

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 : M290	Material Name : Tryptone Soya Agar	Lot No : E000584498
Report No.: 40001347743	Date of Release & Report : 2023-04-17	Expiry Date : 2028-03

Appearance

Cream to yellow homogeneous free flowing powder. Observed : Light yellow

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Basal Medium : Light yellow coloured clear to slightly opalescent gel. After addition of 5-7%w/v sterile defibrinated blood : Cherry red colour ed opaque gel forms in Petri plates

Reaction

pH of 4.0% w/v aqueous solution at 25°C.

pH

pH Range :7.10-7.50 Observed : 7.49

Cultural response

Cultural characteristics was observed after an incubation for Bacterial at 30-35°C 18-24 hours and for Fungal at 30-35°C <=5day's.

Organism	Inoculum (CFU)	Observed Lot value (CFU)	Recovery	Observed Lot value (CFU) w/blood	Recovery w/blood	Haemolysis	Incubation temperature	Incubation period
Cultural response								
<i>Bacillus spizizenii</i> ATCC 6633 (WDCM 00003)	81	76	93%	78	96%	none	35°C	18Hours
<i>Staphylococcus aureus</i> ATCC 25923 (WDCM 00034)	89	81	91%	85	95%	beta	35°C	18Hours
<i>Staphylococcus aureus</i> ATCC 6538 (WDCM 00032)	91	83	91%	86	94%	beta	35°C	18Hours
<i>Escherichia coli</i> ATCC 25922 (WDCM 00013)	85	78	91%	81	95%	none	35°C	18Hours
<i>Escherichia coli</i> ATCC 8739 (WDCM 00012)	87	80	91%	84	96%	none	35°C	18Hours
<i>Escherichia coli</i> NCTC 9002	88	81	92%	84	95%	none	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 27853 (WDCM 00025)	86	76	88%	80	93%	-	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 9027 (WDCM 00026)	89	78	87%	83	93%	-	35°C	18Hours

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<i>Salmonella enterica serovar Abony NCTC 6017 (WDCM 00029)</i>	90	78	86%	82	91%	-	35°C	18Hours
<i>Kocuria rhizophila ATCC 9341</i>	87	77	88%	84	96%	-	35°C	18Hours
<i>Streptococcus pneumoniae ATCC 6305</i>	91	81	89%	84	92%	alpha	35°C	18Hours
<i>Salmonella enterica serovar Typhimurium ATCC 14028 (WDCM 00031)</i>	88	75	85%	80	90%	-	35°C	18Hours
<i>Clostridium sporogenes NCIMB 532 (WDCM 00008)</i>	84	72	85%	79	94%	none	35°C	18Hours
<i>Escherichia coli ATCC 11775 (WDCM 00090)</i>	85	78	91%	81	95%	none	35°C	18Hours
<i>Escherichia coli NCTC 13167</i>	90	82	91%	86	95%	none	35°C	18Hours
<i>Pseudomonas aeruginosa ATCC 10145 (WDCM 00024)</i>	87	81	93%	83	95%	-	35°C	18Hours
<i>Enterococcus faecalis ATCC 29212 (WDCM 00087)</i>	88	78	88%	83	94%	-	35°C	18Hours
<i>Clostridia perfringenes ATCC 13124</i>	85	77	90%	82	96%	-	35°C	18Hours
<i>Candida albicans ATCC 10231 (WDCM 00054)</i>	87	80	91%	85	97%	-	35°C	2Days
<i>Candida albicans ATCC 2091 (WDCM 00055)</i>	89	82	92%	83	93%	-	35°C	2Days
<i>Aspergillus brasiliensis ATCC 16404 (WDCM 00053)</i>	73	51	69%	-	-	-	35°C	5Days

- . 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 , WHO GMP

. 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

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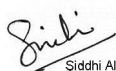
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Spongiform Encephalopathy) and dioxine are not known to exist in India. This material does not contain, nor is derived from the specific risks material as defined in The Maharashtra Animal Preservation Act Govt. of Maharashtra, India.

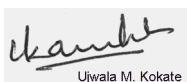
STATUS OF THE MATERIAL : APPROVED

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


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2023-04-17