



HiMedia Laboratories Pvt. Ltd.

Date: 07th March 2024.

TO WHOMSOEVER IT MAY CONCERN

We hereby certify that,

Sanmedico SRL Str. Corobceanu 7A, Apt.9, MD-2012, CITY CHISINAU

Republic of Moldova, Tel:-00-373-231 31515 / 00-373-222 60595

Fax:-00-373-22 62 30 32

E-mail: sanmedico.office@gmail.com

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

This certificate is valid upto 06th March 2026.

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

For HIMEDIA LABORATORIES PVT. LTD.

V.M.WARKE.

DIRECTOR - SALES & MARKETING



CIN: U85195MH1982PTC028194









THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria has issued an IQNet recognized certificate that the organization:

HiMedia Laboratories Pvt. Ltd. Plot NO. C40, ROAD - 21Y, WAGLE INDUSTRIAL ESTATE, THANE (WEST) - 400604 MAHARASHTRA, INDIA

for the following scope:

Design, Development & Testing of Microbiology, Animal Cell Culture, Plant Tissue Culture & Molecular Biology products

EAC: 34

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

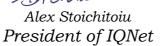
which fulfils the requirements of the following standard

ISO 9001:2015

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

2022-02-28 Issued on: 2025-02-27 Validity date: Quality Austria certified since: 2022-02-28

Registration Number: AT-27302/0



Mag. Friedrich Khuen-Belasi Authorised Representative

of Quality Austria

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^{*} The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **quality**austria certificate to the following organisation: This **quality**austria certificate confirms the application and further development of an effective



HiMedia Laboratories Pvt. Ltd.

Plot NO. C40, Road - 21Y, Wagle Industrial Estate, Thane (West) - 400604 Maharashtra, INDIA

Design, Development & Testing of Microbiology, Animal Cell Culture, Plant Tissue Culture & Molecular Biology products

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

(International Certification Network)

Dok. Nr. FO_24_028

Quality Austria is the

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science. Research and

Quality Austria is accredited as an

Quality Austria is authorized by the VDA (Association of the

Automotive Industry).

For accreditation registration details please

refer to the applicable decisions or recognition

organisation for environmental verification

by the BMLFUW (Federal

Ministry of Agriculture, Forestry, Environment and Water Management).

1702280c-6c19-4683-8f36-3ea2e4167c18 The current validity of the certificate is documented exclusively on the Internet under http://www.qualityaustria.com/en/cert EAC: 34

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

ISO 9001:2015

Registration No.: 27302/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2025

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Q qualityaustria

Net ⁻

Vienna, 28 February 2022

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH, AT-1010 Vienna, Zelinkagasse 10/3

Mag. Christoph Mondl General Manager

Mag. Dr. Werner Paar General Manager Mag. Dr. Anni Koubek Specialist representative





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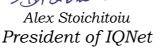
which fulfils the requirements of the following standard

ISO 13485:2016

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2022-02-28 Issued on: Validity date: 2025-02-27 Quality Austria certified since: 2022-02-28

Registration Number: AT-00391/0



Mag. Friedrich Khuen-Belasi Authorised Representative of Quality Austria

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IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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Dok. Nr. FO_24_028

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QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

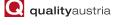
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Vienna, 28 February 2022

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH, AT-1010 Vienna, Zelinkagasse 10/3

Mag. Christoph Mond

Mag. Christoph Mondl General Manager Mag. Dr. Werner Paar General Manager Mag. Dr. Anni Koubek Specialist representative





HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Industrial Area, Thane(W) - 400604, Website: www.himedialabs.com,

Email: info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : DD019	Material Name : Kovac's Reagent Strips (25 Strips / vl)	Lot No : 0000644550
Report No.: 40001468970	Date of Release & Report : 2024-05-07	Expiry Date : 2025-05

Appearance

Filter paper strips of 70 mm x 5 mm.

Cultural Response

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

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

- . ATCC is a registered trade mark of the American Type Culture Collection
- . NCTC and National Collection of Type Culture are registered trade mark of the Health Protection Agency

Control Media:

- . For Bacteria : Soyabean Casein Digest Agar / Columbia Blood Agar base enriched with 5% v/v Sheep/Horse blood.
- . For Yeast & Mold : Sabouraud Dextrose Agar.
- . All ISO 11133: 2014/Amd.1:2018(E) control strains are included in the Quality parameter
- . HiMedia Laboratories Pvt Ltd is Certified for ISO 9001:2015, ISO 13485:2016 and WHO GMP
- . The Quality Assurance Parameters are as per the guidelines specified in CLSI (NCCLS) document M22-A3 wherever applicable.

Storage & Shelf Life

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

STATUS OF THE MATERIAL: APPROVED

This is to certify that this lot passes and it confirms to the above mentioned tests and specifications. The information given here is believed to be correct and accurate, however, both the information and products are offered without warranty for any particulars use, other than that specified in the current HiMedia manual or product sheets. The results reported were obtained at the time of release.

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Microbiologist/Sr.Executive Microbiologist

Asst./Dy/QC Manager

Dy/QA Manager

2024-05-07

PAGE: 1/1



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Email: info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : DD032	Material Name : Spore Strips (25 strips / pack)	Lot No : 0000634709
Report No.: 40001453480	Date of Release & Report : 2024-03-20	Expiry Date : 2026-02

Appearance

Filter paper strip impregnated with spores of standard culture of B.stearothermophilus ATCC 7953

Number of spores

1000000 spores/strip

Cultural response

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

Organism	Unexposed Spore Strip	Exposed Spore Strip	Positive control	Negative control
Cultural response				
Growth in M011	Luxuriant	No growth	Luxuriant	No growth

- . ATCC is a registered trade mark of the American Type Culture Collection
- . NCTC and National Collection of Type Culture are registered trade mark of the Health Protection Agency

Control Media:

- . For Bacteria : Soyabean Casein Digest Agar / Columbia Blood Agar base enriched with 5% v/v Sheep/Horse blood.
- . For Yeast & Mold : Sabouraud Dextrose Agar.
- . All ISO 11133 : 2014/Amd.1:2018(E) control strains are included in the Quality parameter
- . HiMedia Laboratories Pvt Ltd is Certified for ISO 9001:2015, ISO 13485:2016 and WHO GMP
- . The Quality Assurance Parameters are as per the guidelines specified in CLSI (NCCLS) document M22-A3 wherever applicable.
- . Positive control and Negative control tubes should be set up with each cycle. Positive control tubes are inoculated with *B.stearothermophilus* standard culture .The spore strips or broth cultures of *B.stearothermophilus* must be autoclaved at 121°C for at least 30 minutes prior to discarding

Storage & Shelf Life

Store between 15 - 27°C. Use before expiry date on the label.

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Certificate of Analysis, Quality and Conformity

Material Code : DD032	Material Name : Spore Strips (25 strips / pack)	Lot No : 0000634709
Report No.: 40001453480	Date of Release & Report : 2024-03-20	Expiry Date : 2026-02

Shraddha Raval

Microbiologist/Sr.Executive Microbiologist

Ujwala M. Kokate

Asst./Dy/QC Manager

Skankaul Dr. Santosh Kaul

Dy/QA Manager

2024-03-20



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Certificate of Analysis , Quality and Conformity			
Material Code : RM1892	Material Name : Fermentative Peptone	Lot No : 0000516633	
AR No.: 40001199172	Date of Report : 2022-01-19	Exp. Date : 2026-12	
TEST	SPECIFICATIONS	RESULTS	
Appearance			
1 Colour of powder	Light yellow to brownish yellow	Yellow	
2 Nature	Homogenous	Complies	
3 Consistancy	Free flowing powder	Complies	
4 Odour	Characteristic odour but not putrescent	Complies	
Solubility			
1 Solubility	Freely soluble in distilled/purified water, insoluble in alcohol.	Complies	
<u>Clarity</u> 1 Clarity	1% w/v aqueous solution remains clear	Complies	
-	without haziness after autoclaving at 15 lbs pressure (121°C) for 15 minutes.		
Reaction			
1 Reaction	Reaction of 2% w/v aqueous solution at 25°C.	-	
рН	6.20 - 7.20	6.72	
Microbial Load			
1 Total aerobic microbial count	By plate method, when incubated at	-	
(cfu/gm)	30-35°C for not less than 3 days.		
2 total aerobic microbial count (cfu/gm)	<= 2000	10	
3 Total yeast and mold count	By plate method, when incubated at	-	
(cfu/gm)	20-25°C for not less than 5 days.		
4 total yeast and mold count (cfu/gm)	<= 100	7	
Test for Pathogens 1 Test for pathogens	1. E.coli-Negative in 10 gms of sample 2.	Absent	
1. 100t for patriogeria	Salmonella species-Negative in 10 gms of		
	sample 3. Pseudomonas aeruginosa-		
	Negative in 10 gms of sample 4.		
	Staphylococcus aureus- Negative in 10		
	gms of sample 5. C.albicans- Negative in 10 gms of sample 6. Clostridia- Negative in 10		
	gms of sample		



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TEST SPECIFICATIONS RESULTS Indole test I Indole test I Indole Tryptophan content: Passes Compiles Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Nutrient Agar (M001) using Fermentative Peptone as an ingredient. Escherichia coli ATCC 25922 (WDCM00013) I Growth Luxuriant Compiles Staphylococcus aureus Subsp.aureus ATCC Sy32(WDCM 00034) I Growth Luxuriant Compiles Salmonella enterica serovar Typhi ATCC 6532 I Growth Luxuriant Compiles Streptococcus pyogenes ATCC 19615 I Growth Luxuriant Compiles Salmonella enterica serovar Entertitidis ATCC 13076 (WDCM 00030) I Growth Luxuriant Compiles Salmonella enterica serovar Typhimurium ATCC 14028 (WDCM 00031) I Growth Luxuriant Compiles	Material Code : RM1892	Material Name : Fermentative Peptone	Lot No : 0000516633
Indole	AR No.: 40001199172	Date of Report : 2022-01-19	Exp. Date : 2026-12
Indole	TEST	SPECIFICATIONS	RESULTS
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1 Growth Luxuriant Complies Streptococcus pyogenes ATCC 19615 1 Growth Luxuriant Complies Salmonella enterica serovar Enteritidis ATCC 13076 (WDCM 00030) 1 Growth Luxuriant Complies Salmonella enterica serovar Typhimurium ATCC 14028 (WDCM00031)			
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1 Growth Luxuriant Complies	Typhimurium ATCC 14028 (WDCM00031)		Constitution
ļ	1 Growth	Luxuriant	Complies



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Material Code : RM1892	Material Name : Fermentative Peptone	Lot No : 0000516633
AR No.: 40001199172	Date of Report : 2022-01-19	Exp. Date : 2026-12
TEST	SPECIFICATIONS	RESULTS
<u>Yersinia enterocolitica ATCC</u> 9610 (WDCM 00038)		
1 Growth	Luxuriant	Complies
Yersinia enterocolitica ATCC 23715 (WDCM 00160) 1 Growth	Luxuriant	Complies
Chemical Analysis		
1 Total nitrogen	>= 14%	14.76%
2 Amino nitrogen	>= 2.50%	2.92%
3 Sodium chloride	<= 6%	3.65%
4 Loss on drying	<= 7%	3.14%
5 Residue on ignition	<= 14%	9.19%

Information for BSE/TSE Risk The material was subjected to pH <= 7.0 and/or a temperature in excess of 75°C for no less than 2 hours during the manufacturing process. The bovine raw material for this product was collected entirely from Indian Origin animals in a licensed based establishment. The animals are inspected under a Govt. approved veterinarian's supervision and were apparently free from infectious and contagious diseases. BSE (Bovine Spongiform Encephalopathy)/ TSE (Transmissible Spongiform Encephalopathy) and dioxine are not known to exist in India. This material does not contain, nor is derived from the specific risks material as defined in The Maharashtra Animal Preservation Act Govt. of Maharashtra, India.

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Microbiologist/Sr.Executive Microbiologist

Ujwala M. Kokate

Asst./Dy/QC Manager

Dr. Santosh Kaul

Dy/QA Manager



Technical Data

Kovac's Reagent Strip

DD019

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

Directions

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

Preparation of Kovac's reagent

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

Principle And Interpretation

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

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

Quality Control

Appearance

Filter paper strips of 70 mm x 5 mm.

Cultural Response

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

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

Storage and Shelf Life

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

Reference

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

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

Disclaimer :

CE

Revision: 1/2011

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



Technical Data

Spore Strips (Steam Sterilization Monitor Strips)

DD032

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

Directions

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

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

Precautions

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

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

Principle And Interpretation

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

Sterilisation is the freeing of an article from all living organisms including viable spores(1). Sterilization quality control can only be achieved through the use of calibrated biological indicators (endospores). These indicators consist of *Bacillus stearothermophilus* spores impregnated on chromatography paper strips, individually placed into envelopes. Number of spores present per strip: 10^6 . These organisms are difficult to destroy because they are more resistant to heat than other vegetative bacteria and viruses. Therefore, if they are destroyed during sterilization, it is assumed that all other life forms are also destroyed. This test is considered the most sensitive check of the autoclaves efficiency.

Precautions:

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

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

Quality Control

Appearance

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

Number of spores

1000000 spores/strip

Cultural response

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

HiMedia Laboratories Technical Data

Growth	Unexposed	Exposed Spo	re Positive	Negative
	Spore Strip	Strip	control	control
Growth in M011	Luxuriant	No growth	Luxuriant	No growth

Storage and Shelf Life

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

Reference

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

Revision: 1 / 2011

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Technical Data

Fermentive Peptone

RM1892

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Intended use

Fermentive Peptone is recommended for fermentation applications. Also for nutritional purpose in most media formulations for culturing of fastidious organisms.

Warning and Precautions

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

Limitations

1.It is biological origin product since variation in colour of powder and clarity may observed.

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

3.Individual organisms differ in their growth requirement and may show variable growth patterns on the medium prepared by the product.

Performance and Evaluation

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

Quality Control

- → Appearance : Light yellow to brownish yellow homogenous free flowing powder characteristic odour but not putrescent
- → **Solubility**: Freely soluble in distilled/purified water, insoluble in alcohol.
- → Clarity: 1% w/v aqueous solution remains clear without haziness after autoclaving at 15 lbs pressure (121°C) for 15 minutes.
- \rightarrow **pH**: pH of 2% w/v aqueous solution at 25°C 6.2-7.2
- → Microbial Load :

Bacterial Count: <= 2000 CFU/gram by plate method, when incubated at 30-35°C for not less than 3 days Yeast & mould Count: <= 100 CFU/gram by plate method, when incubated at 20-25°C for not less than 5 days.

- → Test for pathogens: 1. Escherichia coli- Absent/gram of sample 2. Salmonella species- Absent/10 gram of sample 3. Pseudomonas aeruginosa- Absent/gram of sample 4. Staphylococcus aureus- Absent/gram of sample 5. Candida albicans- Absent/gram of sample 6. Clostridia- Absent/gram of sample
- → **Indole Test :** Tryptophan content: Passes

→ Cultural Response

.Cultural response: Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Nutrient Agar (M001) using Fermentative Peptone as an ingredient.

Please refer disclaimer Overleaf.

HiMedia Laboratories Technical Data

Organism	Growth
Escherichia coli ATCC 25922 (WDCM00013)	Luxuriant
Pseudomonas aeruginosa ATCC 27853 (WDCM 00025)	Luxuriant
Staphylococcus aureus subsp.aureus ATCC 25923(WDCM 00034)	Luxuriant
Salmonella enterica subsp. enterica Typhi ATCC 6539	Luxuriant
Streptococcus pyogenes ATCC 19615	Luxuriant
Salmonella enterica subsp.enterica Enteritidis ATCC 13076 (WDCM 00030)	Luxuriant
Salmonella enterica subsp.enterica Typhimurium ATCC 14028 (WDCM 00031)	Luxuriant
Yersinia enterocolitica subsp. enterocolitica ATCC 9610 (WDCM 00038)	Luxuriant
Yersinia enterocolitica subsp. enterocolitica ATCC 23715 (WDCM 00160)	Luxuriant

Chemical Analysis:

Total nitrogen : ≥14.00 %

Amino nitrogen : ≥2.50 %

Sodium chloride : ≤6.00 %

Loss on drying : ≤7.00 %

Residue on ignition : ≤14.00 %

Storage and Shelf Life

Store between 10-30°C in tightly closed container and away from bright light. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

Disposal

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



Storage temperature



Do not use if package is damaged



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Revision: 09/2022

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