

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

**REGISTERED OFFICE -**

Plot No. C40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, India.
Tel : +91-22-6147 1919 / 6116 9797 / 6903 4800 | Fax : +91-22-6147 1920
Email : info@himedialabs.com | Web : www.himedialabs.com



... expect only quality from us™
CIN : U85195MH1982PTC028194



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CERTIFICATE

Quality Austria Certification GmbH awards
this **qualityaustria** certificate to the following
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This **qualityaustria** certificate confirms the application
and further development of an effective

HIMEDIA

HiMedia Laboratories Pvt. Ltd.

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

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

ISO 13485:2016

Medical devices - Quality management systems -
Requirements for regulatory purposes

Quality Austria
Certification GmbH is
accredited according to
the Austrian Accreditation
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(Federal Ministry of
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Economy).

Quality Austria is
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Forestry, Environment and
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Quality Austria is the
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Design, Development & Manufacturing of Biosciences
Products for application in Microbiology, Cell Biology
& Molecular Biology Products.

The validity of the **qualityaustria** certificate will be
maintained by annual surveillance audits and one
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Registration No.: M-00391/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2028

Vienna, 10 March 2025

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



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MEMBER OF



Dok. Nr. FO_24_028

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

Mag. Christoph Mondl
CEO

Mag. Dr. Werner Paar
CEO

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



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

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

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(International Certification
Network).



Dok. Nr. FO_24_028

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

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

Registration No.: Q-27302/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2028

Vienna, 10 March 2025

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

Mag. Christoph Mondl
CEO

Mag. Dr. Werner Paar
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Ing. Christoph Baumgartner, MSc, MBA
Authorised representative,
management Customer Service Center



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MEMBER OF



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

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 / vI)	Lot No : 0000711839
Report No.: 40001605260	Date of Release & Report : 2025-07-11	Expiry Date : 2026-07

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		
<i>Escherichia coli</i> ATCC 25922	luxuriant	positive reaction, pink colour at the lower portion of the strip.
<i>Enterobacter aerogenes</i> 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.2:2020 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.

This document has been produced electronically and is valid


Sakshi N

**Microbiologist/Sr.Executive
Microbiologist**


Ujwala M. Kokate

Asst./Dy/QC Manager


Dr. Santosh Kaul

Dy/QA Manager

2025-07-11



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
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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.

Revision : 1 / 2011

Disclaimer :

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