



# Certificate of Analysis

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

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**Product Name** : Pail Trypticase Soy Broth 25Lb  
**Catalog Number** : 211772 **Manufacture Date**: 2023/10/20  
**Batch Number** : 4017680  
**Expiration Date** : 2027/09/30

01. Dehydrated Medium Powder Appearance: Fine, homogeneous, free of extraneous material
02. Solubility (30 g/L): Soluble in distilled or deionized water
03. Prepared Medium Broth Appearance: Light, tan to yellow; clear to slightly hazy
04. Biological Performance: Medium was prepared per label directions. Media is tested per European (EP), Japanese (JP) and United States Pharmacopeia (USP) Growth Promotion Requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for the (\*) organisms, as indicated below, and gave cultural responses as indicated:

CULTURE	ATCC®	INCUBATION	RESULT
*Aspergillus brasiliensis	16404	20-25°C	Growth
Bacillus subtilis	6633	20-25°C/30-35°C	Growth
*Candida albicans	10231	20-25°C	Growth
Escherichia coli	8739	30-35°C	Growth
Pseudomonas aeruginosa	9027	30-35°C	Growth
Salmonella typhimurium	14028	30-35°C	Growth
Staphylococcus aureus	6538	30-35°C	Growth

05. Residual Solvents (CPMP/ICH/283/95): Typical Analysis and supplier-provided information for Trypticase Soy Broth indicates that there is less than 5000 ppm of Acetone, and less than 890 ppm of Toluene. No other solvents were detected during analysis.

Characteristic	Unit	Value	Lower Limit	Upper Limit
Loss on Drying :	%	2		5
pH at 25°C :		7.3	7.1	7.5
Bulk Lot Number :	-	3289703		

Animal source	Country of Origin	Tissue Category		
		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 -

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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](http://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](http://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](http://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](http://www.bd.com/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information).

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.



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Stacie Wright  
Associate Director, Quality Assurance  
Signature Date: 2024/04/03