



Certificate of Analysis

Becton Dickinson and Company
 BD Diagnostic Systems
 PO Box 999
 Sparks MD 21152-0999 US

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Product Name : Plate Sterile TSA L&P80 Rodac 100 Ea
Catalog Number : 222207 **Manufacture Date**: 2023/08/09
Batch Number : 3212084
Expiration Date : 2023/12/28

01. Plate Appearance: Light to medium tan yellow and clear to trace hazy
02. Fill: 11.5 ml ± 1.5 ml
03. Gel Strength: Firm
04. Biological Performance: Samples were inoculated with 10-100 CFU of the test organisms, incubated at 30-35°C for up to 3 days, ATCC 16404 and ATCC 10231 incubated up to 5 days (20-25°C for up to 5 days for *ATCC 16404 and *ATCC 10231, up to 3 days for *ATCC 6633) under appropriate atmospheric conditions and gave cultural responses as indicated:

CULTURE	ATCC®	RESULT*
Aspergillus brasiliensis	16404	Satisfactory
*Aspergillus brasiliensis	16404	Satisfactory
Bacillus subtilis	6633	Satisfactory
subspecies spizizenii		
*Bacillus subtilis	6633	Satisfactory
subspecies spizizenii		
Candida albicans	10231	Satisfactory
*Candida albicans	10231	Satisfactory
Escherichia coli	8739	Satisfactory
Kocuria rhizophila	9341	Satisfactory
Pseudomonas aeruginosa	9027	Satisfactory
Staphylococcus aureus	6538	Satisfactory
Staphylococcus epidermidis	12228	Satisfactory

*A satisfactory result corresponds with moderate to heavy growth of the test organism, recovery greater than 50% and less than 200% of the control and is comparable to a previously released batch.

05. Irradiation exposure is certified to be within 11.8 - 25.0 kGy.

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.3	7.1	7.5
Animal source	Country of	Tissue Category		



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	Origin	BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 13485:2016 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at www.bd.com/regdocs. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at www.bd.com/regdocs under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Diagnostics - Diagnostic Systems, Animal Origin Position Statement", at www.bd.com/regdocs under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information.



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Stability data for this product is on file.
The pH stated was obtained at the time of release, and the pH may vary within the stated range depending on the age of the product and the type of pH meter and probe used.

Zuleika Vargas
Director, Quality Management
Signature Date:2023/08/22