



Certificate of Analysis

Catalog No.: 214322
Sartorius Catalog No.: 14322--47----ACN
Product Description: Microsart® @Media R2A
Lot Number: 4199936
Expiry Date: 31. March 2025
Date of Manufacture: 22. July 2024
Date of Release: 03. September 2024
Storage Temperature: 2 - 8° C

For Laboratory Use Only

Physical Characteristics

Plate type	65 mm
Media colour / appearance	Pale to light tan, clear to trace hazy, and firm
pH	7.2 ± 0.2
Gamma irradiation dose (Actual)	max.: 18.0 kGy min.: 10.5 kGy
Sterility	Sterility Assurance Level: 10 ⁻⁵

Microbiology

Recovery (< 100 CFU / Plate)

Organism	Strain No.	Incubation (aerobic)	Test Count (CFU / Plate)	Standard Count (CFU / Plate)	Recovery (%)	Expected Recovery (%)
Pseudomonas aeruginosa (Filtration*)	ATCC 9027	≤ 2d, 30-35°C	75	96	78	>70
Pseudomonas aeruginosa	ATCC 9027	≤ 3d, 30-35°C	85	96	89	>70
Bacillus subtilis	ATCC 6633	≤ 3d, 30-35°C	50	53	94	>70
Candida albicans	ATCC 10231	≤ 2d, 35-37°C	51	45	113	>70
Escherichia coli	ATCC 8739	≤ 2d, 35-37°C	50	49	102	>70
Kocuria rhizophila	ATCC 9341	≤ 2d, 35-37°C	29	37	78	>70
Staphylococcus aureus	ATCC 6538	≤ 2d, 35-37°C	24	20	120	>70
Staphylococcus epidermidis	ATCC 12228	≤ 2d, 35-37°C	12	16	75	>70

* Membrane filtration testing is performed with one membrane test per batch of media. Inoculum is 10¹-10² CFU in 100.0 ml Ringer solution filtered onto a membrane filter. R2A Agar test includes Pseudomonas aeruginosa ATCC 9027, incubated at 30-35°C for ≤ 2 days.

We confirm that the above mentioned product lot meets the specification.



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CERTIFICATE OF ORIGIN

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The animal or human origin information supplied herein is based upon certified information obtained from the suppliers of these ingredients.

In order to provide information to customers concerning animal tissues used, and yet not divulge proprietary ingredient information, BD provides tissue categories rather than tissue names on our Certificates of Analysis that contain an Animal Source table. BD applies these tissue categories to all animal and human origin materials used, and to all animal tissues used, and not just to bovine, ovine, or other TSE-relevant species. The references shown in the animal origin table are as follows:

BIC: Tissues listed as High Infectivity (BIC I), Medium Infectivity (BIC II), Low Infectivity (BIC III), and No Detectable Infectivity (BIC IV) originated from Executive Summary of the November 21, 1997 meeting of the European Community's Scientific Steering Committee Working Group on SRM (Specified Risk Materials). Categories were designed to reflect BSE infectivity.

SIC: Tissues listed as High Infectivity (SIC I), Medium Infectivity (SIC II), Low Infectivity (SIC III), and No Detectable Infectivity (SIC IV) originated from *Biologicals*, 1992, Volume 20, Pages 155-158, article entitled, "EEC Regulatory Document, Note for Guidance." Categories were designed to reflect relative scrapie infectivity titers.

ABC: Tissues listed as High Infectivity (ABC - IA), Lower Infectivity (ABC - IB) and No Detectable Infectivity (ABC - IC) originated from EMA/410/01 Rev 3, the European Commission's "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products", effective July 1, 2011. Categories were designed to reflect TSE infectivity in TSE-relevant species.

For complete details refer to "Position Statement – Animal Origin Information on BD Diagnostic Systems Certificate of Analysis", located on the Internet website address at <http://www.bd.com/regdocs>.

Animal Source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	USA	II	II	IB

Manufactured exclusively for Sartorius Lab Instruments GmbH & Co. KG

SARTORIUS

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