Declaration of Conformity

Certificate Identification: 3L79

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L79-21;3L79-31; 3L79-41	45789	Calcium	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 3E16
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3E16-02	53109	Lipase Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 1E65

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E65-04	30216	Multiconstituent Calibrator	Self-declared
1E65-05	30216	Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: March 6, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 5P56

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
5P56-01	53356	Lipid Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: January 30, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D29
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D29-20	56676	Water Bath Additive	Self-declared
9D29-21	56676	Water Bath Additive	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 6-11-2015
Date Issued: 6-11-2015
Supersedes: March 28,2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 6-11-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 6-11-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 6K01

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6K01-20	56676	Acid Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D31
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D31-20	58236	Alkaline Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 1J72
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1J72-20	59058	Detergent A	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 2J94
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2J94-21	59058	Detergent B	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: December 4, 2014
Date Issued: December 4, 2014
Supersedes: New

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: December 4, 2014
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): December 4, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 4P52

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4P52-21	61010	Hemoglobin A1c	Self-declared
4P52-02	53315	Hemoglobin A1c Calibrators	Self-declared
4P52-10	44435	Hemoglobin A1c Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: March 6, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 4P52
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4P52-21	59090	Hemoglobin A1c Reagent Kit (300 tests)	Self-declared
4P52-02	53315	Hemoglobin A1c Calibrators	Self-declared
4P52-10	44435	Hemoglobin A1c Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Scott Anderson signing for Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: August 4, 2015
Date Issued: August 4, 2015
Supersedes: November 17, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: August 4, 2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): August 5, 2015

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem A1c	Assayed/bi-level	04V0610

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2022

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 **(Day)** 01 **(Month)** 20 **(Year)**

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass

Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 31-01-20
Place and Date of Issue

TECHNOPATH
CLINICAL DIAGNOSTICS

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations

ABBOTT

Declaration of Conformity

Certificate Identification: 3K33

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3K33-21	30169	Ultra HDL	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: April 4, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
Product:	Direct LDL Catalogue Number 1E31-20 GMDN Code: 53395
Classification:	General IVD
Conformity Assessment Route:	Annex III, self-certified

We hereby declare that the above-mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Prince Edward Island, Canada

Signature: _____ 06-May-2019

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, Prince Edward Island
C1E 2B9 Canada
Tel: 902-566-1396 Fax: 902-628-6504
www.sekisuidiagnostics.com

Abbott

Declaration of Conformity

Certificate Identification:	ARCH Sys Acc LC	IRIS V4
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division	
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	56701	ARCHITECT Septum	**Self-declared**
4D19-01	56701	ARCHITECT Replacement Caps	**Self-declared**
7C14-01	56676	ARCHITECT Sample Cups	**Self-declared**
7C15-02	56676	ARCHITECT Reaction Vessels	**Self-declared**
7C15-03	56676	ARCHITECT Reaction Vessels	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]

Full Name: Katerina Damjanoska

Position: Site Quality Director

Date of Approval: 5/29/2019

Date Issued: 22 July 2019

Supersedes: 02 June 2015

Signature: [signature]

Full Name: MaryCaren Murawski

Position: Regulatory Affairs Director

Date of Approval: 22 July 19

Place Issued: Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064 USA

Effective (Date or Lot Number): 22 July 19

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem S Plus	Unassayed/single level	05P79-10
Multichem S Plus	Unassayed/single level	05P79-11
Multichem S Plus	Unassayed/single level	05P79-12
Multichem S Plus	Assayed/single level	05P78-10
Multichem S Plus	Assayed/single level	05P78-11
Multichem S Plus	Assayed/single level	05P78-12

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2022

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 **(Day)** 01 **(Month)** 20 **(Year)**

TECHNOPATH
CLINICAL DIAGNOSTICS

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass

Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 31-01-20
Place and Date of Issue

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations

Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting

from 9 February 2015 to 13 February 2015

Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 & RSH Service

March 6th – 14th, 2018

Ali Güntekin		14.03.2018
TRAINER NAME	TRAINER SIGNATURE	DATE DD.MM.YYYY
ABBOTT DIAGNOSTICS		**Germany - Delkenheim**

Abbott

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
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РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

REGISTRATION NO. 04720Q10000336

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Chengwu Medical Products Factory

Registered Address: Southern End of Quancheng Road,Chengwu County,274200 Heze City,Shandong Province,P.R.China

Manufacturing Address: Southern End of Quancheng Road,Chengwu County

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The development,production and service of disposable virus specimen collection tube.

Date of issue: July 13,2020

Date of expiry: July 12,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

CE Notification Confirmation

This is to confirm that, according to the council directive 98/79/EC, SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

Shandong Chengwu Medical Products Factory
Southern End of Quancheng Road, Chengwu County,
274200 Heze City, Shandong Province, P.R.China.

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the In Vitro Diagnostic Medical Device (IVDD), as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 98/79/EC.

According to 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Device and has allocated registration number.

Disposable Virus Specimen Collection Tube

Not in List A and List B according to Annex II of 98/79/EC

GMDN CODE : 63232

CIBG Number: NL-CA002-2020-50479

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

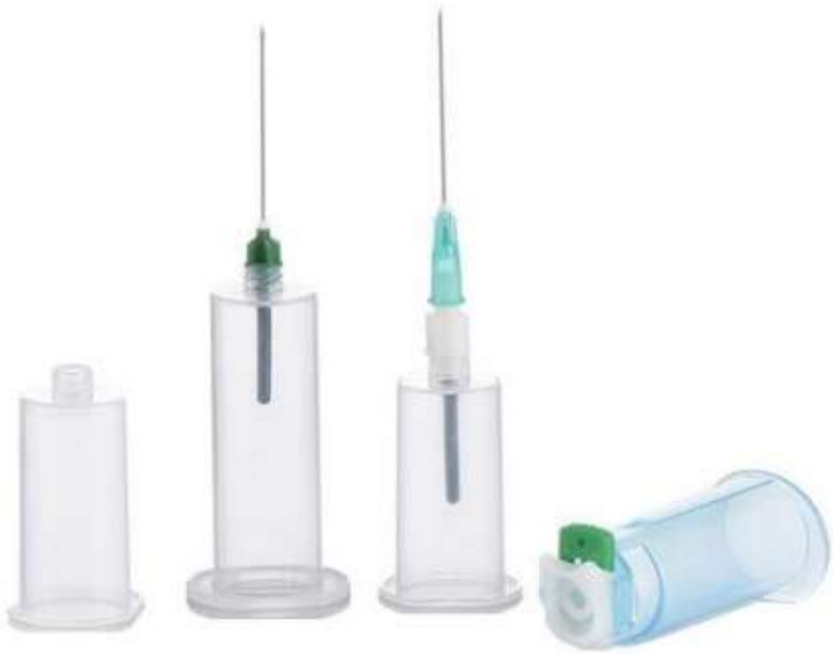
Reference Number: EUCAN00195
Issue date: May, 06, 2020

For and on behalf of
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Authorized Signature
Only used for the EU Representative Signature

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

Blood Collection Needle Holder

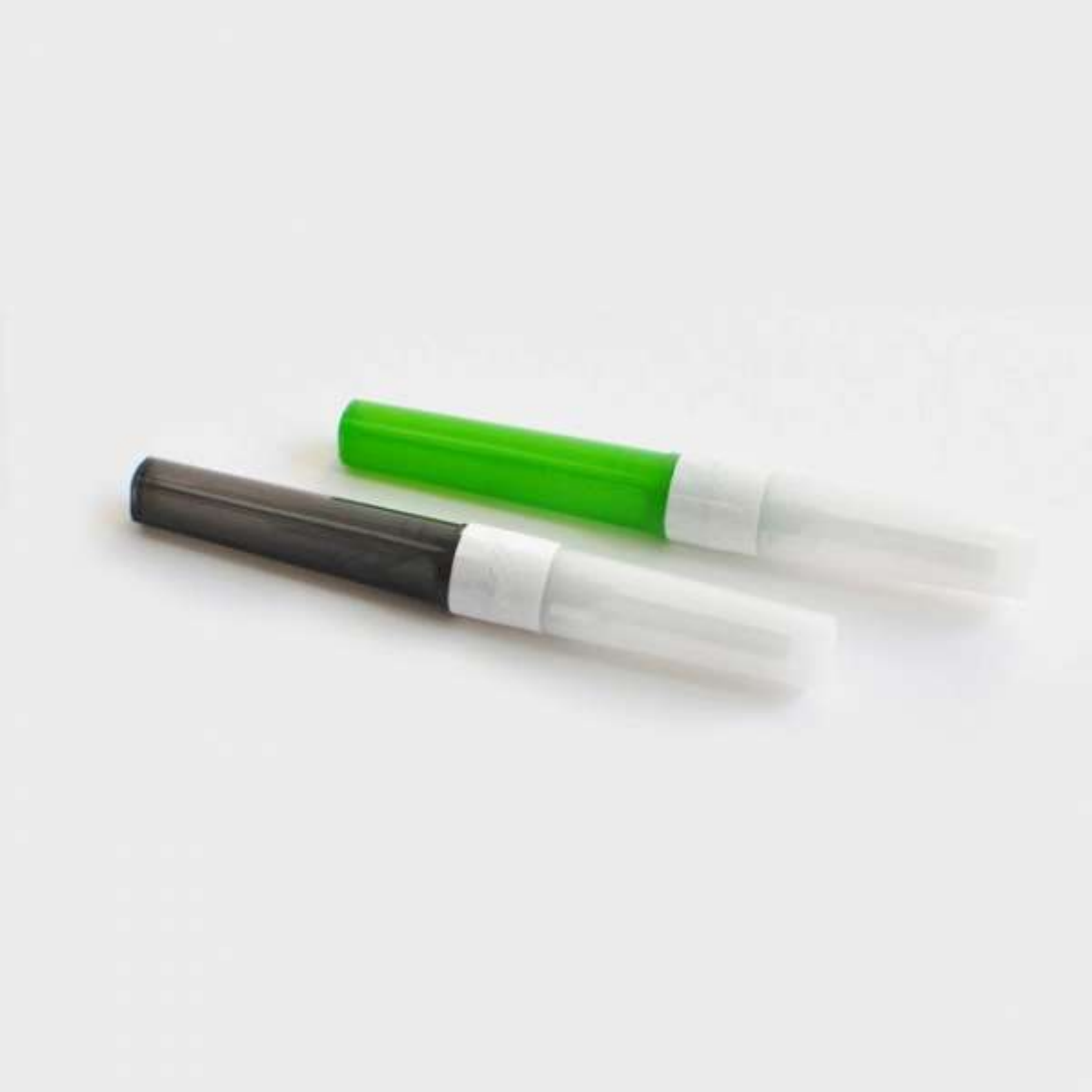


Blood Collection Needle Holder

Blood collection needle holder is compatible with Multi-Sample Needle to collecting blood.
Lock the multi-sample needle short end which is with latex cover directly into holder
Insertions finish when you push the white part of the snap.
After collection finished, press the green color button on holder, needle automatically discharge. Collector can easy finish collection without touch of needle and avoid mistake puncture.
It is non-dangerous products, non-flammable, non-explosive, and can be stored at room temperature.

Cat. No.	Description	Qty/Case(pcs)
632201	Blood Collection Needle holder	4000
632202	Blood Collection Needle holder (safety type)	4000

Blood Collection Needle (Multi-Sample Needle)



Blood Collection Needle (Multi-Sample Needle)

Latex free, multi-sample needles permit several samples to be taken with a single puncture, EO sterile, non toxic, non pyrogenic, polypropylene hubs are color marked.

Cat. No.	Specification	Color	Needle Size	Qty/Case (pcs)
631801	18G	Pink	1"	5000
631802			1 1/2"	5000
631803	20G	Yellow	1"	5000
631804			1 1/4"	5000
631805			1 1/2"	5000
631806	21G	Green	1"	5000
631807			1 1/4"	5000
631808			1 1/2"	5000
631809	22G	Black	1"	5000
631810			1 1/4"	5000
631811			1 1/2"	5000
631812	23G	Blue	1"	5000
631813			1 1/4"	5000

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

ELITech Clinical Systems
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN ENVOY	PROB-0850	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA ENVOY	URSL-0850	
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE	AMSL-M430	52940
AMYLASE ENVOY	AMSL-0850	
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	52954
AST ENVOY	ASVD-0850	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	53003
CK NAC SL	CKSL-0410/0430/0230	
GAMMA-GT	GISL-M230	53027
GAMMA-GT PLUS SL	GISL-0400/0420/0250	
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	53108
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-élements / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL ENVOY	CHSL-0850	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250/M330	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

Vla

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità /*Validity*

Dal / From: **2019-02-11**

Al / To: **2022-02-10**

Data emissione / *Issuing Date*

2019-02-11

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

TÜV Italia S.r.l. • Gruppo TÜV SÜD • Via Carducci 125, Pal. 23 • 20099 Sesto San Giovanni (MI) • Italia • www.tuv.it

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATO
N° Q5 071067 0006 Rev. 00

Titolare del certificato:

Liofilchem S.r.l.
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Stabilimento(i):

Liofilchem S.r.l.
Via Scozia,64026 Roseto degli Abruzzi (TE), ITALIA

Liofilchem S.r.l.
Contrada Piane Vomano,Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Marchio di certificazione:

Campo di applicazione:

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro

Norma(e) applicata(e):

EN ISO 13485:2016
Dispositivi medici – Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Vedere anche note sul retro.

N° del rapporto: ITA1070742

Valido da: 2018-12-19
Valido fino al: 2021-12-18

Data, 2018-12-19

Stefan Preiß

Traduzione per scopi informativi. La sola versione inglese (tedesca) è legalmente impegnativa.

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 071067 0006 Rev. 00

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Facility(ies):
Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Certification Mark:

Scope of Certificate: **Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1070742

Valid from: 2018-12-19
Valid until: 2021-12-18

Date, 2018-12-19

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II , List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco

10002	DNA AGAR + BLU DI TOLUIDINA
10004	CLED ANDRADE AGAR
10004*	CLED ANDRADE AGAR
10005	MAC CONKEY SORBITOL AGAR
10005*	MAC CONKEY SORBITOL AGAR
10006	TRYPTIC SOY AGAR + 0,6% YEAST EXTRACT
10007	BACILLUS CEREUS AGAR (PEMBA)
10007*	BACILLUS CEREUS AGAR (PEMBA)
10013	DNase TEST AGAR
10013*	DNase TEST AGAR
10014	Purple Lactose Agar
10014*	Purple Lactose Agar
10017	CZAPEK DOX AGAR
10018	DRIGALSKY LACTOSE AGAR
10020	Baird Parker Agar
10020*	Baird Parker Agar
10021	BIGGY (NICKERSON) AGAR
10021*	BIGGY (NICKERSON) AGAR
10022	BRILLIANT GREEN AGAR
10022*	BRILLIANT GREEN AGAR
10023	Chocolate Agar
10023*	Chocolate Agar
10024	TRYPTOSE AGAR
10024*	TRYPTOSE AGAR
10025	COLUMBIA AGAR (Horse Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)
10026	CLED AGAR
10026*	CLED AGAR
10027	BACILLUS CEREUS AGAR (Mossel)
10027*	BACILLUS CEREUS AGAR (Mossel)
10028	ISOSENSITEST AGAR
10028*	ISOSENSITEST AGAR
10029	MAC CONKEY AGAR
10029*	MAC CONKEY AGAR
10030	MANNITOL SALT AGAR
10030*	MANNITOL SALT AGAR
10031	MUELLER HINTON II AGAR
10031*	MUELLER HINTON II AGAR
10033	PSEUDOMONAS (CETRIMIDE) AGAR
10033*	PSEUDOMONAS (CETRIMIDE) AGAR
10035	SABOURAUD AGAR
10035*	SABOURAUD AGAR
10035S	SABOURAUD AGAR Irradiated
10036	S.S. AGAR
10036*	S.S. AGAR
10037	Tryptic Soy Agar
10037*	Tryptic Soy Agar
10037S	TRYPTIC SOY AGAR Irradiated
10039	ROGOSA AGAR
10039*	ROGOSA AGAR
10040	NEW YORK CITY AGAR
10040*	NEW YORK CITY AGAR
10041	LISTERIA PALCAM AGAR
10041*	LISTERIA PALCAM AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)
10042*	CRYSTAL VIOLET AGAR (Sheed 5%)
10043	HEKTOEN ENTERIC AGAR
10043*	HEKTOEN ENTERIC AGAR
10044	NUTRIENT AGAR
10044*	NUTRIENT AGAR

10046	SERUM TELLURITE AGAR
10047	BISMUTH SULFITE AGAR
10047*	BISMUTH SULFITE AGAR
10048	E.M.B. LEVINE AGAR
10048*	E.M.B. LEVINE AGAR
10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10051	Legionella BCYE Agar
10051*	Legionella BCYE Agar
10052	YERSINIA SELECTIVE AGAR
10052*	YERSINIA SELECTIVE AGAR
10053	WILKINS CHALGREEN AGAR
10053*	WILKINS CHALGREEN AGAR
10054	WURTZ LACTOSE AGAR
10054*	WURTZ LACTOSE AGAR
10056	X.L.D. AGAR
10056*	X.L.D. AGAR
10057	BILE AESCULIN AGAR
10057*	BILE AESCULIN AGAR
10058S	TRYPTIC SOY AGAR Irradiated -30 mL-
10060	BRAIN HEART INFUSION AGAR
10060*	BRAIN HEART INFUSION AGAR
10064	CHRISTENSEN UREA AGAR
10065	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10065*	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10067	SCHAEDLER KVN AGAR (Sheep Blood 5%)
10069	XLT 4 Agar
10069*	XLT 4 Agar
10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10078	MUELLER HINTON II MOD. AGAR
10078*	MUELLER HINTON II MOD. AGAR
10079	CASITONE AGAR
10079*	CASITONE AGAR
10080	HAEMOPHYLUS TEST AGAR
10080*	HAEMOPHYLUS TEST AGAR
10082	HELICOBACTER PYLORI AGAR
10082*	HELICOBACTER PYLORI AGAR
10090	M.R.S. Agar
10090*	M.R.S. Agar
10095	BRAIN HEART AGAR FOR HAEMOPHILUS
10129	MAC CONKEY AGAR MMG
10129*	MAC CONKEY AGAR MMG
10131	Mueller Hinton II Agar (Sheep Blood 5%)
10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD)
10132*	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD)
10134	Legionella BMPA Agar
10141	SALMONELLA TEST AGAR
10141*	SALMONELLA TEST AGAR
10142	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10142*	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10143	Mueller Hinton Agar + 5 % Horse Blood Lysed
10145	CAMPYLOBACTER KARMALI AGAR
10146	CAMPYLOBACTER PRESTON AGAR
10148	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10224	Baird Parker Agar
10225	LISTERIA PALCAM AGAR 140 mm
10231	MUELLER HINTON II AGAR 140 mm
10233	R.P.M.I. AGAR

10235	Sabouraud CAF Agar + Gentamicin
10235*	Sabouraud CAF Agar + Gentamicin
10235S	Sabouraud CAF Agar + Gentamicin Irradiated
10236	CLED AGAR 140 mm
10240	SCHAEDLER K AGAR (Sheep Blood 5%) 140mm
10241	SCHAEDLER KKV AGAR(Sheep blood 5%) 140mm
10242	SABOURAUD CAF AGAR 140 mm
10243	Sabouraud CAF Agar + Gentamicin 140mm
10244	DERMATOPHYTE (D.T.M.) AGAR 140 mm
10245	BRUCELLA BLOOD AGAR w HEMIN AND VITAMIN K1
10246	Chromatic™ MH
10247	Brucella Blood Agar with Hemin and Vitamin K1
10249	Purple Lactose Agar 140 mm
10334	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10334*	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10335	MUELLER HINTON CHOCOLATE AGAR
10353	BORDET GENGOU AGAR (Sheep Blood 15%)
10353*	BORDET GENGOU AGAR (Sheep Blood 15%)
10405	SCHAEDLER CNA AGAR (Sheep Blood 5%)
10407	VANCOMYCIN SCREEN AGAR
10408	WILKINS CHALGREN AGAR +5% SHEEP BLOOD
10409	CAMPYLOBACTER CCDA AGAR
10410	MUELLER HINTON AGAR w VITALEX
10411	BILE ESCULIN AZIDE AGAR w VANCOMYCIN
10412	Legionella BCYE Agar w/o Cysteine
10413	XLD Agar EP, USP, JP Formulation
10416	MIDDLEBROOK 7H11 AGAR
10424	Legionella BCYE Agar w Vancomycin + Colistin
10425	SCEDOSPORIUM SELECTIVE AGAR
10438	MacConkey Agar No.2
10438*	MacConkey Agar No.2
10439	Group A Selective Strep Agar w/ 5% Sheep Blood
10441	Sabouraud CAF Agar 50 mg
10445	Chocolate Agar w/ Bacitracin, Vancomycin, Clindamycin
10599	CHROMATIC™ MRSA
10600	OXACILLIN RESISTANCE STAPHYLOCOCCUS AGAR
10601	CHOCOLATE AGAR w/o VITOX
10602	CAMPYLOBACTER SKIRROW AGAR
10605	HELICOBACTER PYLORI EGG YOLK EMULSION AGAR
10620	O.A.LISTERIA
11023	CHOCOLATE BACITRACIN AGAR
11023*	CHOCOLATE BACITRACIN AGAR
11024	COLUMBIA CNA AGAR (Sheep Blood 5%)
11024*	COLUMBIA CNA AGAR (Sheep Blood 5%)
11025	COLUMBIA AGAR (Sheep Blood 5%)
11025*	COLUMBIA AGAR (Sheep Blood 5%)
11027	DESOXYCHOLATE AGAR
11027*	DESOXYCHOLATE AGAR
11030	ANAEROBIC AGAR
11033	PSEUDOMONAS ISOLATION AGAR
11033*	PSEUDOMONAS ISOLATION AGAR
11035	SABOURAUD CAF AGAR
11035*	SABOURAUD CAF AGAR
11035S	SABOURAUD CAF AGAR Irradiated
11037	TRYPTIC SOY AGAR (Sheep Blood 5%)
11037*	TRYPTIC SOY AGAR (Sheep Blood 5%)
11038	TRYPTIC SOY AGAR (Horse Blood 5%)
11038*	TRYPTIC SOY AGAR (Horse Blood 5%)
11040	THAYER MARTIN AGAR
11040*	THAYER MARTIN AGAR

11041	AZIDE AGAR (Sheep Blood 5%)
11041*	AZIDE AGAR (Sheep Blood 5%)
11052	DERMATOPHYTE (D.T.M.) AGAR
11052*	DERMATOPHYTE (D.T.M.) AGAR
11054	GARDNERELLA AGAR (Sheep Blood 5%)
11054*	GARDNERELLA AGAR (Sheep Blood 5%)
11057	ENTEROCOCCO AGAR
11057*	ENTEROCOCCO AGAR
11058	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11058*	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11060	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11060*	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11065	SCHAEDLER K AGAR (Sheep Blood 5%)
11065*	SCHAEDLER K AGAR (Sheep Blood 5%)
11070	MYCOSEL AGAR
11070*	MYCOSEL AGAR
11124	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11124*	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (140 mm)
11135	SABOURAUD AGAR MODIFIED
11135*	SABOURAUD AGAR MODIFIED
11143	HERELLEA AGAR
11143*	HERELLEA AGAR
11185	VOGEL JOHNSON AGAR
11185*	VOGEL JOHNSON AGAR
11195	T.C.B.S. AGAR
11195*	T.C.B.S. AGAR
11196	SPS AGAR
11196*	SPS AGAR
11200	PAR TEST AGAR
11200*	PAR TEST AGAR
11205	MYCOPLASMA AGAR
11206	Mueller Hinton II Agar + 2% NaCl
11231	Mueller Hinton II Agar (Sheep Blood 5%) 140 mm
11235	SABOURAUD CAF AGAR + TTC
11235*	SABOURAUD CAF AGAR + TTC
11236	Sabouraud CAF Agar + Actidione
11250	TINSDALE AGAR
11250*	TINSDALE AGAR
11335	SABOURAUD AGAR + GENTAMICIN
11335*	SABOURAUD AGAR + GENTAMICIN
11501	ENTEROCOCCUS AGAR + VANCOMYCIN
11506	BURKHOLDERIA CEPACIA SELECTIVE AGAR
11509	R.P.M.I. AGAR
11510	M.HINTON+GLUCOSE+METHYLEN BLUE
11512	NUTRIENT AGAR acc.to ISO 21528
11513	NUTRIENT AGAR acc.to ISO 6579
11517	COLUMBIA AGAR(Sheep Blood 5%)+VANCOMYCIN
11518	Mueller Hinton Agar + Cloxacillin
11610	Chromatic™ E.coli O157
11611	CHROMATIC™ DETECTION
11612	CHROMATIC™ CANDIDA
11614	CHROMATIC™ SALMONELLA
11616	CHROMATIC™ STAPH AUREUS
11617	CHROMATIC™ STREPTO B
11618	CHROMATIC™ MH
11619	CHROMATIC™ CRE
11621	CHROMATIC™ VRE
11622	CHROMATIC™ ESBL
11627	Chromatic™ Enterococcus

11629	CHROMATIC™ ESBL + AmpC
11629*	CHROMATIC™ ESBL + AmpC
11631	Chromatic™ OXA-48
11632	Chromatic™ Clostridium difficile
11633	Chromatic™ Vibrio
11634	Chromatic™ Detection opaque
11635	Chromatic™ Pseudomonas
12031	MUELLER HINTON II AGAR (120X120 mm)
12032	Mueller Hinton II Agar (Sheep Blood 5%) (120 mm x 120 mm)
12033	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (120 mm x 120 mm)
13012	CLED/MACCONKEY/TSA BLOOD AGAR
13012*	CLED/MACCONKEY/TSA BLOOD AGAR
13013	BAIRD PARKER/BIGGY/MACCONKEY
13013*	BAIRD PARKER/BIGGY/MACCONKEY
13014	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13014*	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13017	CLED/MACCONKEY MMG/MALTO
13017*	CLED/MACCONKEY MMG/MALTO
13018	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13018*	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13019	CLED/MACCONKEY/CETRIMIDE
13019*	CLED/MACCONKEY/CETRIMIDE
13020	MAC CONKEY/B.PARKER/TSA BLOOD
13345	GARDNERELLA V./ROGOSA/THAYER MARTIN
13345*	GARDNERELLA V./ROGOSA/THAYER MARTIN
13356	Gard.V. / Chocolate / Thayer Martin
13371	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13371*	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13480	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13480*	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13602	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13602*	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13607	CHOC. BAC./COLUMBIA/MAC CONKEY
13607*	CHOC. BAC./COLUMBIA/MAC CONKEY
13614	CLED/MACCONKEY/ENTEROCOCCO
13614*	CLED/MACCONKEY/ENTEROCOCCO
165312	MYCOPLASMA AGAR
18007	CHROMATIC™ STAPH AUREUS/ MRSA
18008	TSA BLOOD/CROMagar ORIENTATION
18008*	TSA BLOOD/CROMagar ORIENTATION
18009	Chromatic™ Salmonella/Hektoen Enteric
18011	CHROMATIC™ DETECTION/ESBL
18012	BRILLIANT GREEN / SS AGAR
18012*	BRILLIANT GREEN / SS AGAR
18015	BIGGY (NICKERSON) / MALT AGAR
18015*	BIGGY (NICKERSON) / MALT AGAR
18017	COLUMBIA CNA BLOOD/CHROMAGAR
18017*	COLUMBIA CNA BLOOD/CHROMAGAR
18018	MAC CONKEY/ SABOURAUD CAF
18020	EMB LEVINE / TSA BLOOD
18020*	EMB LEVINE / TSA BLOOD
18021	Chromatic™ CRE / Chromatic™ ESBL
18021*	Chromatic™ CRE / Chromatic™ ESBL
18022	TSA Blood/Columbia CNA
18023	Chromatic™ CRE / Chromatic™ OXA-48
18024	MSA / Chromatic™ MRSA
18025	Schaedler K / Schaedler KKV
18327	COLUMBIA CNA / MAC CONKEY
18327*	COLUMBIA CNA / MAC CONKEY

18379	GARDNERELLA V. / THAYER MARTIN
18379*	GARDNERELLA V. / THAYER MARTIN
18380	MAC CONKEY / TSA BLOOD
18380*	MAC CONKEY / TSA BLOOD
18390	BAIRD PARKER / SABOURAUD CAF
18390*	BAIRD PARKER / SABOURAUD CAF
18391	HEKTOEN ENTERIC / YERSINIA
18391*	HEKTOEN ENTERIC / YERSINIA
18422	COLUMBIA CNA / GARDNERELLA
18422*	COLUMBIA CNA / GARDNERELLA
18500	BAIRD PARKER / MAC CONKEY
18500*	BAIRD PARKER / MAC CONKEY
18502	CLED / MAC CONKEY
18502*	CLED / MAC CONKEY
18503	HEKTOEN ENTERIC / SS
18503*	HEKTOEN ENTERIC / SS
18505	MAC CONKEY / S.S.AGAR
18505*	MAC CONKEY / S.S.AGAR
18507	COLUMBIA CNA / CHOCOLATE
18507*	COLUMBIA CNA / CHOCOLATE
18595	D.T.M. / SABOURAUD
18595*	D.T.M. / SABOURAUD
18700	Group A Selective/TSA II + Sheep Blood 5%
18703	CHOCOLATE AGAR /THAYER MARTIN
20075	MAC CONKEY BROTH(7516MC2) 20x5ml
20077	PHYSIOLOGICAL SOLUTION 2.5 ml
20079	PHYSIOLOGICAL SOLUTION 4.5 ML
20081	INOCULUM SOLUTION 5 ML
20089	SUSPENSION BROTH
20090	HELICOBACTER PYLORI TEST
20095	PHYSIOLOGICAL SOLUTION
20105	Glucose Broth
20121	INOCULUM BROTH 7 ML
20129	TRYPTIC SOY BROTH 15 ml
20140	PURPLE LACTOSE BROTH
20156	SUSPENSION MEDIUM 7 ML
20158	MYCOPLASMA TRANSPORT BROTH
20159	TRICHOMONAS BROTH w/o CLORAMPHENICOL
20171	Thioglycollate Medium w Vit.K1 & Hemin
20340	VAGITUBE
21241	Fluid Thioglycollate Medium
22130	SCHAEDLER BROTH
23001	F.B. FASTIDIOUS BROTH
23002	MUELLER HINTON BROTH w HORSE BLOOD (11ml)
23003	MUELLER HINTON BROTH
24070	MYCOSEL BROTH 20PV
24071	Cooked Meat Medium
24091	HAEMOPHILUS TEST BROTH 20 PV
24098	PEPTONE WATER 20PV
24100	Alkaline Peptone Water
24103	NUTRIENT BROTH 20PV
24104	BRAIN HEART INFUSION BROTH 20PV
24105	Glucose Broth
24107	MUELLER HINTON II BROTH 20 PV
24108	MULLER KAUFFMANN BROTH 20PV
24109	Sabouraud Dextrose Broth
24110	Selenite Broth
24111	TODD HEWITT BROTH 20PV
24112	TRYPTOSE BROTH 20PV
24115	TRICHOMONAS BROTH 20PV

24117	Pergola Broth
24119	GN HAJNA BROTH 20PV
24120	BILE AESCULIN BROTH 20PV
24124	Fluid Thioglycollate Medium
24125	SERUM BROTH 20PV
24127	Fluid Thioglycollate Medium + 1% Tween 80
24128	TRYPTIC SOY BROTH + TWEEN 80 1% 20PV
24135	SALMONELLA DIFFERENTIAL BROTH 20PV
24136	TRYPTONE WATER 20PV
24137	MALONATE BROTH 20PV
24139	LYSINE DECARBOXYLASE BROTH 20PV
24141	BRAIN HEART INFUSION BROTH 2 ml 20PV
24142	PHYSIOLOGICAL SOLUTION 3ml 20PV
24143	Selenite Broth
24144	TODD HEWITT w Gentam/Nalidixic acid 20PV
24145	TODD HEWITT B. w Colistin/Nalid.a. 20PV
24146	THIOGLYCOLLATE M w/o INDICATOR acc.USP 20PV
24147	Thiogycollate Bile
24149	MR-VP MEDIUM 20PV
24161	Sabouraud Dextrose Broth + CAF
24241	Fluid Thioglycollate Medium
24342	Motility Test Medium
24343	MIU Semisolid Agar
24345	O.F. Medium with Glucose
24400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH 20PV
24403	BIOTONE BROTH 20PV
24404	CAMPYLOBACTER BROTH 20PV
24411	S.F. BROTH 20PV
24412	STREPTOCOCCUS BROTH 20PV
24413	MOSSEL AND MARTIN w MANNITOL 20PV
24416	UREA BROTH 20PV
24417	Wilkins Chalgren Broth
24430	SCHAEDLER BROTH 20PV
24432	YERSINIA BROTH 20PV
24433	EUGON BROTH 20PV
24436	MIDDLEBROOK 7H9 BROTH 20PV
24446	PHENOL RED BROTH 20PV
24450	Rappaport Broth w/o Soy
24451	Tetrathionate Broth
24459	CASO BROTH (Double Concentration) CE 20PV
24461	RPMI Broth
24462	RPMI Broth (double strength)
24471	Listeria Motility Medium
24513	TRYPTIC SOY BROTH (Harm.EP)
24514	TRYPTIC SOY BROTH
24516	UREA BROTH
26105	Glucose Broth
26124	Fluid Thioglycollate Medium 100 x 10 ml
26342	Motility Test Medium
26400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH
26475	Tryptic Soy Agar
26513	Tryptic Soy Broth
27001	GESA MEDIUM
27500	Triptic Soy Broth
27501	Todd Hewitt Broth
27502	Brain Heart Infusion Broth
27503	Nutrient Broth
29000	CHECK-SET BROTH Irradiated 20 Test
30007	CAMPYLOBACTER SELECTIVE THIOGLYCOLLATE MEDIUM
30008	CLOSTRIDIUM AGAR (Sheep Blood 5%)

30009	HELICOBACTER PYLORI AGAR
30010	STREPTOCOCCAL KF + TTC AGAR
30011	SIMMONS CITRATE AGAR
30013	NITRATI AGAR
30014	MOSSEL AGAR
30022	T.C.B.S. AGAR
30023	Sabouraud CAF Agar
30024	SABOURAUD CAF + ACTIDIONE AGAR
30030	M.R.S. AGAR
30080	BORDET GENGOU AGAR (Sheep Blood 15%)
30081	CHRISTENSEN UREA AGAR
30082	Tryptic Soy Agar
30083	NUTRIENT AGAR
30084	BRAIN HEART INFUSION AGAR
30085	PHENYLALANINE AGAR
30087	KLIGLER IRON AGAR
30088	KLIGLER IRON AGAR + NaCl 2%
30090	Mueller Hinton II Agar
30091	BIGGY (NICKERSON) AGAR
30093	SABOURAUD AGAR
30095	SIM MEDIUM
30096	T.S.I. AGAR
30097	Tryptose Agar
30098	LYSINE IRON AGAR
30099	Chocolate Agar
30116	LOEFFLER MEDIUM
30117	PERGOLA MEDIUM
30118	Lowenstein Jensen Medium
30119	LOWENSTEIN JENSEN MEDIUM w/o GLYCEROL
30121	Stonebrink Medium
30125	DORSET EGG MEDIUM
30368	MIDDLEBROOK 7H10 AGAR
31023	Sabouraud CAF Agar
31065	SPS Agar
31075	Mueller Hinton II Agar
31082	Tryptic Soy Agar
31083	Nutrient Agar ISO 16266
31090	Mueller Hinton II Agar
31097	Tryptose Agar
31099	Chocolate Agar
31121	Stonebrink Medium
31204	MIU Agar
33040	THAYER MARTIN AGAR
33055	MYCOSEL AGAR
33060	SERUM TELLURITE AGAR
33066	O.N.P.G. AGAR
33085	BILE AESCULIN AGAR
33086	DERMATHOPHYTE (D.T.M.) AGAR
33118	I.U.T.M. MEDIUM
33120	PETRAGNANI MEDIUM
34070	CAMPYLOBACTER AGAR
34071	CYSTINE TRYPTIC AGAR (CTA)
34075	Mueller Hinton II Agar
34121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/mL
34121/1	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/mL
34121/2	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/mL
34121/3	LOWENSTEIN JENSEN + RIFAMPICIN 25 µg/mL
34121/4	LOWENSTEIN JENSEN + RIFAMPICIN 50 µg/mL
34121/5	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
34121/6	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL

34122	LOWENSTEIN JENSEN + RIFAPENTIN 9 µg/mL
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/mL
34123/1	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/mL l
34123/2	LOWENSTEIN JENSEN + ISONIAZID 1 µg/mL
34123/3	LOWENSTEIN JENSEN + ISONIAZID 5 µg/mL
34123/4	LOWENSTEIN JENSEN + ISONIAZID 10 µg/mL
34124/1	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/mL
34124/2	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/mL
34124/3	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/mL
34124/4	LOWENSTEIN JENSEN+PYRAZINAMIDE 200 µg/mL
34125/1	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
34125/2	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/mL
34125/3	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/mL
34125/4	LOWENSTEIN JENSEN + STREPTOMYCIN 2 µg/mL
34125/5	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/mL
34126/1	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
34126/2	LOWENSTEIN JENSEN + ETHAMBUTOL 4 µg/mL
34126/3	LOWENSTEIN JENSEN + ETHAMBUTOL 5 µg/mL
34126/4	LOWENSTEIN JENSEN + ETHAMBUTOL 1 µg/mL
34126/5	LOWENSTEIN JENSEN + ETHAMBUTOL 3 µg/mL
34126/6	LOWENSTEIN JENSEN + ETHAMBUTOL 10 µg/mL
34127	LOWENSTEIN JENSEN + AMIKACIN 5 µg/mL
34127/1	LOWENSTEIN JENSEN + AMIKACIN 40 µg/mL
34128/1	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/mL
34128/2	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/mL
34128/3	LOWENSTEIN JENSEN + OFLOXACIN 25 µg/mL
34128/4	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/mL
34128/5	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/mL
34129/1	LOWENSTEIN JENSEN + PAS 1 µg/mL
34129/2	LOWENSTEIN JENSEN + PAS 10 µg/mL
34129/3	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
34129/4	LOWENSTEIN JENSEN + PAS 0.1 µg/mL
34129/5	LOWENSTEIN JENSEN + PAS 5 µg/mL
34130/1	LOWENSTEIN JENSEN + RIFABUTIN 10 µg/mL
34130/2	LOWENSTEIN JENSEN + RIFABUTIN 30 µg/mL
34130/3	LOWENSTEIN JENSEN + RIFABUTIN 50 µg/mL
34131/1	LOWENSTEIN JENSEN+CLARITHROMICIN 4 µg/mL
34131/2	LOWENSTEIN JENSEN+CLARITHROMYCIN 32 µg/mL
34132/1	LOWENSTEIN JENSEN + ETHIONAMIDE 10 µg/mL
34132/2	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
34132/3	LOWENSTEIN JENSEN + ETHIONAMIDE 30 µg/mL
34132/4	LOWENSTEIN JENSEN + ETHIONAMIDE 40 µg/mL
34135/1	LOWENSTEIN JENSEN + NICOTINAMIDE 10 µg/mL
34135/2	LOWENSTEIN JENSEN + NICOTINAMIDE 20 µg/mL
34135/3	LOWENSTEIN JENSEN + NICOTINAMIDE 30 µg/mL
34136	LOWENSTEIN JENSEN + PEFLOXACIN 2 µg/mL
34137/1	LOWENSTEIN JENSEN + CYCLOSERINE 30 µg/mL
34137/2	LOWENSTEIN JENSEN + CYCLOSERINE 10 µg/mL
34137/3	LOWENSTEIN JENSEN + CYCLOSERINE 20 µg/mL
34137/4	LOWENSTEIN JENSEN + CYCLOSERINE 40 µg/mL
34137/5	LOWENSTEIN JENSEN + CYCLOSERINE 50 µg/mL
34138/1	LOWENSTEIN JENSEN + CAPREOMYCIN 10 µg/mL
34138/2	LOWENSTEIN JENSEN + CAPREOMYCIN 40 µg/mL
34138/3	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/mL
34138/4	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/mL
34139/1	LOWENSTEIN JENSEN + CLOFAZIMINE 5 µg/mL
34139/2	LOWENSTEIN JENSEN + CLOFAZIMINE 10 µg/mL
34143/1	LOWENSTEIN JENSEN + KANAMYCIN 10 µg/mL
34143/2	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
34143/3	LOWENSTEIN JENSEN + KANAMYCIN 30 µg/mL

34144	LOWENSTEIN JENSEN + PYRUVATE 0.2%
34145	LOW.JENSEN + PACT
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml
35000	LOWENSTEIN JENSEN MEDIUM
35001	LOWENSTEIN JENSEN + ISONIAZID 0.20 µg/mL
35002	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml
35010	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
35011	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
35020	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
35021	LOWENSTEIN JENSEN + STREPTOMYCIN 10µg/ml
35030	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
35040	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
35041	LOWENSTEIN JENSEN + ETHIONAMIDE 30µg/ml
35050	LOWENSTEIN JENSEN + PYRAZINAMIDE 1 µg/mL
35060	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
35061	LOWENSTEIN JENSEN + KANAMYCIN 30µg/ml
35070	LOWENSTEIN JENSEN + PAS 1 µg/mL
35071	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
35080	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/ml
35081	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml
35082	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml
35090	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/ml
35091	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/ml
35147	LOWENSTEIN JENSEN + PNB 500 µg/ml
35148	LOWENSTEIN JENSEN + TCH 2 µg/ml
36001/1	IUTM + STREPTOMYCIN 2 µg/mL
36001/2	IUTM + STREPTOMYCIN 4 µg/mL
36001/3	IUTM + STREPTOMYCIN 10 µg/mL
36001/4	IUTM + STREPTOMYCIN 25 µg/mL
36001/5	IUTM + STREPTOMYCIN 50 µg/mL
36002/1	IUTM + ISONIAZID 0.1 µg/mL
36002/2	IUTM + ISONIAZID 0.2 µg/mL
36002/3	IUTM + ISONIAZID 1 µg/mL
36002/4	IUTM + ISONIAZID 5 µg/mL
36002/5	IUTM + ISONIAZID 10 µg/mL
36003/1	IUTM + ETHAMBUTOL 1 µg/mL
36003/2	IUTM + ETHAMBUTOL 2 µg/mL
36003/3	IUTM + ETHAMBUTOL 3 µg/mL
36003/4	IUTM + ETHAMBUTOL 5 µg/mL
36003/5	IUTM + ETHAMBUTOL 10 µg/mL
36004/1	IUTM + RIFAMPICIN 5 µg/mL
36004/2	IUTM + RIFAMPICIN 10 µg/mL l
36004/3	IUTM + RIFAMPICIN 20 µg/mL
36004/4	IUTM + RIFAMPICIN 40 µg/mL
36004/5	IUTM + RIFAMPICIN 50 µg/mL
36005/1	IUTM + RIFABUTIN 10 µg/mL
36005/2	IUTM + RIFABUTIN 20 µg/mL
36005/3	IUTM + RIFABUTIN 30 µg/mL
36005/4	IUTM + RIFABUTIN 40 µg/mL
36005/5	IUTM + RIFABUTIN 50 µg/mL
36006/1	IUTM + CYCLOSERINE 10 µg/mL
36006/2	IUTM + CYCLOSERINE 20 µg/mL
36006/3	IUTM + CYCLOSERINE 30 µg/mL
36006/4	IUTM + CYCLOSERINE 40 µg/mL
36006/5	IUTM + CYCLOSERINE 50 µg/mL
36007/1	IUTM + OFLOXACIN 1.25 µg/mL
36007/2	IUTM + OFLOXACIN 2.5 µg/mL
36007/3	IUTM + OFLOXACIN 10 µg/mL
36007/4	IUTM + OFLOXACIN 25 µg/mL
36007/5	IUTM + OFLOXACIN 50 µg/mL

36008/1	IUTM + PAS 0.1 µg/mL
36008/2	IUTM + PAS 0.5 µg/mL
36008/3	IUTM + PAS 1 µg/mL
36008/4	IUTM + PAS 5 µg/mL
36008/5	IUTM + PAS 10 µg/mL
36009/1	IUTM + PYRAZINAMIDE 10 µg/mL
36009/2	IUTM + PYRAZINAMIDE 30 µg/mL
36009/3	IUTM + PYRAZINAMIDE 50 µg/mL
36009/4	IUTM + PYRAZINAMIDE 70 µg/mL
36009/5	IUTM + PYRAZINAMIDE 90 µg/mL
37000	MIDDLEBROOK 7H11
37001	MIDDLEBROOK 7H11 + AMIKACIN 2 µg/mL
37002	MIDDLEBROOK 7H11 + AMIKACIN 4 µg/mL
37006	MIDDLEBROOK 7H11 + ETHAMBUTOL 7.5 µg/mL
37011	MIDDLEBROOK 7H11 + ETHIONAMIDE 10 µg/mL
37016	MIDDLEBROOK 7H11 + ISONIAZIDE 0.2 µg/mL
37017	MIDDLEBROOK 7H11 + ISONIAZIDE 1 µg/mL
37021	MIDDLEBROOK 7H11 + KANAMYCIN 6 µg/mL
37026	MIDDLEBROOK 7H11 + PAS 8 µg/mL
37031	MIDDLEBROOK 7H11 + PYRAZINAMIDE 25 µg/mL
37036	MIDDLEBROOK 7H11 + RIFABUTIN 1 µg/mL
37037	MIDDLEBROOK 7H11 + RIFABUTIN 0.5 µg/mL
37041	MIDDLEBROOK 7H11 + RIFAMPICIN 1 µg/mL
37046	MIDDLEBROOK 7H11 + STREPTOMYCIN 2 µg/mL
37051	MIDDLEBROOK 7H11 + OFLOXACIN 2 µg/mL
37056	MIDDLEBROOK 7H11 + CYCLOSERINE 30 µg/mL
400020	Fluid Thioglycollate Medium 6 x 100 ml
400120	Fluid Thioglycollate Medium 6 x 300 ml
400220	Fluid Thioglycollate Medium 6 x 1000 ml
401890	BUFFER SOLUTION pH 7 6X100 ml
401930	SPS Agar 6X150 ml
401980	TRYPTONE WATER 6X100 ml
401990	Alkaline Peptone Water 6 x 100 ml
402000	NUTRIENT BROTH 6X100 ml
402020	MUELLER HINTON II BROTH 6X100 ml
402030	MULLER KAUFFMANN BROTH 6X100 ml
402040	Sabouraud Dextrose Broth 6 x 100 ml
402050	Selenite Broth 6 x 100 ml
402060	SALMONELLA DIFF.BROTH 6X90 ml
402070	TRYPTOSE BROTH 6X100 ml
402120	MRS AGAR 6X100 ml
402130	PEPTONE WATER 6X100 ml
402140	BLOOD AGAR BASE 6X100 ml
402170	AZIDE BLOOD AGAR BASE 6X100 ml
402180	CLED AGAR 6X100 ml
402190	NUTRIENT AGAR 6X100 ml
402200	DERMATHOPHYTE (D.T.M.) AGAR 6X100 ml
402210	COLUMBIA CNA AGAR BASE 6X100 ml
402220	DRIGALSKI LACTOSE AGAR 6X100 ml
402230	HEKTOEN ENTERIC AGAR 6X100 ml
402240	MAC CONKEY AGAR 6X100 ml
402250	MUELLER HINTON II AGAR 6X100 ml
402270	PSEUDOMONAS CETRIMIDE AGAR 6X100 ml
402280	SABOURAUD AGAR 6X100 ml
402290	MANNITOL SALT AGAR 6X100 ml
402300	S.S. AGAR 6X100 ml
402320	TRYPTOSE AGAR 6X100 ml
402330	BRILLIANT GREEN AGAR 6X100 ml
402340	DESOXYCHOLATE AGAR 6X100 ml
402350	E.M.B. LEVINE AGAR 6X100 ml
402360	SALMONELLA RAPID TEST 6X100 ml
402370	SABOURAUD CAF AGAR 6X100 ml
402380	BRAIN HEART INFUSION AGAR 6X100 ml
402430	PEPTONE DILUITIONS 6X100 ml
402450	MAC CONKEY SORBITOL AGAR 6X100 ml
402500	Fluid Thioglycollate Medium + 1% Tween 80
402570	X.L.D. AGAR 6X100 ml
403030	BIOTONE BROTH 6X100 ml
403050	S.I.M. MEDIUM 6X100 ml
403060	UREA INDOLE BROTH 6X100 ml
403130	Monsur Agar 6 x 100 ml
403140	TCBS Agar 6 x 100 ml
412010	BRAIN HEART INFUSION BROTH 6X200 ml
412030	SIMMONS CITRATE AGAR 6X200 ml
412040	LYSINE IRON AGAR 6X200 ml
412050	Selenite Broth 6 x 200 ml
412060	TODD HEWITT BROTH 6X200 ml
412080	TRICHOMONAS BROTH 6X200 ml
412100	CHRISTENSEN UREA AGAR 5X200 ml
412110	TRYPTIC SOY BROTH + TWEEN80 1% 6x200ml
412130	PSEUDOMONAS AGAR BASE 6x200ml
412150	AZIDE BLOOD AGAR BASE 6X200 ml
412170	PHENILALANINE AGAR 6X200 ml
412180	CLED AGAR 6X200 ml
412190	NUTRIENT AGAR 6X200 ml
412210	COLUMBIA CNA AGAR BASE 6X200 ml
412230	HEKTOEN ENTERIC AGAR 6X200 ml
412240	MAC CONKEY AGAR 6X200 ml
412250	MUELLER HINTON II AGAR 6X200 ml
412270	PSEUDOMONAS CETRIMIDE AGAR 6X200 ml
412280	SABOURAUD AGAR 6X200 ml
412290	MANNITOL SALT AGAR 6X200 ml
412300	S.S. AGAR 6X200 ml
412370	SABOURAUD CAF AGAR 6X200 ml
413010	ISOSENSITEST AGAR 6X200 ml
413030	CAMPYLOBACTER AGAR 6X200 ml
413040	CLOSTRIDIUM AGAR BASE 6X200 ml
413080	NUTRIENT AGAR acc. to ISO 6579
413130	Nutrient Agar semisolid 6 x 200 ml
414010	PEPTONE WATER pH 8.4 + NaCl 1% 6X225 ml
432050	Selenite Broth (Double Concentration)
432080	TRYPTIC SOY BROTH 6X225 ml
432250	D-Nase TEST AGAR 6X200 ml
432290	Tryptic Soy Agar 6 x 200 ml
442080	TRYPTIC SOY BROTH 6X200 ml
442220	Chocolate Agar 6x 100 ml
442280	SABOURAUD MODIFIED AGAR 6X100 ml
442290	Tryptic Soy Agar 6 x 100 ml
442300	WURTZ LACTOSE AGAR 6X100 ml
442320	BILE AESCULIN AGAR 6X100 ml
442350	BIGGY (NICKERSON) AGAR 6X100 ml
442490	SPS AGAR 6X100 ml
451404	Alkaline Peptone Water 25 x 225 ml
452040	Sabouraud Dextrose Broth 25 x 100 mL
452060	Fluid Thioglycollate Medium 6 x 100 ml
452080	TRYPTIC SOY BROTH 6X100 ml
452210	COLUMBIA AGAR BASE 6X200 ml
452500	Fluid Thioglycollate Medium + 1% Tween 80 25 x 100 ml
453060	Fluid Thioglycollate Medium 25 x 100 ml
463100	Fluid Thioglycollate Medium 6 x 900 ml

463130	Selenite Broth 6 x 1000 ml
470010	Tryptic Soy Agar 6 x 500 ml
470020	Selenite Broth 6 x 500 ml
470030	DESOXYCHOLATE AGAR 6X500 ml
470040	SABOURAUD AGAR 6X500 ml
470050	NUTRIENT BROTH 6X500 ml
470060	NUTRIENT AGAR 6X500 ml
470070	Mueller Hinton II Agar 6X500 ml
470080	MANNITOL SALT AGAR 6X500 ml
470090	MAC CONKEY AGAR 6X500 ml
470100	COLUMBIA AGAR BASE 6X500 ml
470110	CLED AGAR 6X500 ml
470120	Chocolate Agar 6 x 500 ml
470130	BLOOD AGAR BASE 6X500 ml
470140	BILE AESCULIN AGAR 6X500 ml
470150	TRICHOMONAS BROTH 6X500 ml
470160	DESOXYCHOLATE CITRATE AGAR 6X500 ml
470210	Alkaline Peptone Water 6 x 500 ml
470220	CZAPEK DOX AGAR 6X500 ml
470280	DRIGALSKI LACTOSE AGAR 6X500 ml
470290	CARY BLAIR TRANSPORT MEDIUM 6X500 ml
470300	Fluid Thioglycollate Medium 6 x 500 ml
470320	PEPTONE WATER 6X500 ml
470370	TRYPTIC SOY BROTH 6 x 500 ml
471070	Sabouraud Dextrose Broth 6 x 500 ml
471120	PHYSIOLOGICAL SOLUTION 6X240 ml
473000	PHYSIOLOGICAL SOLUTION 6X500 ml
481110	CHROMATIC™ CANDIDA 6X100 ml
481130	CHROMATIC™ DETECTION 6X100 ml
481140	CHROMATIC™ SALMONELLA 6X100 ml
481160	CHROMATIC™ STAPH AUREUS 6X100 ml
481180	CHROMATIC™ STREP B 6X100ml
482190	Chromatic™ E.coli O157 6 x 200 ml
490010	HEMO-AEROBIC culturing 6X80 ml
490020	HEMO-ANAEROBIC culturing 6X80 ml
490030	HEMO-AEROBIC culturing-Pediatric 6X40 ml
490040	HEMO-ANAEROBIC culturing-Pediatric 6X40ml
490050	HEMO-AEROBIC culturing NEONATAL 6x9 ml
490060	HEMO-ANAEROBIC culturing NEONATAL 6x9 ml
493000	Fluid Thioglycollate Medium 6 x 100 ml
495010	TRYPTIC SOY BROTH 6x100 ml
495020	Fluid Thioglycollate Medium 6 x 100 ml
500142	URITEST PENTA
500152	URITEST
500182	URITEST M
500702	URITEST EF
50020	VAGITEST
50021	DERMATEST
500232	URITEST N
500302	URITEST 2
500402	URITEST MALTO
500412	URITEST EC
51014	URITEST PENTA
51015	URITEST
51018	URITEST M
51020	VAGITEST 120 slide
51021	DERMATEST
51023	URITEST N
51024	URITEST C
51030	URITEST 2
51040	URITEST MALTO
51041	URITEST EC
51070	URITEST EF
51118	URITEST M
51123	URITEST N 500 slide
51130	URITEST 2 500 slide
51140	URITEST MALTO
51170	CLED/MAC CONKEY/ BILE AESCULIN
52115	CLED/MAC CONKEY/SLANETZ 120 slide
52119	URITEST SF 500 slide
610001	BILE AESCULIN AZIDE AGAR
610002	DEXTROSE AGAR
610005	BLOOD AGAR BASE
610006	BORDET GENGOU AGAR BASE
610007	BRAIN HEART INFUSION AGAR
610008	BRAIN HEART INFUSION BROTH
6100085	BRAIN HEART INFUSION BROTH
610009	BRILLIANT GREEN AGAR
610012	CLED AGAR
6100125	CLED AGAR
610013	COLUMBIA AGAR BASE
6100135	COLUMBIA AGAR BASE
610014	DESOXYCHOLATE AGAR
6100145	DESOXYCHOLATE AGAR
610015	DESOXYCHOLATE CITRATE AGAR
610016	DRIGALSKI LACTOSE AGAR
610019	E.M.B. LEVINE AGAR
610021	HEKTOEN ENTERIC AGAR
6100215	HEKTOEN ENTERIC AGAR
610022	G.C. MEDIUM
610023	KLIGLER IRON AGAR
610024	M.R.S. AGAR (ISO/FDIS 15214)
610025	M.R.S. BROTH (ISO/FDIS 15214)
610026	LOWENSTEIN JENSEN MEDIUM
6100265	LOWENSTEIN JENSEN MEDIUM
610027	LYSINE IRON AGAR
610028	MAC CONKEY AGAR
6100285	MAC CONKEY AGAR
610029	MANNITOL SALT AGAR
6100295	MANNITOL SALT AGAR
610032	MR-VP BROTH
610033	MUELLER HINTON AGAR
6100335	MUELLER HINTON AGAR
610034	MUELLER HINTON BROTH
610035	MULLER KAUFFMANN BROTH
610036	Nutrient Agar ISO 16266
6100365	Nutrient Agar ISO 16266
610037	NUTRIENT BROTH
6100375	NUTRIENT BROTH
610038	PEPTONE WATER
610039	PHENYLALANINE AGAR
610041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
6100415	PSEUDOMONAS CETRIMIDE AGAR
610042	SS AGAR (MODIFIED)
6100425	SS AGAR (MODIFIED)
610043	SCHAEDLER AGAR BASE
610044	PURPLE LACTOSE AGAR
610046	SIMMONS CITRATE AGAR
610047	MONSUR AGAR
610048	AEROMONAS AGAR BASE

610049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
610050	Fluid Thioglycollate Medium
6100505	Fluid Thioglycollate Medium
610051	TODD HEWITT BROTH
6100515	TODD HEWITT BROTH
610052	Tryptic Soy Agar
6100525	Tryptic Soy Agar
610053	TRYPTIC SOY BROTH
6100535	TRYPTIC SOY BROTH
610055	T.S.I. AGAR USP
610056	CLOSTRIDIUM BROTH
6100565	CLOSTRIDIUM BROTH
610057	MAC CONKEY AGAR No.2
6100575	MAC CONKEY AGAR No.2 5 KG
610060	X.L.D. AGAR (ISO 6579)
6100605	X.L.D. AGAR
610061	TRICHOMONAS BROTH
610065	GSB AGAR BASE (ISLAM)
610071	PSEUDOMONAS AGAR BASE
610072	CZAPEK DOX BROTH
610075	PHENYLALANINE MALONATE BROTH
610079	BRUCELLA AGAR BASE
610080	WORT BROTH W/O NaCl
610092	XLT 4 AGAR
610095	CZAPEK DOX AGAR
610096	REINFORCED CLOSTRIDIAL AGAR
610097	STAPHYLOCOCCUS BROTH
610098	Alkaline Peptone Water
610101	MALT AGAR
610103	SABOURAUD AGAR
6101035	SABOURAUD AGAR
610104	Sabouraud Dextrose Broth
610107	UREA AGAR BASE (ISO 6785)
610108	MAC CONKEY SORBITOL AGAR
610109	P.P.L.O. BROTH
610110	MUELLER HINTON AGAR MODIFIED
610111	YERSINIA SELECTIVE AGAR BASE
610112	CLED ANDRADE AGAR
610113	COLUMBIA CNA AGAR BASE
610114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
610115	CLOSTRIDIUM DIFFICILE AGAR BASE
610117	TRYPTONE YEAST AGAR
610118	ANDRADE LACTOSE PEPTONE WATER
610123	CORN MEAL AGAR
610125	LEGIONELLA CYE AGAR BASE
610128	MAC CONKEY AGAR w/o BILE SALT
610130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
610131	CAMPYLOBACTER ENRICHMENT BROTH BASE
610132	MOTILITY TEST AGAR
610134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
610135	BIGGY (NICKERSON) AGAR
610136	BACILLUS CEREUS AGAR BASE (PEMBA)
610137	SCHAEDLER BROTH
610140	E.M.B. AGAR w LACTOSE + SUCROSE
610143	LIVER BROTH
610144	MRS BROTH w/o GLUCOSE
610145	Selenite Broth
6101455	Selenite Broth
610146	SABOURAUD MALTOSE AGAR
610147	SLANETZ AND BARTLEY AGAR + TTC
6101475	SLANETZ AND BARTLEY AGAR + TTC
610148	SPS AGAR
610151	BILE AESCULIN BROTH
610152	AMIES TRANSPORT MEDIUM + CHARC.
6101525	AMIES TRANSPORT MEDIUM + CHARC.
610153	AZIDE BLOOD AGAR BASE
610155	AZIDE VIOLET BLOOD AGAR BASE
610157	BIOTONE AGAR
610158	BIOTONE BROTH
610159	CPLM SELECTIVE WITH CAF
610160	DERMATOPHYTE (D.T.M.) AGAR
610161	DEXTROSE BROTH
610163	G.N. HAJNA BROTH
610164	HERELLEA AGAR
6101645	HERELLEA AGAR
610165	KOSER CITRATE MEDIUM
610168	LISTERIA PALCAM AGAR
610169	I.U.T.M. MEDIUM
610170	MAC CONKEY MMG AGAR
6101705	MAC CONKEY MMG AGAR
610172	MALONATE BROTH
610174	PHENOL RED BROTH BASE
610175	RAPPAPORT VASSILIADIS BROTH (ISO 6785-6579)
610176	ROGOSA AGAR
610177	ROGOSA BROTH
610179	SABOURAUD CAF AGAR + ACTIDIONE
610180	S.F. BROTH
610181	S.I.M. MEDIUM
610182	STUART TRANSPORT MEDIUM
610183	TETRATHIONATE BROTH BASE
610185	TRYPTIC (CTA) MEDIUM
610186	VOGEL JOHNSON AGAR
610188	BLOOD AGAR BASE N. 2
610191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
6101915	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
610193	TRYPTOSE AGAR
610195	MAC CONKEY AGAR w/o CRYSTAL VIOLET
610196	TRYPTIC BILE AGAR
610197	TRYPTOFAN BROTH
610200	CAMPYLOBACTER KARMALI AGAR BASE
610203	SABOURAUD CAF AGAR
6102035	SABOURAUD CAF AGAR 5 KG
610205	DNase TEST AGAR
610206	TRYPTONE WATER (ISO/DIS 3811)
610207	CLOSTRIDIUM PERFRIGENS AGAR BASE
610210	BILE AESCULIN AGAR
610211	KLIGLER IRON AGAR MOD.
610214	MIDDLEBROOK 7H9 BROTH BASE
610217	NUTRIENT BROTH N.2
610218	Mueller Hinton II Broth
610221	ANTIBIOTIC TEST MEDIUM
610222	CLOSTRIDIUM BROTH w/o AGAR
6102225	CLOSTRIDIUM BROTH w/o AGAR
610223	MAC CONKEY AGAR w/o Salt
610227	PHENOL RED AGAR BASE
610229	ANTIBIOTIC MEDIUM E
610230	OXIDATIVE/FERMENTATIVE MEDIUM
610233	TRYPTOSE BROTH
610235	MANNITOL MOTILITY TEST MEDIUM
610236	MOTILITY INDOLE UREA AGAR (M.I.U.)

610245	LB AGAR
610301	BISMUTH SULPHITE AGAR
610303	Lysine Decarboxylase Broth
610304	OF BASAL MEDIUM
610305	ORNITHINE DECARBOXYLASE BROTH
610306	ARGININE DECARBOXYLASE BROTH
610308	PHENOL RED AGAR BASE
610309	PSEUDOMONAS AGAR F
610310	PSEUDOMONAS AGAR P
610311	UREA BROTH
610315	ANTIBIOTIC AGAR N.11
610319	PFIZER SELECTIVE ENTEROCOCCUS AGAR
610322	NITRATE BROTH
610331	DIAGNOSTIC SENSITIVITY TEST AGAR (D.S.T.)
610339	T.S.I. AGAR acc.EP
610341	EMGON BROTH
610343	MANNITOL SALT BROTH
610363	Yeast Extract Sodium Lactate medium
610364	Tryptose Phosphate Broth
6103645	Tryptose Phosphate Broth
610372	Cooked Meat Medium
610492	POLYPEPTONE
610495	BRAIN HEART INFUSION
6104955	BRAIN HEART INFUSION
610496	ACID HYDROLISATE OF CASEIN
610497	BEEF EXTRACT
6104975	BEEF EXTRACT
610498	LACTOSE
6104985	LACTOSE
610506	CYSTINE HEART AGAR
610611	CHROMATIC™ SALMONELLA
610612	CHROMATIC™ DETECTION
6106125	CHROMATIC™ DETECTION
610613	CHROMATIC™ CANDIDA
610614	Chromatic™ E.coli O157
610615	CHROMATIC™ MRSA
610616	CHROMATIC™ STAPH AUREUS
610617	CHROMATIC™ STREP B
610625	SABOURAUD CAF (50 mg/L) AGAR
610627	MUELLER HINTON II AGAR
6106275	MUELLER HINTON II AGAR
610629	CHROMATIC™ ESBL
610633	Chromatic™ Vibrio
611000	SODIUM CHLORIDE
611001	AGAR
6110015	AGAR
611002	GELATIN BACTERIOLOGICAL
6110025	GELATIN BACTERIOLOGICAL
611003	SODIUM SELENITE
6110035	SODIUM SELENITE
611004	TRYPTONE
6110045	TRYPTONE
611005	YEAST EXTRACT
6110055	YEAST EXTRACT
611006	MALT EXTRACT
6110065	MALT EXTRACT
611007	CAMPYLOBACTER AGAR BASE
611008	TRYPTOSE
6110085	TRYPTOSE
611009	GLUCOSIO
611010	T.C.B.S. AGAR
611015	SIERRA LIPOLYTIC AGAR
611021	HEART INFUSION BROTH
6110215	HEART INFUSION BROTH
611022	MIDDLEBROOK 7H10 AGAR BASE
611203	SABOURAUD CAF (1g/l) AGAR
611210	WURTZ LACTOSE AGAR
611265	ISOSENSITEST AGAR
611366	STAPHYLOCOCCUS 110 AGAR
611367	BILE BACTERIOLOGICAL
611401	IRON SULPHITE AGAR
611402	CARY BLAIR TRANSPORT MEDIUM
611502	CASEIN PEPTONE
611601	GLUCOSE
6116015	GLUCOSE
611602	Maltose
611618	CHROMATIC™ MH
611619	CHROMATIC™ CRE AGAR BASE
611701	PEPTONE BACTERIOLOGICAL
6117015	PEPTONE BACTERIOLOGICAL
611706	Hemoglobin
611801	SUCROSE
6118015	SUCROSE
611901	BILE SALT N.3
6119015	BILE SALT N.3
612001	LIVER EXTRACT
6120015	LIVER EXTRACT
612101	PEPTONE MYCOLOGICAL
6121015	PEPTONE MYCOLOGICAL
612201	PROTEOSE PEPTONE
6122015	PROTEOSE PEPTONE
612202	STREPTOCOCCUS SELECTIVE AGAR
612203	STREPTOCOCCUS BROTH
612501	SOY PEPTONE
6125015	SOY PEPTONE
620001	BILE AESCULIN AZIDE AGAR
620002	DEXTROSE AGAR
620005	BLOOD AGAR BASE
620006	BORDET GENGOU AGAR BASE
620007	BRAIN HEART INFUSION AGAR
620008	BRAIN HEART INFUSION BROTH
620009	BRILLIANT GREEN AGAR
620012	CLED AGAR
620013	COLUMBIA AGAR BASE
620014	DESOXYCHOLATE AGAR
620015	DESOXYCHOLATE CITRATE AGAR
620016	DRIGALSKY LACTOSE AGAR
620019	E.M.B. LEVINE AGAR
620021	HEKTOEN ENTERIC AGAR
620022	G.C. MEDIUM
620023	KLIGLER IRON AGAR
620024	M.R.S. AGAR (ISO/FDIS 15214)
620025	M.R.S. BROTH (ISO/FDIS 15214)
620026	LOWENSTEIN JENSEN MEDIUM
620027	LYSINE IRON AGAR
620028	MAC CONKEY AGAR
620029	MANNITOL SALT AGAR
620032	MR-VP BROTH
620033	MUELLER HINTON AGAR
620034	MUELLER HINTON BROTH

620035	MULLER KAUFFMANN BROTH
620036	Nutrient Agar ISO 16266
620037	NUTRIENT BROTH
620038	PEPTONE WATER
620039	PHENYLALANINE AGAR
620041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
620042	SS AGAR (MODIFIED)
620043	SCHAEDLER AGAR BASE
620044	PURPLE LACTOSE AGAR
620046	SIMMONS CITRATE AGAR
620047	MONSUR AGAR
620048	AEROMONAS AGAR BASE
620049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
620050	Fluid Thioglycollate Medium
620051	TODD HEWITT BROTH
620052	Tryptic Soy Agar
620053	TRYPTIC SOY BROTH
620055	T.S.I. AGAR USP
620056	CLOSTRIDIUM BROTH
620057	MAC CONKEY AGAR No.2
620060	X.L.D. AGAR (ISO 6579)
620061	TRICHOMONAS BROTH
620065	GSB AGAR BASE (ISLAM)
620071	PSEUDOMONAS AGAR BASE
620072	CZAPEK DOX BROTH
620075	PHENYLALANINE MALONATE BROTH
620079	BRUCELLA AGAR BASE
620092	XLT 4 AGAR
620095	CZAPEK DOX AGAR
620096	REINFORCED CLOSTRIDIAL AGAR
620097	STAPHYLOCOCCUS BROTH
620098	Alkaline Peptone Water
620101	MALT AGAR
620103	SABOURAUD AGAR
620104	Sabouraud Dextrose Broth
620107	UREA AGAR BASE (ISO 6785)
620108	MAC CONKEY SORBITOL AGAR
620109	P.P.L.O. BROTH
620110	MUELLER HINTON AGAR MODIFIED
620111	YERSINIA SELECTIVE AGAR BASE
620112	CLED ANDRADE AGAR
620113	COLUMBIA CNA AGAR BASE
620114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
620115	CLOSTRIDIUM DIFFICILE AGAR BASE
620117	TRYPTONE YEAST AGAR
620118	ANDRADE LACTOSE PEPTONE WATER
620122	MIDDLEBROOK 7H10 AGAR BASE
620123	CORN MEAL AGAR
620125	LEGIONELLA CYE AGAR BASE
620130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
620131	CAMPYLOBACTER ENRICHMENT BROTH BASE
620132	MOTILITY TEST AGAR
620134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
620135	BIGGY (NICKERSON) AGAR
620136	BACILLUS CEREUS AGAR BASE (PEMBA)
620137	SCHAEDLER BROTH
620140	E.M.B. AGAR w LACTOSE + SUCROSE
620143	LIVER BROTH
620144	MRS BROTH w/o GLUCOSE
620145	Selenite Broth
620146	SABOURAUD MALTOSE AGAR
620147	SLANETZ AND BARTLEY AGAR + TTC
620148	SPS AGAR
620151	BILE AESCULIN BROTH
620152	AMIES TRANSPORT MEDIUM + CHARC.
620153	AZIDE BLOOD AGAR BASE
620155	AZIDE VIOLET BLOOD AGAR BASE
620157	BIOTONE AGAR
620158	BIOTONE BROTH
620159	CPLM SELECTIVE WITHCAF
620160	DERMATOPHYTE (D.T.M.) AGAR
620161	DEXTROSE BROTH
620163	G.N. HAJNA BROTH
620164	HERELLEA AGAR
620165	KOSER CITRATE BROTH
620168	LISTERIA PALCAM AGAR
620169	I.U.T.M. MEDIUM
620170	MAC CONKEY MMG AGAR
620172	MALONATE BROTH
620174	PHENOL RED BROTH BASE
620175	RAPPAPORT VASSILIADIS BROTH
620176	ROGOSA AGAR
620177	ROGOSA BROTH
620179	SABOURAUD CAF AGAR + ACTIDIONE
620180	S.F. BROTH
620181	S.I.M. MEDIUM
620182	STUART TRANSPORT MEDIUM
620183	TETRATHIONATE BROTH BASE
620185	TRYPTIC (CTA) MEDIUM
620186	VOGEL JOHNSON AGAR
620188	BLOOD AGAR BASE N. 2
620191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
620193	TRYPTOSE AGAR
620195	MAC CONKEY AGSAR w/o CRYSTAL VIOLET
620196	TRYPTIC BILE AGAR
620197	TRYPTOFAN BROTH
620200	CAMPYLOBACTER KARMALI AGAR BASE
620203	SABOURAUD CAF AGAR
620205	DNase TEST AGAR
620206	TRYPTONE WATER (ISO/DIS 3811)
620207	CLOSTRIDIUM PERFRIGENS AGAR BASE
620210	BILE AESCULIN AGAR
620211	KLIGLER IRON AGAR MOD.
620214	MIDDLEBROOK 7H9 BROTH BASE
620217	NUTRIENT BROTH N.2
620218	Mueller Hinton II Broth
620227	PHENOL RED AGAR BASE
620229	ANTIBIOTIC MEDIUM E
620233	TRYPTOSE BROTH
620235	MANNITOL MOTILITY TEST MEDIUM
620303	Lysine Decarboxylase Broth
620309	PSEUDOMONAS AGAR F
620311	UREA BROTH
620495	BRAIN HEART INFUSION
620496	ACID HYDROLISATE OF CASEIN
620497	BEEF EXTRACT
620498	LACTOSE
620611	CHROMATIC™ SALMONELLA
620612	CHROMATIC™ DETECTION
620613	CHROMATIC™ CANDIDA

620614	Chromatic™ E.coli O157
620615	CHROMATIC™ MRSA
620616	CHROMATIC™ STAPH AUREUS
620617	CHROMATIC™ STREP B
620627	MUELLER HINTON II AGAR
620629	CHROMATIC™ ESBL
621000	SODIUM CHLORIDE
621001	AGAR
621003	SODIUM SELENITE
621004	TRYPTONE
621005	YEAST EXTRACT
621006	MALT EXTRACT
621007	CAMPYLOBACTER AGAR BASE
621010	TCBS AGAR
621015	SIERRA LIPOLYTIC AGAR
621021	HEART INFUSION BROTH
621022	MIDDLEBROOK 7H10 AGAR BASE
621210	WURTZ LACTOSE AGAR
621265	ISOSENSITEST AGAR
621367	BILE BACTERIOLOGICAL
621401	IRON SULPHITE AGAR
621402	CARY BLAIR TRANSPORT MEDIUM
621601	GLUCOSE
621618	CHROMATIC™ MH
621619	CHROMATIC™ CRE AGAR BASE
621701	PEPTONE BACTERIOLOGICAL
622202	STREPTOCOCCUS SELECTIVE AGAR
630026	LOWENSTEIN JENSEN MEDIUM w GLYCEROL 1 litre
71618	ENTEROSYSTEM 18R 20 Test
71619	Enterosytem 24R 20 Test
71620	Anaerobe System 20 Test
71630	STAF SYSTEM 18 R 20 Test
71670	COPRO SYSTEM 40 Test
71675	COPRO SYSTEM Plus 20 Test
71678	PATHOGENIC SYSTEM DOUBLE 40 Test
71679	PATHOGENIC SYSTEM 20 Test
71681	PATHOGENIC SYSTEM AST
71714	INTEGRAL SYSTEM ENTEROBATTERI 20 Test
71718	INTEGRAL SYSTEM STAFILOCOCCHI 20 Test
71720	INTEGRAL SYSTEM STREPTOCOCCHI 20 Test
71724	INTEGRAL SYSTEM GARDNERELLA 20 TEST
71822	INTEGRAL SYSTEM YEASTS Plus 20 Test
72560	STREPTO SYSTEM 12 R 40 Test
72592	MYCOPLASMA SYSTEM Plus 20 Test
74156	A.F. GENITAL SYSTEM 20 Test
74160	URIN SYSTEM Plus 20 Test
74161	URIN SYSTEM Chrom 20 Test
75001	SensiTest Colistin 0.25 - 16 mg/L
76010	Sensi Test gram-negative 20 Test
76020	Sensi Test gram-positive 20 Test
76031	SensiQuattro Gram-negative 20 Test
76032	SensiQuattro Gram-positive 20 Test
76033	SensiQuattro Candida EU 20 Test
78618	ENTERO PLURI TEST 10 Test
78619	ENTERO PLURI TEST 25 Test
78620	OXI/FERM PLURI TEST 10 Test
78621	OXI/FERM PLURI TEST 25 Test
79010	Sensi Test gram-negative 4 Test
79020	Sensi Test gram-positive 4 Test
79031	SensiQuattro Gram-negative 4 Test
79032	SensiQuattro Gram-positive 4 Test
79033	SensiQuattro Candida EU 4 Test
79156	A.F. GENITAL SYSTEM 4 Test
79160	URIN SYSTEM Plus 4 Test
79161	URIN SYSTEM Chrom 4 Test
79560	STREPTO SYSTEM 12 R 8 Test
79592	MYCOPLASMA SYSTEM Plus 4 Test
79618	ENTEROSYSTEM 18R 4 Test
79619	Enterosytem 24R 4 Test
79620	Anaerobe System 4 Test
79630	STAF SYSTEM 18 R 4 Test
79670	COPRO SYSTEM 8 Test
79675	COPRO SYSTEM Plus 4 Test
79678	PATHOGENIC SYSTEM DOUBLE 8 Test
79679	PATHOGENIC SYSTEM 4 Test
79681	PATHOGENIC SYSTEM AST
79714	INTEGRAL SYSTEM ENTEROBATTERI 4 Test
79718	INTEGRAL SYSTEM STAFILOCOCCHI 4 Test
79720	INTEGRAL SYSTEM STREPTOCOCCHI 4 Test
79724	INTEGRAL SYSTEM GARDNERELLA 4 Test
79822	INTEGRAL SYSTEM YEASTS Plus 4 Test
80009	IODINE MKTT SOLUTION 10 x 10 ml
80010	XLT 4 supplement 2 x 50 ml
80021	GLYCEROL supplement 4 x 50 ml
80022	POTASSIUM TELLURITE 1% suppl. 5 x 10 ml
80031	TWEEN 80 supplement 2 x 50 ml
80040	CHROMATIC™ SALMONELLA Supplement 2x50 ml
80047	MULLER KAUFFMANN 3X50 ml (Iodio/B.G.0.1%)
80053	VITAMIN K 1% supplement 5 x 5 ml
80056	LEGIONELLA growth supplement 10 vials
80057	H2O2 REAGENT 1 x 10 ml
80060	DECONTAM-KIT
80110	UREA 40% 6X100 ml
80219	EGG YOLK emulsion 4 x 50 ml
80252	ENTEROSYSTEM 18R REAGENT 100/200 Test
80253	COPRO SYSTEM REAGENTS (antisera)
80257	LISTERIA SYSTEM 18R -REAG 100/200 Test
80258	AF GENITAL SYSTEM REAGENT
80260	IDENTIF. SYSTEM-REAGENT 100/200 Test
80271	KOVAC'S REAGENT 4x25 ml
80272	FERRIC CHLORIDE 10% 2x 25 ml
80273	NINHYDRIN 7% 10 ml
80275	MIF COLOR KIT 50 Test
80276	ZIEHL-NEELSEN 3 x 250 ml
80277	METHYLENE BLUE Solution 250 ml
80279	VASELINE OIL 4 x 50 ml
80280	V.P. TEST-Reagent 10x10ml
80281	V.P. TEST EP 10 x 10 mL
80282	Kit May-Grünwald Giemsa
80290	SAFRANIN SOLUTION 1000 ml
80291	POTASSIUM TELLURITE 3.5% suppl.5x10 ml
80292	UREA 40 % supplement 10 x 5 ml
80293	GRAM COLOR KIT 4 x 250 ml
80294	KIT COLOR ALBERT 2 x 250 ml
80295	DECOLOURIZING SOLUTION 1000 ml
80296	LUGOL PVP SOLUTION 1000 ML
80298	LUGOL PVP SOLUTION 250 ml
80299	CRYSTAL VIOLET SOLUTION 1000 ml
80300	TTC 1% supplement 5 x 10 ml
80350	ANTIBIOTIC TEST

80351	RAPID ANTIBIOTIC TEST 50 Test
80380	KINYOUN COLOR KIT 2 x 250 ml
80390	FIXUR 1
80409	IODINE SOLUTION 10 x 10 ml
80410	XLT 4 SUPPLEMENT 4 x 50 ml
80422	POTASSIUM TELLURITE 1% Supplement 10 x 10 ml
80430	TTC 1% supplement 10 x 10 ml
80431	TWEEN 80 Supplement 4 x 50 ml
80453	VITAMIN K 1% SUPPLEMENT 10 x 5 ml
81001	AMPICILLIN supplement 10 vials
81002	LEGIONELLA (BMPA) supplement 10 vials
81003	BRUCELLA supplement 10 vials
81004	CAMPYLOBACTER Preston supplem 10 vials
81006	CN (Pseudomonas) supplement 10 vials
81007	CLOSTRIDIUM difficile suppleme 10 vials
81008	LEGIONELLA (GVPC) supplement 10 vials
81009	IODINE solution 5 x 10 ml
81011	CLOSTRIDIUM perfrigens (T.S.C.) sup.10 v.
81012	LCAT supplement 10 vials
81013	BORDETELLA supplement 10 vials
81014	HAEMOPHILUS supplement 10 vials
81015	CAMPYLOBACTER Butzler supplement 10 vials
81016	BACILLUS Cereus Supplement 10 Vials
81017	CHLORAMPHENICOL supplement 10 vials
81019	LEGIONELLA (MWY) supplement 10 vials
81020	MMG Supplement 10 vials
81022	V.C.N. supplement 10 vials
81023	VITALEX growth supplement 10 vials
81024	V.C.N.T. supplement 10 vials
81025	DERMATOPHYTE supplement 10 vials
81026	LISTERIA PALCAM supplement 10 vials
81032	ONPG 1.5% Supplement 10 vials
81033	GENTAMYCIN supplement 10 vials
81035	MIDDLEBROOK 7H 10 supplement 4 x 50 ml
81036	CAMPYLOBACTER KARMALI Supplement 10 vials
81037	CAMPYLOBACTER CCDA supplement 10 vials
81038	CAMPYLOBACTER C.T.V.N. Supplement 10 vials
81039	YERSINIA supplement 10 vials
81040	GARDNERELLA vaginalis Supplement 10vials
81041	V.C.A.T. supplement 10 vials
81042	LISTERIA FRASER supplement (1125mg)10 vials
81048	CNA (Staf/Strep) supplemet 10 vials
81050	CAMPYLOBACTER growth supplement 10 vials
81051	CAMPYLOBACTER Blaser Wang supp 10 vials
81054	SCHAEDLER supplement 10 vials
81055	CAMPYLOBACTER Skirrow supple 10 vials
81056	LEGIONELLA (BCYE) growth suppl.10 vials
81062	VANCOMYCIN Supplement for VRE 10 vials
81077	CAMPYLOBACTER C.T.V.A. Supplement 10 vials
81078	CHROMATIC™ MRSA Supplement
81079	UREA-ARGININE SCREEN
81082	CEFIXIME TELLURITE Supplement
81083	MEROPENEM Supplement
81084	NEOMYCIN Solution
81085	CHROMATIC™ STAPH AUREUS Supplement
81086	VCC MOD SELECTIVE Supplement
81088	CHROMATIC™ CRE Supplement
81089	Chromatic™ ESBL Supplement
81090	CHROMATIC™ ESBL+AmpC Supplement
81091	Legionella BCYE Growth Supplement w/o L-Cysteine

81098	D-Cycloserine 4-MUP Supplement
85501	COPRO KIT (SELENITE BROTH)
85502	COPRO KIT 2 (SALMONELLA BROTH)
87001	KOVAC'S Reagent
87002	VP (NaOH) Reagent
87003	CATALASE Reagent
87004	PHENYLALANINE Reagent
87005	OXIDASE Reagent
87006	Vaseline Oil
87007	VP (KOH) Reagent
87008	Lactophenol Cotton Blue Droppers
87009	Methyl Red Droppers
87101	GRAM COLOR KIT
88003	OXIDASE TEST SWABS 30 Test
88004	OXIDASE TEST DISCS 30 Discs
88005	O.N.P.G. TEST 30 Test
88006	E.COLI TEST 30 Test
88007	HIPPURATE TEST 30 Test
88008	AESCULIN BILE TEST 30 Test
88009	NITRATI TEST 30 Test 30 Test
88010	LISTERIA MONO TEST 20 Test
88011	UREA RAPID TEST 30 Test
88013	H2S RAPID TEST 30 Test
88014	LYSINE DECARBOXYLASE TEST 30 Test
88015	ORNITHINE DECARBOXYLASE TEST 30 Test
88016	ARGININE DECARBOXYLASE TEST 30 Test
88017	INDOLE TEST 30 Test
88020	S F RAPID TEST 30 Test
88021	CAMP TEST-S 30 Test
88023	CATALASI/OXY TEST 30 Test
88024	UREA / INDOLO TEST 30 Test
88027	CAMP TEST-R 30 Test
88028	PEPTIDASE A TEST 30 Test
88029	OXIDASE TEST STICKS 50 Test
88029N	Oxidase Test Stick
88030	COAGULASE TEST 40 Test
88031	GRAM TEST STICK 30 Test
88032	INDOLO TEST STICK 30 Test
88033	BETA LACTAMASE STICKS 30 Test
88034	PEPTIDASE A STICKS 30 Test
88035	VP TEST KIT
88040	C 390 50 Discs
88041	Brilliant Green 100 µg
88042	CITRATE TEST
88043	O129 Disc 150 µg
88044	O129 Disc 10 µg
88105	O.N.P.G. TEST
88201	GALACTOSE TEST 30 Test
88202	GLUCOSE TEST 30 Test
88203	LACTOSE TEST 30 Test
88204	MALTOSE TEST 30 Test
88205	RAFFINOSE TEST 30 Test
88206	SUCROSE TEST 30 Test
88207	ARABITOL TEST 30 Test
88208	ADONITOL TEST 30 Test
88209	ARABINOSE TEST 30 Test
88210	DULCITOL TEST 30 Test
88211	INOSITOL TEST 30 Test
88212	INULIN TEST 30 Test
88213	LEVULOSE TEST 30 Test

88214	MANNITOL TEST 30 Test
88215	MANNOSE TEST 30 Test
88216	RHAMNOSE TEST 30 Test
88217	SALICIN TEST 30 Test
88218	SORBITOL TEST 30 Test
88219	TREHALOSE TEST 30 Test
88220	XYLOSE TEST 30 Test
89021	CultiControl™ Aspergillus brasiliensis ATCC® 16404™
89022	CultiControl™ Bacillus Cereus ATCC® 11778™
89023	CultiControl™ Bacillus subtilis ATCC® 6633™
89024	CultiControl™ Candida albicans ATCC® 10231™
89025	CultiControl™ Enterococcus faecalis ATCC® 19433™
89026	CultiControl™ Enterococcus faecalis ATCC® 29212™
89027	CultiControl™ Escherichia coli ATCC® 25922™
89028	CultiControl™ Escherichia coli ATCC® 8739™
89029	CultiControl™ Listeria innocua ATCC® 33090™
89030	CultiControl™ Listeria ivanovii ATCC® 19119™
89031	CultiControl™ Listeria monocytogenes ATCC® 19111™
89032	CultiControl™ Proteus mirabilis ATCC® 25933™
89033	CultiControl™ Pseudomonas aeruginosa ATCC® 27853™
89034	CultiControl™ Pseudomonas aeruginosa ATCC® 9027™
89035	CultiControl™ Rhodococcus equi ATCC® 6939™
89036	CultiControl™ Saccharomyces cerevisiae ATCC® 9763™
89037	CultiControl™ Salmonella typhimurium ATCC® 14028™
89038	CultiControl™ Shigella flexneri ATCC® 12022™
89039	CultiControl™ Staphylococcus aureus NCTC 12493
89040	CultiControl™ Staphylococcus aureus ATCC® 25923™
89041	CultiControl™ Staphylococcus aureus ATCC® 29213™
89042	CultiControl™ Staphylococcus aureus ATCC® 33862™
89043	CultiControl™ Staphylococcus aureus ATCC® 43300™
89044	CultiControl™ Staphylococcus aureus ATCC® 6538™
89045	CultiControl™ Staphylococcus epidermidis ATCC® 12228™
89046	CultiControl™ Streptococcus agalactiae ATCC® 13813™
89047	CultiControl™ Streptococcus pneumoniae ATCC® 49619™
89048	CultiControl™ Streptococcus pyogenes ATCC® 19615™
89049	CultiControl™ Proteus mirabilis ATCC® 12453™
89050	CultiControl™ Yersinia enterocolitica ATCC® 9610™
89051	CultiControl™ Listeria monocytogenes ATCC® 19115™
89052	CultiControl™ Legionella pneumophila subsp. pneumophila ATCC® 33152™
89053	CultiControl™ Clostridium perfringens ATCC® 13124™
89054	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™
89055	CultiControl™ Lactobacillus paracasei subsp. paracasei ATCC ® BAA-52™
89056	CultiControl™ Vibrio parahaemolyticus ATCC ® 17802™
89057	CultiControl™ Aspergillus fumigatus ATCC ® 204305™
89058	CultiControl™ Shigella sonnei ATCC ® 25931™
89059	CultiControl™ Clostridium sordellii ATCC ® 9714™
89060	CultiControl™ Listeria monocytogenes ATCC ® 7644™
89061	CultiControl™ Streptococcus bovis ATCC ® 33317™
89062	CultiControl™ Streptococcus mutans ATCC ® 25175™
89063	CultiControl™ Streptococcus pneumoniae ATCC ® 27336™
89064	CultiControl™ Streptococcus sanguinis ATCC ® 10556™
89065	CultiControl™ Enterobacter cloacae subsp. cloacae ATCC ® BAA-1143™
89066	CultiControl™ Enterococcus faecalis ATCC ® 49532™
89067	CultiControl™ Enterococcus faecalis ATCC ® 49533™
89068	CultiControl™ Escherichia coli NCTC 11954™
89069	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-2146™
89070	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 700603™
89071	CultiControl™ Candida parapsilosis ATCC ® 22019™
89072	CultiControl™ Candida albicans ATCC ® 90028™
89073	CultiControl™ Issatchenkia orientalis ATCC ® 6258™
89074	CultiControl™ Neisseria gonorrhoeae ATCC ® 19424™
89075	CultiControl™ Neisseria gonorrhoeae ATCC ® 31426™
89076	CultiControl™ Haemophilus influenzae ATCC® 49766™
89077	CultiControl™ Haemophilus influenzae ATCC® 49247™
89078	CultiControl™ Bacteroides fragilis ATCC® 25285™
89079	CultiControl™ Bacteroides thetaiotaomicron ATCC® 29741™
89080	CultiControl™ Lactobacillus acidophilus ATCC ® 4356™
89081	CultiControl™ Lactobacillus leichmannii ATCC ® 4797™
89082	CultiControl™ Lactococcus lactis ATCC ® 19435™
89083	CultiControl™ Proteus mirabilis ATCC ® 29906™
89084	CultiControl™ Salmonella enterica subsp. enterica serovar Enteritidis ATCC ® 13076™
89085	CultiControl™ Listeria monocytogenes ATCC ® 13932™
89086	CultiControl™ Campylobacter jejuni ATCC ® 33291™
89087	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1706™
89088	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1705™
89089	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 13883™
89090	CultiControl™ Clostridium difficile ATCC ® 9689™
89091	CultiControl™ Aggregatibacter aphrophilus ATCC ® 7901™
89092	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 700698™
89093	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 700699™
89094	CultiControl™ Plesiomonas shigelloides ATCC ® 14029™
89095	CultiControl™ Clostridium sporogenes ATCC ® 19404™
89096	CultiControl™ Micrococcus luteus ATCC ® 10240™
89097	CultiControl™ Candida tropicalis ATCC ® 750™
89098	CultiControl™ Candida krusei ATCC ® 14243™
89099	CultiControl™ Gardnerella vaginalis ATCC ® 14018™
89100	CultiControl™ Lactobacillus fermentum ATCC ® 9338™
89101	CultiControl™ Listeria grayi ATCC ® 25401™
89102	CultiControl™ Micrococcus luteus ATCC ® 4698™
89103	CultiControl™ Moraxella (Branhamella) catarrhalis ATCC ® 25238™
89104	CultiControl™ Neisseria gonorrhoeae ATCC ® 49226™
89105	CultiControl™ Proteus mirabilis ATCC ® 35659™
89106	CultiControl™ Proteus mirabilis ATCC ® 43071™
89107	CultiControl™ Proteus vulgaris ATCC ® 6380™
89108	CultiControl™ Pseudomonas aeruginosa ATCC ® 10145™
89109	CultiControl™ Pseudomonas aeruginosa ATCC ® 15442™
89110	CultiControl™ Pseudomonas fluorescens ATCC ® 13525™
89111	CultiControl™ Bacteroides ovatus ATCC ® 8483™
89112	CultiControl™ Clostridium histolyticum ATCC ® 19401™
89113	CultiControl™ Bacteroides fragilis ATCC ® 23745™
89114	CultiControl™ Actinomyces odontolyticus ATCC ® 17929™
89115	CultiControl™ Enterococcus faecalis ATCC ® 33186™
89116	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 33591™
89117	CultiControl™ Enterococcus faecium ATCC ® 51559™
89118	CultiControl™ Fusobacterium nucleatum ATCC ® 25586™
89119	CultiControl™ Aeromonas hydrophila ATCC ® 7966™
89120	CultiControl™ Haemophilus influenzae ATCC ® 10211™
89121	CultiControl™ Serratia marcescens ATCC ® 8100™
89122	CultiControl™ Neisseria gonorrhoeae ATCC ® 49981™

89123	CultiControl™ Haemophilus haemolyticus ATCC ® 33390™
89124	CultiControl™ Haemophilus influenzae ATCC ® 33533™
89125	CultiControl™ Providencia stuartii ATCC ® 33672™
89126	CultiControl™ Staphylococcus haemolyticus ATCC ® 29970™
89127	CultiControl™ Streptococcus anginosus ATCC ® 33397™
89128	CultiControl™ Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388™
89129	CultiControl™ Streptococcus mitis ATCC ® 6249™
89130	CultiControl™ Streptococcus pyogenes ATCC ® 49399™
89131	CultiControl™ Streptococcus salivarius ATCC® 13419™
89132	CultiControl™ Salmonella enterica subsp. enterica serovar Abony NCTC 6017
89133	CultiControl™ Staphylococcus xylosus ATCC ® 29971™
89134	CultiControl™ Prevotella melaninogenica ATCC ® 25845™
89135	CultiControl™ Propionibacterium acnes ATCC® 11827™
89136	CultiControl™ Haemophilus influenzae NCTC 8468
89137	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 19095™
89138	CultiControl™ Cronobacter sakazakii ATCC ® 29544™
89139	CultiControl™ Bordetella bronchiseptica ATCC ® 4617™
89140	CultiControl™ Trichophyton mentagrophytes ATCC ® 9533™
89141	CultiControl™ Acinetobacter baumannii ATCC ® BAA-747™
89144	CultiControl™ Vibrio alginolyticus ATCC ® 17749™
89145	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 33560™
89146	CultiControl™ Citrobacter freundii ATCC ® 43864™
89147	CultiControl™ Burkholderia cepacia ATCC ® 25416™
89148	CultiControl™ Listeria monocytogenes ATCC ® 35152™
89149	CultiControl™ Stenotrophomonas maltophilia ATCC® 13637™
89151	CultiControl™ Legionella pneumophila subsp. fraseri ATCC ® 33156™
89152	CultiControl™ Enterococcus faecium ATCC ® 6057™
89153	CultiControl™ Staphylococcus saprophyticus ATCC ® 15305™
89154	CultiControl™ Salmonella enterica subsp. arizonae ATCC ® 13314™
89155	CultiControl™ Bacillus cereus ATCC ® 10876™
89156	CultiControl™ Enterobacter aerogenes ATCC ® 13048™
89158	CultiControl™ Cronobacter muytjensii ATCC ® 51329™
89159	CultiControl™ Citrobacter freundii ATCC ® 8090™
89160	CultiControl™ Haemophilus influenzae ATCC ® 19418™
89162	CultiControl™ Porphyromonas gingivalis ATCC ® 33277™
89163	CultiControl™ Escherichia coli ATCC ® 35218™
89164	CultiControl™ Neisseria meningitidis ATCC ® 13090™
89165	CultiControl™ Peptostreptococcus anaerobius ATCC ® 27337™
89166	CultiControl™ Burkholderia cepacia ATCC ® 25608™
89167	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 29428™
89168	CultiControl™ Yersinia enterocolitica subsp. enterocolitica ATCC ® 23715™
89170	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® BAA-44™
89171	CultiControl™ Enterococcus faecium ATCC ® 19434™
89172	CultiControl™ Enterococcus faecium ATCC ® BAA-2319™
89173	CultiControl™ Enterococcus faecalis ATCC ® 51299™
89174	CultiControl™ Acinetobacter baumannii ATCC ® 19606™
89175	CultiControl™ Streptococcus pneumoniae ATCC ® 700671™
89176	CultiControl™ Haemophilus influenzae ATCC ® 33391™
89177	CultiControl™ Candida albicans ATCC ® 18804™
89178	CultiControl™ Candida albicans ATCC ® 64124™
89179	CultiControl™ Shigella boydii ATCC ® 9207™
89180	CultiControl™ Shigella sonnei ATCC ® 9290™
89181	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 49476™
89182	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 9144™
89183	CultiControl™ Candida albicans ATCC ® 14053™
89184	CultiControl™ Escherichia coli ATCC ® 11303™
89186	CultiControl™ Streptococcus salivarius subsp. thermophilus ATCC ® 19258™
89189	CultiControl™ Nocardia brasiliensis ATCC ® 19296™
89191	CultiControl™ Serratia marcescens ATCC ® 14756™
89192	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 4352™
89193	CultiControl™ Bacteroides ovatus ATCC ® BAA-1296™
89194	CultiControl™ Stenotrophomonas maltophilia ATCC ® 17666™
89195	CultiControl™ Enterococcus casseliflavus ATCC ® 700327™
89196	CultiControl™ Eikenella corrodens ATCC ® BAA-1152™
89197	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC ® 49416™
89198	CultiControl™ Shigella flexneri ATCC ® 9199™
89199	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 31488™
89200	CultiControl™ Enterobacter cloacae ATCC ® 49141™
9001	NALIDIXIC ACID NA 30 µg 250 Discs
9001/1	NALIDIXIC ACID NA 30 µg 50 Discs
9002	Oxolinic acid OA 2 µg 250 Discs
9002/1	Oxolinic acid OA 2 µg 50 Discs
9003	PIPEMIDIC ACID PI 20 µg 250 Discs
9003/1	PIPEMIDIC ACID PI 20 µg 50 Discs
9004	AMIKACIN AK 30 µg 250 Discs
9004/1	AMIKACIN AK 30 µg 50 Discs
9005	AMOXICILLIN AML 30 µg 250 Discs
9005/1	AMOXICILLIN AML 30 µg 50 Discs
9006	AMPICILLIN AMP 10 µg 250 Discs
9006/1	AMPICILLIN AMP 10 µg 50 Discs
9007	AZLOCILLIN AZL 75 µg 250 Discs
9007/1	AZLOCILLIN AZL 75 µg 50 Discs
9008	AZTREONAM ATM 30 µg 250 Discs
9008/1	AZTREONAM ATM 30 µg 50 Discs
9009	CARBENICILLIN CAR 100 µg 250 Discs
9009/1	CARBENICILLIN CAR 100 µg 50 Discs
9010	CEFACLOR CEC 30 µg 250 Discs
9010/1	CEFACLOR CEC 30 µg 50 Discs
9011	CEPHALEXIN CL 30 µg 250 Discs
9011/1	CEPHALEXIN CL 30 µg 50 Discs
9013	CEPHALOTHIN KF 30 µg 250 Discs
9013/1	CEPHALOTHIN KF 30 µg 50 Discs
9014	CEFAMANDOLE MA 30 µg 250 Discs
9014/1	CEFAMANDOLE MA 30 µg 50 Discs
9015	CEFAZOLIN KZ 30 µg 250 Discs
9015/1	CEFAZOLIN KZ 30 µg 50 Discs
9016	CEFOPERAZONE CFP 30 µg 250 Discs
9016/1	CEFOPERAZONE CFP 30 µg 50 Discs
9017	CEFOTAXIME CTX 30 µg 250 Discs
9017/1	CEFOTAXIME CTX 30 µg 50 Discs
9018	CEFOXITIN FOX 30 µg 250 Discs
9018/1	CEFOXITIN FOX 30 µg 50 Discs
9019	CEFTAZIDIME CAZ 30 µg 250 Discs
9019/1	CEFTAZIDIME CAZ 30 µg 50 Discs
9020	CEFTRIAXONE CRO 30 µg 250 Discs
9020/1	CEFTRIAXONE CRO 30 µg 50 Discs
9021	CEFUROXIME CXM 30 µg 250 Discs
9021/1	CEFUROXIME CXM 30 µg 50 Discs

9022	CHLORAMPHENICOL C 30 µg 250 Discs
9022/1	CHLORAMPHENICOL C 30 µg 50 Discs
9023	COLISTIN SULFATE CS 10 µg 250 Discs
9023/1	COLISTIN SULFATE CS 10 µg 50 Discs
9024	ERYTHROMYCIN E 15 µg 250 Discs
9024/1	ERYTHROMYCIN E 15 µg 50 Discs
9025	FOSFOMYCIN FOS 50 µg 250 Discs
9025/1	FOSFOMYCIN FOS 50 µg 50 Discs
9026	GENTAMICIN CN 10 µg 250 Discs
9026/1	GENTAMICIN CN 10 µg 50 Discs
9027	KANAMYCIN K 30 µg 250 Discs
9027/1	KANAMYCIN K 30 µg 50 Discs
9028	LINCOMYCIN MY 2 µg 250 Discs
9028/1	LINCOMYCIN MY 2 µg 50 Discs
9029	METHICILLIN MET 5 µg 250 Discs
9029/1	METHICILLIN MET 5 µg 50 Discs
9030	MINOCYCLINE MN 30 µg 250 Discs
9030/1	MINOCYCLINE MN 30 µg 50 Discs
9031	AMPICILLIN-SULBACTAM AMS 20 µg 250 Discs
9031/1	AMPICILLIN-SULBACTAM AMS 20µg 50 DISCS
9032	NEOMYCIN N 30 µg 250 Discs
9032/1	NEOMYCIN N 30 µg 50 Discs
9033	NETILMICIN NET 30 µg 250 Discs
9033/1	NETILMICIN NET 30 µg 50 Discs
9034	NITROFURANTOIN F 300 µg 250 Discs
9034/1	NITROFURANTOIN F 300 µg 50 Discs
9035	NORFLOXACIN NOR 10µg 250 Discs
9035/1	NORFLOXACIN NOR 10 µg 50 Discs
9036	OXACILLIN OX 1µg 250 Discs
9036/1	OXACILLIN OX 1 µg 50 Discs
9037	PENICILLIN G P 10 IU 250 Discs
9037/1	PENICILLIN G P 10 IU 50 Discs
9038	PIPERACILLIN PRL 100 µg 250 Discs
9038/1	PIPERACILLIN PRL 100 µg 50 Discs
9039	RIFAMPICIN RD 30 µg 250 Discs
9039/1	RIFAMPICIN RD 30 µg 50 Discs
9040	STREPTOMYCIN S 10 µg 250 Discs
9040/1	STREPTOMYCIN S 10 µg 50 Discs
9041	SULFAFURAZOLE SF 300 µg 250 Discs
9041/1	SULFAFURAZOLE SF 300 µg 50 Discs
9042	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 250 Discs
9042/1	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 50 Discs
9043	TETRACYCLINE TE 30 µg 250 Discs
9043/1	TETRACYCLINE TE 30 µg 50 Discs
9044	TOBRAMYCIN TOB 10 µg 250 Discs
9044/1	TOBRAMYCIN TOB 10 µg 50 Discs
9045	VANCOMYCIN VA 30 µg 250 Discs
9045/1	VANCOMYCIN VA 30 µg 50 Discs
9046	SISOMYCIN SIS 30µg 250 Discs
9046/1	SISOMYCIN SIS 30 µg 50 Discs
9047	CLINDAMYCIN CD 2 µg 250 Discs
9047/1	CLINDAMYCIN CD 2 µg 50 Discs
9048	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 250 Discs
9048/1	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 50 Discs
9049	FUSIDIC ACID FC 10 µg 250 Discs
9049/1	FUSIDIC ACID FC 10 µg 50 Discs
9050	TEICOPLANIN TEC 30 µg 250 Discs
9050/1	TEICOPLANIN TEC 30 µg 50 Discs
9051	BACITRACIN BA 10 IU 250 Discs
9051/1	BACITRACIN BA 10 IU 50 Discs
9052	CEFADROXIL CDX 30 µg 250 Discs
9052/1	CEFADROXIL CDX 30 µg 50 Discs
9053	CEFSULODIN CSD 30 µg 250 Discs
9053/1	CEFSULODIN CSD 30 µg 50 Discs
9054	CEFTIZOXIME CZX 30 µg 250 Discs
9054/1	CEFTIZOXIME CZX 30 µg 50 Discs
9055	CEPHRADINE CE 30 µg 250 Discs
9055/1	CEPHRADINE CE 30 µg 50 Discs
9056	CIPROFLOXACIN CIP 5 µg 250 Discs
9056/1	CIPROFLOXACIN CIP 5 µg 50 Discs
9057	CINOXACIN CIN 100 µg 250 Discs
9057/1	CINOXACIN CIN 100 µg 50 Discs
9058	CLOXACILLIN CX 5 µg 250 Discs
9058/1	CLOXACILLIN CX 5 µg 50 Discs
9059	DOXYCYCLINE DXT 30 µg 250 Discs
9059/1	DOXYCYCLINE DXT 30 µg 50 Discs
9060	ROXITROMYCIN RXT 15 µg 250 Discs
9060/1	ROXITROMYCIN RXT 15 µg 50 Discs
9061	ERTAPENEM ETP 10 µg 250 Discs
9061/1	ERTAPENEM ETP 10 µg 50 Discs
9062	MEZLOCILLIN MEZ 75 µg 250 Discs
9062/1	MEZLOCILLIN MEZ 75 µg 50 Discs
9063	NOVOBIOCIN NO 30 µg 250 Discs
9063/1	NOVOBIOCIN NO 30 µg 50 Discs
9064	CEFPODOXIME PX 10 ug 250 Discs
9064/1	CEFPODOXIME PX 10 ug 50 Discs
9065	OXYTETRACYCLINE OT 30 µg 250 Discs
9065/1	OXYTETRACYCLINE OT 30 µg 50 Discs
9066	POLYMYXIN B PB 100 IU 250 Discs
9066/1	POLYMYXIN B PB 100 IU 50 Discs
9067	SPECTINOMYCIN SPC 100 µg 250 Discs
9067/1	SPECTINOMYCIN SPC 100 µg 50 Discs
9068	MEROPENEM MRP 10 µg 250 Discs
9068/1	MEROPENEM MRP 10 µg 50 Discs
9069	FLUCONAZOLE FLU 100 µg 250 Discs
9069/1	FLUCONAZOLE FLU 100 µg 50 Discs
9070	TICARCILLIN TC 75 µg 250 Discs
9070/1	TICARCILLIN TC 75 µg 50 Discs
9071	AMPHOTERICIN B AMB 20 µg 250 Discs
9071/1	AMPHOTERICIN B AMB 20 µg 50 Discs
9072	ECONAZOLE ECN 10 µg 250 Discs
9072/1	ECONAZOLE ECN 10 µg 50 Discs
9073	FLUCYTOSINE AFY 1 µg 250 Discs
9073/1	FLUCYTOSINE AFY 1 µg 50 Discs
9074	GRISEOFULVIN AGF 10 µg 250 Discs
9074/1	GRISEOFULVIN AGF 10 µg 50 Discs
9075	KETOCONAZOLE KCA 10 µg 250 Discs
9075/1	KETOCONAZOLE KCA 10 µg 50 Discs
9076	METRONIDAZOLE MTZ 5 µg 250 Discs
9076/1	METRONIDAZOLE MTZ 5 µg 50 Discs
9077	MICONAZOLE MCL 10 µg 250 Discs
9077/1	MICONAZOLE MCL 10 µg 50 Discs
9078	NYSTATIN NY 100 IU 250 Discs
9078/1	NYSTATIN NY 100 IU 50 Discs
9079	IMIPENEM IMI 10 µg 250 Discs
9079/1	IMIPENEM IMI 10 µg 50 Discs
9080	OFLOXACIN OFX 5 µg 250 Discs
9080/1	OFLOXACIN OFX 5 µg 50 Discs
9081	CEFOTETAN CTT 30 µg 250 Discs

9081/1	CEFOTETAN CTT 30 µg 50 Discs
9082	TYLOSIN TY 30 µg 250 Discs
9082/1	TYLOSIN TY 30 µg 50 Discs
9083	TRIMETHOPRIM TM 2.5 µg 250 Discs
9083/1	TRIMETHOPRIM TM 2.5 µg 50 Discs
9084	SULFAMETHOXAZOLE SMX 50 µg 250 Discs
9084/1	SULFAMETHOXAZOLE SMX 50µg 50 Discs
9085	Imipenem + Phenylboronic acid IMI + BO 250 Discs
9085/1	Imipenem + Phenylboronic acid IMI + BO 50 Discs
9086	Imipenem + Cloxacillin IMI + CL 250 Discs
9086/1	Imipenem + Cloxacillin IMI + CL 50 Discs
9087	EDTA ED 250 Discs
9087/1	EDTA ED 50 Discs
9088	SPIRAMYCIN SP 100 µg 250 Discs
9088/1	SPIRAMYCIN SP 100 µg 50 Discs
9089	CEFIXIME CFM 5 µg 250 Discs
9089/1	CEFIXIME CFM 5 µg 50 Discs
9090	Daptomycin DAP 30 µg 250 Discs
9090/1	Daptomycin DAP 30 µg 50 Discs
9091	PEFLOXACIN PEF 5 µg 250 Discs
9091/1	PEFLOXACIN PEF 5 µg 50 Discs
9093	DICLOXACILLIN DCX 1 µg 250 Discs
9093/1	DICLOXACILLIN DCX 1 µg 50 Discs
9094	TIAMULIN T 30 µg 250 Discs
9094/1	TIAMULIN T 30 µg 50 Discs
9095	IMIPENEM/CILASTATIN IMC 20 µg 250 Discs
9095/1	IMIPENEM/CILASTATIN IMC 20 µg 50 Discs
9096	TICARCILLIN-CLAVULINC ACID TTC 85 µg 250 Discs
9096/1	TICARCILLIN-CLAVULINC ACID TTC 85 µg 50 Discs
9097	CLOTRIMAZOLE CLO 50 µg 250 Discs
9097/1	CLOTRIMAZOLE CLO 50 µg 50 Discs
9098	CLARITHROMYCIN CLR 15 µg 250 Discs
9098/1	CLARITHROMYCIN CLR 15 µg 50 Discs
9099	FURAZOLIDON FR 50 µg 250 Discs
9099/1	FURAZOLIDON FR 50 µg 50 Discs
9100	PIPERACILLIN-TAZOBACTAM TZP 110 µg 250 Discs
9100/1	PIPERACILLIN-TAZOBACTAM TZP 110 µg 50 Disc
9101	CEFTIBUTEN CTB 30 µg 250 Discs
9101/1	CEFTIBUTEN CTB 30 µg 50 Discs
9102	LEVOFLOXACIN LEV 5 µg 250 Discs
9102/1	LEVOFLOXACIN LEV 5 µg 50 Discs
9103	MOXIFLOXACIN MOX 5 µg 250 Discs
9103/1	MOXIFLOXACIN MOX 5 µg 50 Discs
9104	CEFEPIME FEP 30 µg 250 Discs
9104/1	CEFEPIME FEP 30 µg 50 Discs
9105	AZITHROMYCIN AZM 15 µg 250 Discs
9105/1	AZITHROMYCIN AZM 15 µg 50 Discs
9106	MYOKAMYCIN MK 15 µg 250 Discs
9106/1	MYOKAMYCIN MK 15 µg 50 Discs
9107	ITRACONAZOLE ITC 50 µg 250 Discs
9107/1	ITRACONAZOLE ITC 50 µg 50 Discs
9108	CEFOPERAZONE CFP 75 µg 250 Discs
9108/1	CEFOPERAZONE CFP 75 µg 50 Discs
9109	FOSFOMYCIN (includes G-6-p) FOS 200 µg 250 Discs
9109/1	FOSFOMYCIN (includes G-6-p) FOS 200 µg 50 Discs
9110	TRIMETHOPRIM TM 5 µg 250 Discs
9110/1	TRIMETHOPRIM TM 5 µg 50 Discs
9111	FUSIDIC ACID FC 30 µg 250 Discs
9111/1	FUSIDIC ACID FC 30 µg 50 Discs
9112	CEFPROZIL CPR 30 µg 250 Discs
9112/1	CEFPROZIL CPR 30 µg 50 Discs
9113	LOMEFLOXACIN LOM 10 µg 250 Discs
9113/1	LOMEFLOXACIN LOM 10 µg 50 Discs
9115	AMPICILLIN AMP 2 µg 250 Discs
9115/1	AMPICILLIN AMP 2 µg 50 Discs
9116	LINCOMYCIN MY 15 µg 250 Discs
9116/1	LINCOMYCIN MY 15 µg 50 Discs
9117	NOVOBIOCIN NO 5 µg 250 Discs
9117/1	NOVOBIOCIN NO 5 µg 50 Discs
9118	RIFAMPICIN RD 5 µg 250 Discs
9118/1	RIFAMPICIN RD 5µg 50 Discs
9119	METRONIDAZOLE MTZ 50 µg 250 Discs
9119/1	METRONIDAZOLE MTZ 50 µg 50 Discs
9120	POLYMYXIN B PB 300 UI 250 Discs
9120/1	POLYMYXIN B PB 300 UI 50 Discs
9121	FOSFOMYCIN (includes G-6-p) FOS 100 µg 250 Discs
9121/1	FOSFOMYCIN (includes G-6-p) FOS 100 µg 50 Discs
9122	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 250 Discs
9122/1	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 50 Discs
9124	GENTAMICIN CN 120 µg 250 Discs
9124/1	GENTAMICIN CN 120 µg 50 Discs
9125	GENTAMICIN CN 30 µg 250 Discs
9125/1	GENTAMICIN CN 30 µg 50 Discs
9126	SULFONAMIDE S3 300 µg 250 Discs
9126/1	SULFONAMIDE S3 300 µg 50 Discs
9127	PENICILLIN G P 2 IU 250 Discs
9127/1	PENICILLIN G P 2 IU 50 Discs
9128	CHLORAMPHENICOL C 10 µg 250 Discs
9128/1	CHLORAMPHENICOL C 10 µg 50 Discs
9129	SULBACTAM SU 20µg 250 Discs
9129/1	SULBACTAM SU 20µg 50 Discs
9130	PENICILLIN G P 1 IU 250 Discs
9130/1	PENICILLIN G P 1 IU 50 Discs
9131	SODIUM FUSIDATE FC 30 250 Discs
9132	SULFAPRIM SXT 50 µg 250 Discs
9132/1	SULFAPRIM SXT 50 µg 50 Discs
9133	AMOXICILLIN AML 10 µg 250 Discs
9133/1	AMOXICILLIN AML 10 µg 50 Discs
9134	CEFOTAXIME CTX 75 µg 250 Discs
9134/1	CEFOTAXIME CTX 75 µg 50 Discs
9135	OXACILLIN OX 5µg 250 Discs
9135/1	OXACILLIN OX 5µg 50 Discs
9136	LINEZOLID LNZ 30µg 250 Discs
9136/1	LINEZOLID LNZ 30µg 50 Discs
9137	AMPHOTERICIN B AMB 10 µg 250 Discs
9137/1	AMPHOTERICIN B AMB 10 µg 50 Discs
9139	ITRACONAZOLE ITC 8 µg 250 Discs
9139/1	ITRACONAZOLE ITC 8 µg 50 Discs
9140	KETOCONAZOLE KCA 15 µg 250 Discs
9140/1	KETOCONAZOLE KCA 15 µg 50 Discs
9141	COLISTIN SULFATE CS 30 UI 250 Discs
9141/1	COLISTIN SULFATE CS 30 UI 50 Discs
9143	CEFEPIME+CLAVULANIC ACID FEL 40 µg 250 Discs
9144	Cefoxitin+Cloxacillin FOC 230 µg 250 Discs
9144/1	Cefoxitin+Cloxacillin FOC 230 µg 50 Discs
9145	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 250 Discs
9145/1	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 50 Discs
9146	CLINDAMYCIN CD 10 µg 250 Discs
9146/1	CLINDAMYCIN CD 10 µg 50 Discs
9147	TIGECYCLIN TGC 15 µg 250 Discs

9147/1	TIGECYCLIN TGC 15 µg 50 Discs
9148	FLUCYTOSINE AFY 10 µg 250 Discs
9148/1	FLUCYTOSINE AFY 10 µg 50 Discs
9150	SULFADIAZINE SUZ 300 ug 250 Discs
9150/1	SULFADIAZINE SUZ 300 ug 50 Discs
9151	AMOXICILLIN AML 2 µg 250 Discs
9151/1	AMOXICILLIN AML 2 µg 50 Discs
9152	CEFOTAXIME CTX 5 µg 250 Discs
9152/1	CEFOTAXIME CTX 5 µg 50 Discs
9153	CEFTAZIDIME CAZ 10 µg 250 Discs
9153/1	CEFTAZIDIME CAZ 10 µg 50 Discs
9154	DORIPENEM DOR 10 µg 250 Discs
9154/1	DORIPENEM DOR 10 µg 50 Discs
9155	LINEZOLID LNZ 10 µg 250 Discs
9155/1	LINEZOLID LNZ 10 µg 50 Discs
9156	MECILLINAM MEC 10 µg 250 Discs
9156/1	MECILLINAM MEC 10 µg 50 Discs
9157	MUPIROCIN MUP 200 µg 250 Discs
9157/1	MUPIROCIN MUP 200 µg 50 Discs
9158	NITROFURANTOIN F 100 µg 250 Discs
9158/1	NITROFURANTOIN F 100 µg 50 Discs
9159	PIPERACILLIN PRL 30 µg 250 Discs
9159/1	PIPERACILLIN PRL 30 µg 50 Discs
9160	PIPERACILLIN-TAZOBACTAM TZP 36 µg 250 Discs
9160/1	PIPERACILLIN-TAZOBACTAM TZP 36 µg 50 Discs
9161	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 250 Discs
9161/1	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 50 Discs
9162	STREPTOMYCIN S 300 µg 250 Discs
9162/1	STREPTOMYCIN S 300 µg 50 Discs
9163	TOBRAMYCIN TOB 30 ug 250 Discs
9163/1	TOBRAMYCIN TOB 30 ug 50 Discs
9164	VANCOMYCIN VA 5 µg 250 Discs
9164/1	VANCOMYCIN VA 5 µg 50 Discs
9165	CASPOFUNGIN CAS 5 µg 250 Discs
9165/1	CASPOFUNGIN CAS 5 µg 50 Discs
9166	FLUCONAZOLE FLU 25 µg 250 Discs
9166/1	FLUCONAZOLE FLU 25 µg 50 Discs
9167	POSACONAZOLE POS 5 µg 250 Discs
9167/1	POSACONAZOLE POS 5 µg 50 Discs
9168	VORICONAZOLE VO 1 µg 250 Discs
9168/1	VORICONAZOLE VO 1 µg 50 Discs
9169	GATIFLOXACIN GAT 5 µg 250 Discs
9169/1	GATIFLOXACIN GAT 5 µg 50 Discs
9170	NETILMICIN NET 10 µg 250 Discs
9170/1	NETILMICIN NET 10 µg 50 Discs
9171	PHENOXYMETHYLPENICILLIN PV 10 µg 250 Discs
9171/1	PHENOXYMETHYLPENICILLIN PV 10 µg 50 Discs
9172	TELITHROMYCIN TEL 15 µg 250 Discs
9172/1	TELITHROMYCIN TEL 15 µg 50 Discs
9173	LORACARBEF LOR 30 µg 250 Discs
9173/1	LORACARBEF LOR 30 µg 50 Discs
9174	NAFCILLIN NAF 1 µg 250 Discs
9174/1	NAFCILLIN NAF 1 µg 50 Discs
9175	MEROPENEM+CLOXACILLIN MR+CL 250 Discs
9175/1	MEROPENEM+CLOXACILLIN MR+CL 50 Discs
9176	Meropenem + Phenylboronic acid MR + BO 250 Discs
9176/1	Meropenem + Phenylboronic acid MR + BO 50 Discs
9177	MEROPENEM+DIPICOLINIC ACID MR+DP 250 Discs
9177/1	MEROPENEM+DIPICOLINIC ACID MR+DP 50 Discs
9178	Meropenem + EDTA MR + ED 250 Discs
9178/1	Meropenem + EDTA MR + ED 50 Discs
9179	AMOXICILLIN AML 25 µg 250 Discs
9179/1	AMOXICILLIN AML 25 µg 50 Discs
9180	ERYTHROMYCIN E 2 µg 250 Discs
9180/1	ERYTHROMYCIN E 2 µg 50 Discs
9181	NITROFURANTOIN F 50 µg 250 Discs
9181/1	NITROFURANTOIN F 50 µg 50 Discs
9182	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 250 Discs
9182/1	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 50 Discs
9183	Imipenem + EDTA IMI + ED 250 Discs
9183/1	Imipenem + EDTA IMI + ED 50 Discs
9184	COLISTIN SULFATE CS 25 µg 250 Discs
9184/1	COLISTIN SULFATE CS 25 µg 50 Discs
9185	CEFPIROME CR 30 µg 250 Discs
9185/1	CEFPIROME CR 30 µg 50 Discs
9186	TEMOCILLIN TMO 30 µg 250 Discs
9186/1	TEMOCILLIN TMO 30 µg 50 Discs
9187	Sulfamethoxazole SMX 100 µg 250 Discs
9187/1	Sulfamethoxazole SMX 100 µg 50 Discs
9188	Metronidazole MTZ 10 µg 250 Discs
9188/1	Metronidazole MTZ 10 µg 50 Discs
9189	MUPIROCIN MUP 5 µg 250 Discs
9190	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 250 Discs
9190/1	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 50 Discs
9191	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 250 Discs
9191/1	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 50 Discs
9192	ROKITAMYCIN ROK 30 µg 250 Discs
9192/1	ROKITAMYCIN ROK 30 µg 50 Discs
9193	Phenylboronic acid BO 250 Discs
9193/1	Phenylboronic acid BO 50 Discs
9194	DIPICOLINIC ACID DP 250 Discs
9194/1	DIPICOLINIC ACID DP 50 Discs
9195	CEFTAROLINE CPT 5 µg 250 Discs
9195/1	CEFTAROLINE CPT 5 µg 50 Discs
9198	CEFTAROLINE CPT 30 µg 250 Discs
9198/1	CEFTAROLINE CPT 30 µg 50 Discs
9199	ERTAPENEM+CLOXACILLIN ET+CL 250 Discs
9199/1	ERTAPENEM+CLOXACILLIN ET+CL 50 Discs
9202	Ertapenem+Phenylboronic acid ET+BO 250 Discs
9202/1	Ertapenem+Phenylboronic acid ET+BO 50 Discs
9203	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 250 Discs
9203/1	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 50 Discs
9204	Ceftazidime+Clavulanic acid+Cloxacillin CALC 250 Discs
9204/1	Ceftazidime+Clavulanic acid+Cloxacillin CALC 50 Discs
9205	Ceftazidime-avibactam CZA 50 µg 250 Discs
9205/1	Ceftazidime -avibactam CZA 50 µg 50 Discs
9206	Ceftazidime -avibactam CZA 14 µg 250 Discs
9206/1	Ceftazidime-avibactam CZA 14 µg 50 Discs
9209	Nitroxolin NI 30 µg
9209/1	Nitroxolin NI 30 µg
9219	Cefepime FEP 5 µg
9219/1	Cefepime FEP 5 µg
9220	Cefepime FEP 10 µg
9220/1	Cefepime FEP 10 µg
9224	Cefotaxime + Cloxacillin CTC
9224/1	Cefotaxime + Cloxacillin CTC
9225	Ceftazidime + Cloxacillin CAC
9225/1	Ceftazidime + Cloxacillin CAC
9246	Ceftolozane-tazobactam C/T 40 µg

9246/1	Ceftolozane-tazobactam C/T 40 µg
9247	Solithromycin SOL 15 µg 250 Discs
9247/1	Solithromycin SOL 15 µg 50 Discs
9248	Rifampicin 2 µg
9248/1	Rifampicin 2 µg
91200	DISC DISPENSER 8 CARTRIDGES
91203	DISC DISPENSER 6 CARTRIDGES
92000	AMOX*/SULB 2/1 AXS 0.016-256* 30 MIC Test
920000	AMOX*/SULB 2/1 AXS 0.016-256* 100 MIC Test
92001	Rifampicin RD 0.002-32 mg/L 30 MIC Test
920010	Rifampicin RD 0.002-32 mg/L 100 MIC Test
920011	Rifampicin RD 0.002-32 mg/L 10 MIC Test
92002	Fusidic Acid FU 0.016-256 mg/L 30 MIC Test
920020	Fusidic Acid FU 0.016-256 mg/L 100 MIC Test
920021	Fusidic Acid FU 0.016-256 mg/L 10 MIC Test
92003	Ampicillin AMP 0.016-256 mg/L 30 MIC Test
920030	Ampicillin AMP 0.016-256 mg/L 100 MIC Test
920031	Ampicillin AMP 0.016-256 mg/L 10 MIC Test
92004	Polymyxin B PB 0.064-1024 mg/L 30 MIC Test
920040	Polymyxin B PB 0.064-1024 mg/L 100 MIC Test
920041	Polymyxin B PB 0.064-1024 mg/L 10 MIC Test
92005	Cefpodoxime PX 0.016-256 mg/L 30 MIC Test
920050	Cefpodoxime PX 0.016-256 mg/L 100 MIC Test
920051	Cefpodoxime PX 0.016-256 mg/L 10 MIC Test
92006	Cefotaxime CTX 0.016-256 mg/L 30 MIC Test
920060	Cefotaxime CTX 0.016-256 mg/L 100 MIC Test
920061	Cefotaxime CTX 0.016-256 mg/L 10 MIC Test
92007	Cefotaxime CTX 0.002-32 mg/L 30 MIC Test
920070	Cefotaxime CTX 0.002-32 mg/L 100 MIC Test
920071	Cefotaxime CTX 0.002-32 mg/L 10 MIC Test
92008	Cefpirome CR 0.016-256 mg/L 30 MIC Test
920080	Cefpirome CR 0.016-256 mg/L 100 MIC Test
920081	Cefpirome CR 0.016-256 mg/L 10 MIC Test
92009	Gentamicin CN 0.016-256 mg/L 30 MIC Test
920090	Gentamicin CN 0.016-256 mg/L 100 MIC Test
920091	Gentamicin CN 0.016-256 mg/L 10 MIC Test
92010	Gentamicin CN 0.064-1024 mg/L 30 MIC Test
920100	Gentamicin CN 0.064-1024 mg/L 100 MIC Test
920101	Gentamicin CN 0.064-1024 mg/L 10 MIC Test
92011	Gatifloxacin GAT 0.002-32 mg/L 30 MIC Test
920110	Gatifloxacin GAT 0.002-32 mg/L 100 MIC Test
920111	Gatifloxacin GAT 0.002-32 mg/L 10 MIC Test
92012	Teicoplanin TEC 0.016-256 mg/L 30 MIC Test
920120	Teicoplanin TEC 0.016-256 mg/L 100 MIC Test
920121	Teicoplanin TEC 0.016-256 mg/L 10 MIC Test
92013	Enrofloxacin ENR 0.002-32 mg/L 30 MIC Test
920130	Enrofloxacin ENR 0.002-32 mg/L 100 MIC Test
920131	Enrofloxacin ENR 0.002-32 mg/L 10 MIC Test
92014	Spectinomycin SPC 0.064-1024 mg/L MIC Test
920140	Spectinomycin SPC 0.064-1024 mg/L 100 MICTest
920141	Spectinomycin SPC 0.064-1024 mg/L 10 MIC Test
92015	Oxacillin OX 0.016-256 mg/L 30 MIC Test
920150	Oxacillin OX 0.016-256 mg/L 100 MIC Test
920151	Oxacillin OX 0.016-256 mg/L 10 MIC Test
92016	Ceftizoxime CZX 0.016-256 mg/L 30 MIC Test
920160	Ceftizoxime CZX 0.016-256 mg/L 100 MIC Test
920161	Ceftizoxime CZX 0.016-256 mg/L 10 MIC Test
92017	Mecillinam MEC 0.016-256 mg/L 30 MIC Test
920170	Mecillinam MEC 0.016-256 mg/L 100 MIC Test
920171	Mecillinam MEC 0.016-256 mg/L 10 MIC Test

92018	Amikacin AK 0.016-256 mg/L 30 MIC Test
920180	Amikacin AK 0.016-256 mg/L 100 MIC Test
920181	Amikacin AK 0.016-256 mg/L 10 MIC Test
92019	Bacitracin BA 0.016-256 mg/L 30 MIC Test
920190	Bacitracin BA 0.016-256 mg/L 100 MIC Test
920191	Bacitracin BA 0.016-256 mg/L 10 MIC Test
92020	Cefotetan CTT 0.016-256 mg/L 30 MIC Test
920200	Cefotetan CTT 0.016-256 mg/L 100 MIC Test
920201	Cefotetan CTT 0.016-256 mg/L 10 MIC Test
92021	Amoxicillin AML 0.016-256 mg/L 30 MIC Test
920210	Amoxicillin AML 0.016-256 mg/L 100 MIC Test
920211	Amoxicillin AML 0.016-256 mg/L 10 MIC Test
92022	Nitrofurantoin F 0.032-512 mg/L 30 MIC Test
920220	Nitrofurantoin F 0.032-512 mg/L 100 MIC Test
920221	Nitrofurantoin F 0.032-512 mg/L 10 MIC Test
92023	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 30 MIC Test
920230	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 100 MIC Test
920231	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 10 MIC Test
92024	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 30 MIC Test
920240	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 100 MIC Test
920241	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 10 MIC Test
92025	Rifampicin RD 0.016-256 mg/L 30 MIC Test
920250	Rifampicin RD 0.016-256 mg/L 100 MIC Test
920251	Rifampicin RD 0.016-256 mg/L 10 MIC Test
92026	Quinupristin-dalfopristin QDA 0.002-32 mg/L 30 MIC Test
920260	Quinupristin-dalfopristin QDA 0.002-32 mg/L 100 MIC Test
920261	Quinupristin-dalfopristin QDA 0.002-32 mg/L 10 MIC Test
92027	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 30 MIC Test
920270	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 100 MIC Test
920271	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 10 MIC Test
92028	Sulbactam SUL 0.016-256 mg/L 30 MIC Test
920280	Sulbactam SUL 0.016-256 mg/L 100 MIC Test
920281	Sulbactam SUL 0.016-256 mg/L 10 MIC Test
92029	Temocillin TMO 0.064-1024 mg/L 30 MIC Test
920290	Temocillin TMO 0.064-1024 mg/L 100 MIC Test
920291	Temocillin TMO 0.064-1024 mg/L 10 MIC Test
92030	Azithromycin AZM 0.016-256 mg/L 30 MIC Test
920300	Azithromycin AZM 0.016-256 mg/L 100 MIC Test
920301	Azithromycin AZM 0.016-256 mg/L 10 MIC Test
92031	Sulfamethoxazole SMX 0.064-1024 mg/L 30 MIC Test
920310	Sulfamethoxazole SMX 0.064-1024 mg/L 100 MIC Test
920311	Sulfamethoxazole SMX 0.064-1024 mg/L 10 MIC Test
92032	Minocycline MN 0.016-256 mg/L 30 MIC Test
920320	Minocycline MN 0.016-256 mg/L 100 MIC Test
920321	Minocycline MN 0.016-256 mg/L 10 MIC Test
92033	Aztreonam ATM 0.016-256 mg/L 30 MIC Test
920330	Aztreonam ATM 0.016-256 mg/L 100 MIC Test
920331	Aztreonam ATM 0.016-256 mg/L 10 MIC Test
92034	Kanamycin K 0.016-256 mg/L 30 MIC Test
920340	Kanamycin K 0.016-256 mg/L 100 MIC Test
920341	Kanamycin K 0.016-256 mg/L 10 MIC Test
92035	Gemifloxacin GEM 0.002-32 mg/L 30 MIC Test
920350	Gemifloxacin GEM 0.002-32 mg/L 100 MIC Test
920351	Gemifloxacin GEM 0.002-32 mg/L 10 MIC Test
92036	Cefaclor CEC 0.016-256 mg/L 30 MIC Test

920360	Cefaclor CEC 0.016-256 mg/L 100 MIC Test
920361	Cefaclor CEC 0.016-256 mg/L 10 MIC Test
92037	Trimethoprim TM 0.002-32 mg/L 30 MIC Test
920370	Trimethoprim TM 0.002-32 mg/L 100 MIC Test
920371	Trimethoprim TM 0.002-32 mg/L 10 MIC Test
92038	Mupirocin MUP 0.064-1024 mg/L 30 MIC Test
920380	Mupirocin MUP 0.064-1024 mg/L 100 MIC Test
920381	Mupirocin MUP 0.064-1024 mg/L 10 MIC Test
92039	Cephalotin KF 0.016-256 mg/L 30 MIC Test
920390	Cephalotin KF 0.016-256 mg/L 0.016-256 100 MIC Test
920391	Cephalotin KF 0.016-256 mg/L 10 MIC Test
92040	Doripenem DOR 0.002-32 mg/L 30 MIC Test
920400	Doripenem DOR 0.002-32 mg/L 100 MIC Test
920401	Doripenem DOR 0.002-32 mg/L 10 MIC Test
92041	Pefloxacin PEF 0.016-256 mg/L 30 MIC Test
920410	Pefloxacin PEF 0.016-256 mg/L 100 MIC Test
920411	Pefloxacin PEF 0.016-256 mg/L 10 MIC Test
92042	Ceftriaxone CRO 0.016-256 mg/L 30 MIC Test
920420	Ceftriaxone CRO 0.016-256 mg/L 100 MIC Test
920421	Ceftriaxone CRO 0.016-256 mg/L 10 MIC Test
92043	Ceftriaxone CRO 0.002-32 mg/L 30 MIC Test
920430	Ceftriaxone CRO 0.002-32 mg/L 100 MIC Test
920431	Ceftriaxone CRO 0.002-32 mg/L 10 MIC Test
92044	Cloxacillin CX 0.016-256 mg/L 30 MIC Test
920440	Cloxacillin CX 0.016-256 mg/L 100 MIC Test
920441	Cloxacillin CX 0.016-256 mg/L 10 MIC Test
92045	Ciprofloxacin CIP 0.002-32 mg/L 30 MIC Test
920450	Ciprofloxacin CIP 0.002-32 mg/L 100 MIC Test
920451	Ciprofloxacin CIP 0.002-32 mg/L 10 MIC Test
92046	Spiramycin SP 0.002-32 mg/L 30 MIC Test
920460	Spiramycin SP 0.002-32 mg/L 100 MIC Test
920461	Spiramycin SP 0.002-32 mg/L 10 MIC Test
92048	Clarithromycin CLR 0.016-256 mg/L 30 MIC Test
920480	Clarithromycin CLR 0.016-256 mg/L 100 MIC Test
920481	Clarithromycin CLR 0.016-256 mg/L 10 MIC Test
92049	Ceftaroline CPT 0.016-256 mg/L 30 MIC Test
920490	Ceftaroline CPT 0.016-256 mg/L 100 MIC Test
920491	Ceftaroline CPT 0.016-256 mg/L 10 MIC Test
92050	Fosmidomycin FOM 0.016-256 mg/L 30 MIC Test
920500	Fosmidomycin FOM 0.016-256 mg/L 100 MIC Test
920501	Fosmidomycin FOM 0.016-256 mg/L 10 MIC Test
92051	Erythromycin E 0.016-256 mg/L 30 MIC Test
920510	Erythromycin E 0.016-256 mg/L 100 MIC Test
920511	Erythromycin E 0.016-256 mg/L 10 MIC Test
92052	Telavancin TLV 0.002-32 mg/L 30 MIC Test
920520	Telavancin TLV 0.002-32 mg/L 100 MIC Test
920521	Telavancin TLV 0.002-32 mg/L 10 MIC Test
92053	Telavancin TLV 0.016-256 mg/L 30 MIC Test
920530	Telavancin TLV 0.016-256 mg/L 100 MIC Test
920531	Telavancin TLV 0.016-256 mg/L 10 MIC Test
92054	Imipenem IMI 0.002-32 mg/L 30 MIC Test
920540	Imipenem IMI 0.002-32 mg/L 100 MIC Test
920541	Imipenem IMI 0.002-32 mg/L 10 MIC Test
92056	Ceftaroline CPT 0.002-32 mg/L 30 MIC Test
920560	Ceftaroline CPT 0.002-32 mg/L 100 MIC Test
920561	Ceftaroline CPT 0.002-32 mg/L 10 MIC Test
92057	Vancomycin VA 0.016-256 mg/L 30 MIC Test
920570	Vancomycin VA 0.016-256 mg/L 100 MIC Test
920571	Vancomycin VA 0.016-256 mg/L 10 MIC Test
92058	Ceftibuten CTB 0.002-32 mg/L 30 MIC Test
920580	Ceftibuten CTB 0.002-32 mg/L 100 MIC Test
920581	Ceftibuten CTB 0.002-32 mg/L 10 MIC Test
92060	Cefixime CFM 0.016-256 mg/L 30 MIC Test
920600	Cefixime CFM 0.016-256 mg/L 100 MIC Test
920601	Cefixime CFM 0.016-256 mg/L 10 MIC Test
92066	Cefoxitin FOX 0.016-256 mg/L 30 MIC Test
920660	Cefoxitin FOX 0.016-256 mg/L 100 MIC Test
920661	Cefoxitin FOX 0.016-256 mg/L 10 MIC Test
92070	Plazomicin PLZ 0.016-256 mg/L 30 MIC Test
920700	Plazomicin PLZ 0.016-256 mg/L 100 MIC Test
920701	Plazomicin PLZ 0.016-256 mg/L 10 MIC Test
92072	Clindamycin CD 0.016-256 mg/L 30 MIC Test
920720	Clindamycin CD 0.016-256 mg/L 100 MIC Test
920721	Clindamycin CD 0.016-256 mg/L 10 MIC Test
92074	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 30 MIC Test
920740	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 100 MIC Test
920741	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 10 MIC Test
92075	Chloramphenicol C 0.016-256 mg/L 30 MIC Test
920750	Chloramphenicol C 0.016-256 mg/L 100 MIC Test
920751	Chloramphenicol C 0.016-256 mg/L 10 MIC Test
92078	Fosfomycin FOS 0.016-256 mg/L 30 MIC Test
920780	Fosfomycin FOS 0.016-256 mg/L 100 MIC Test
920781	Fosfomycin FOS 0.016-256 mg/L 10 MIC Test
92079	Fosfomycin FOS 0.064-1024 mg/L 30 MIC Test
920790	Fosfomycin FOS 0.064-1024 mg/L 100 MIC Test
920791	Fosfomycin FOS 0.064-1024 mg/L 10 MIC Test
92080	Delafloxacin DLX 0.002-32 mg/L 30 MIC Test
920800	Delafloxacin DLX 0.002-32 mg/L 100 MIC Test
920801	Delafloxacin DLX 0.002-32 mg/L 10 MIC Test
92081	Levofloxacin LEV 0.002-32 mg/L 30 MIC Test
920810	Levofloxacin LEV 0.002-32 mg/L 100 MIC Test
920811	Levofloxacin LEV 0.002-32 mg/L 10 MIC Test
92084	Meropenem MRP 0.002-32 mg/L 30 MIC Test
920840	Meropenem MRP 0.002-32 mg/L 100 MIC Test
920841	Meropenem MRP 0.002-32 mg/L 10 MIC Test
92085	Meropenem MRP 0.016-256 mg/L 30 MIC Test
920850	Meropenem MRP 0.016-256 mg/L 100 MIC Test
920851	Meropenem MRP 0.016-256 mg/L 10 MIC Test
92087	Metronidazole MTZ 0.016-256 mg/L 30 MIC Test
920870	Metronidazole MTZ 0.016-256 mg/L 100 MIC Test
920871	Metronidazole MTZ 0.016-256 mg/L 10 MIC Test
92090	Moxifloxacin MXF 0.002-32 mg/L 30 MIC Test
920900	Moxifloxacin MXF 0.002-32 mg/L 100 MIC Test
920901	Moxifloxacin MXF 0.002-32 mg/L 10 MIC Test
92093	Netilmicin NET 0.016-256 mg/L 30 MIC Test
920930	Netilmicin NET 0.016-256 mg/L 100 MIC Test
920931	Netilmicin NET 0.016-256 mg/L 10 MIC Test
92096	Norfloxacin NOR 0.016-256 mg/L 30 MIC Test
920960	Norfloxacin NOR 0.016-256 mg/L 100 MIC Test
920961	Norfloxacin NOR 0.016-256 mg/L 10 MIC Test
92099	Ofloxacin OFX 0.002-32 mg/L 30 MIC Test
920990	Ofloxacin OFX 0.002-32 mg/L 100 MIC Test
920991	Ofloxacin OFX 0.002-32 mg/L 10 MIC Test
92102	Penicillin G P 0.016-256 mg/L 30 MIC Test
921020	Penicillin G P 0.016-256 mg/L 100 MIC Test
921021	Penicillin G P 0.016-256 mg/L 10 MIC Test
92103	Penicillin G P 0.002-32 mg/L 30 MIC Test
921030	Penicillin G P 0.002-32 mg/L 100 MIC Test
921031	Penicillin G P 0.002-32 mg/L 10 MIC Test

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

4426

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC

Check Certificate Status: here

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE

EC No 1434-IVDD-134/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley, Berkshire RG6 4UT, United Kingdom

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 649/2019
Module: H7

mgr Anna Wyroba
Vice-President

Certificate No **1434-IVDD-134/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-134/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-134/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

CERTIFICATE

EC No 1434-IVDD-132/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley, Berkshire RG6 4UT, United Kingdom

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List B

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 22.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 648/2019
Module: H7

mgr Anna Wyroba
Vice-President

Certificate No **1434-IVDD-132/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-132/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-Jka Polyclonal 323002	52586
Anti-Jkb Polyclonal 324002	52587
Anti-Fyb Polyclonal 317002	52570
AHG Elite Clear 415010	52731
AHG Elite Green 435010	52731
Anti-Fya Monoclonal 774002	52569
Anti-Human IgG Clear 401010	45811
Anti-Human IgG Green 402010	45811
Anti-Jka Monoclonal 775002	52586
Anti-Jkb Monoclonal 776002	52587

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-132/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

IFTA AG
Natürlich. Für Zukunft.

CERTIFICATE

The certification body IFTA AG certifies

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

the conformity of the introduced quality management system for the field of the development, manufacturing and sale of products for human and veterinary medical in-vitro-diagnostics as well as for the microbiological examination of water and food and other diagnostic applications with the standard

DIN EN ISO 9001:2015

Start of validity:	07.07.2020
End of validity:	06.07.2023
Report and certificate number:	IC00016 038 20
The certificate consists of	1 page

This certificate includes an annual examination of the QMS by IFTA AG according to the specified standard.

Berlin, 17.06.2020

Prof. Dr. Jörn Karge
CEO

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16072-01-00

Certificate

mdc medical device certification GmbH
certifies that

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

development, manufacturing and distribution of
in vitro diagnostic medical devices for the product groups:
blood grouping, bacteriological test reagents and culture media as well as
manufacturing of raw materials for manufacturing of
in vitro diagnostic medical devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-10-23
Valid until	2024-10-22
Registration no.	D1058700050
Report no.	P21-00883-206453
Stuttgart	2021-07-23

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

sifin

EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 105

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella O:2	**Anti-Salmonella O:19**	**Anti-Salmonella O:43**	**Anti-Salmonella O:58**
Anti-Salmonella O:4	**Anti-Salmonella O:20**	**Anti-Salmonella O:44**	**Anti-Salmonella O:59**
Anti-Salmonella O:5	**Anti-Salmonella O:21**	**Anti-Salmonella O:45**	**Anti-Salmonella O:60**
Anti-Salmonella O:6_1	**Anti-Salmonella O:25**	**Anti-Salmonella O:46**	**Anti-Salmonella O:61**
Anti-Salmonella O:7	**Anti-Salmonella O:27**	**Anti-Salmonella O:47**	**Anti-Salmonella O:62**
Anti-Salmonella O:8	**Anti-Salmonella O:28**	**Anti-Salmonella O:48**	**Anti-Salmonella O:63**
Anti-Salmonella O:9	**Anti-Salmonella O:30**	**Anti-Salmonella O:50**	**Anti-Salmonella O:65**
Anti-Salmonella O:10	**Anti-Salmonella O:34**	**Anti-Salmonella O:51**	**Anti-Salmonella O:66**
Anti-Salmonella O:11	**Anti-Salmonella O:35**	**Anti-Salmonella O:52**	**Anti-Salmonella O:67**
Anti-Salmonella O:13	**Anti-Salmonella O:38**	**Anti-Salmonella O:53**	**Anti-Salmonella Vi**
Anti-Salmonella O:14	**Anti-Salmonella O:39**	**Anti-Salmonella O:54**	
Anti-Salmonella O:15	**Anti-Salmonella O:40**	**Anti-Salmonella O:55**	
Anti-Salmonella O:16	**Anti-Salmonella O:41**	**Anti-Salmonella O:56**	
Anti-Salmonella O:17	**Anti-Salmonella O:42**	**Anti-Salmonella O:57**	

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen: Normes harmonisés appliqués: Applied harmonized standards:	DIN EN ISO 13485:2016, DIN EN 13612:2002, DIN EN 13641:2002, DIN EN ISO 14971:2013, DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013, DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015
Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	**Anhang III** Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz
Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

sifin

EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 111

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD): le dispositif médical (IVD): the medical device (IVD):	**Anti-Shigella dysenteriae type 1** **Anti-Shigella dysenteriae type 2** **Anti-Shigella flexneri type 1** **Anti-Shigella flexneri type 2** **Anti-Shigella flexneri type 3** **Anti-Shigella flexneri type 4** **Anti-Shigella flexneri type 5** **Anti-Shigella flexneri type 6** **Anti-Shigella flexneri group 3,4 (y)** **Anti-Shigella flexneri group 6** **Anti-Shigella flexneri group 7,8 (x)** **Anti-Shigella sonnei S-form (phase I)** **Anti-Shigella sonnei F-form (phase II)** **Anti-Shigella sonnei S- and F-form (phase I and II)**
	Sonstiges Produkt Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen: Normes harmonisés appliqués: Applied harmonized standards:	DIN EN ISO 13485:2016, DIN EN 13612:2002, DIN EN 13641:2002, DIN EN ISO 14971:2013, DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013, DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015
Konformitätsbewertungsverfahren: Procédure d'évaluation de la conformità: Conformity assessment procedure:	**Anhang III** Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

МЕДИКЛОН®

ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ - СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 203312 **Единица:** 100 мл

Изготовлен: 21.12.2020 **Количество единиц** 20

Годен до: 21.12.2022 **Объем серии:** 10000 мл.

Паспорт: Дс203312 от 21.12.2020

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета.	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32	Соответствует 1:32
	Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микроплате не ниже 1:256	Соответствует 1:256

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая
ОТК ООО «Медиклон» К.В. Ющенко

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127276 Москва, Ботаническая ул., 35 , т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-Kell Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Kell Супер

Серия: 102312 **Единица:** 100 мл

Изготовлен: 01.12.2020 **Количество единиц** 5

Годен до: 01.12.2022 **Объем серии:** 10000 мл.

Паспорт: К102312 от 01.12.2020

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-)	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микропланте не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(юридический адрес лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(фактический адрес лица)

ИНН: 3234007127 **ОГРН: 1023202138332**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации: (подпись) **В. И. Погодин**

Председатель экспертной комиссии: (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ