

HiMedia Laboratories Private Limited

23, Vadhani Industrial Estate, L.B.S. Marg,
Mumbai - 400086 , Website : www.himedialabs.com,
Email : info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : M1327	Material Name : Fraser Broth Base	Lot No: 0000582784
Report No.: 40001344353	Date of Release & Report : 2023-04-23	Expiry Date : 2028-02

Organism	Inoculum (CFU)	Growth	Esculin Hydrolysis	Recovery on M1540I*	Colour of colony on M1540I*
Productivity					
<i>Listeria monocytogenes 1/2a</i> ATCC 35152 (WDCM 00109) + <i>Escherichia coli</i> ATCC 25922 (WDCM 00013) + <i>Enterococcus faecalis</i> ATCC 29212 (WDCM 00087)	50-100 ≥10 ⁴ ≥10 ⁴	good-luxuriant	positive reaction, blackening of medium	>10 colonies	Blue green colonies w/ opaque halo
<i>Listeria monocytogenes 1/2a</i> ATCC 35152 (WDCM 00109) + <i>Escherichia coli</i> ATCC 8739(WDCM 00012) + <i>Enterococcus faecalis</i> ATCC 19433 (WDCM 00009)	50-100 ≥10 ⁴ ≥10 ⁴	good-luxuriant	positive reaction, blackening of medium	>10 colonies	Blue green colonies w/ opaque halo
<i>Listeria monocytogenes 4b</i> ATCC 13932(WDCM 00021) + <i>Escherichia coli</i> ATCC 25922 (WDCM 00013) + <i>Enterococcus faecalis</i> ATCC 29212 (WDCM 00087)	50-100 ≥10 ⁴ ≥10 ⁴	good-luxuriant	positive reaction, blackening of medium	>10 colonies	Blue green colonies w/ opaque halo
<i>Listeria monocytogenes 4b</i> ATCC 13932(WDCM 00021) + <i>Escherichia coli</i> ATCC 8739 (WDCM 00012) + <i>Enterococcus faecalis</i> ATCC 19433 (WDCM 00009)	50-100 ≥10 ⁴ ≥10 ⁴	good-luxuriant	positive reaction, blackening of medium	>10 colonies	Blue green colonies w/ opaque halo

Selectivity

Cultural characteristic observed on addition of FD125I and FD141 after an incubation at 30 ± 1°C for 25 ± 1 hour. Further subculture is carried on Tryptone Soya Agar (M290) after an incubation at 37 ± 1°C for 48 ± 4 hours.

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Selectivity					
<i>Escherichia coli</i> ATCC 25922 (WDCM 00013)	>=10 ⁴	inhibition	-	-	0%
<i>Escherichia coli</i> ATCC 8739 (WDCM 00012)	>=10 ⁴	inhibited	-	-	0%
<i>Enterococcus faecalis</i> ATCC 19433 (WDCM 00009)	>=10 ⁴	none-poor	-	-	<100 colonies
<i>Enterococcus faecalis</i> ATCC 29212 (WDCM 00087)	>=10 ⁴	none-poor	-	-	<100 colonies

- . 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 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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2023-04-23