CERTIFICATE OF ANALYSIS

LETHEEN BROTH SPONGE-STICK

Lot	Manufacturing date	Shelf-life
7200624ECLH	12-jun-2024	01 year

Sterilization Method

Gamma irradiation

Physical characteristics	Specification	Results
pH (25°C)	7,2±0,2	7,2
Visual appearance	Sponge: yellow to orange-yellow, free of impurities, may contain dark spots. Medium: liquid, medium amber, clear.	Conform

Microbiology analysis

Sterility test

Incubation	Specification	Results
35±2°C for 24h	Absence of microbial growth	Conform

Growth promotion tests

Strain	Inoculum	Incubation	Specification	Results
Salmonella enterica ATCC 14028	≤10^2 CFU	Aerobic, 35±2°C for 18-24h	Good growth	Conform
Escherichia coli ATCC 25922	≤10^2 CFU	Aerobic, 35±2°C for 18-24h	Good growth	Conform
Staphylococcus aureus ATCC 25922	≤10^2 CFU	Aerobic, 35±2°C for 18-24h	Good growth	Conform

Conclusion

This lot was analyzed and satisfy all the product specifications; therefore, it was **APPROVED** for use. bioBoaVista guarantees the quality of its products with sealed packages. The Instructions For Use are displayed overleaf.

Approval: 20-jun-2024
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Quality Analyst

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bioBoaVista	TECHNICAL DATA SHEET	Revision 2.0

LETHEEN BROTH SPONGE-STICK

Presentation
Sampling bag containing 1 sponge-stick and 10ml of sterile Letheen broth.

Sterilization method
Gamma irradiation.

Application
Used as a swab to test the antimicrobial activity of disinfectants applied to surfaces of sanitary importance.

Principle
Lecithin in the medium neutralizes quaternary ammonium compounds. Polysorbate 80 neutralizes phenols, hexachlorophenes, and formalin. Together, they neutralize ethanol.

How to use
Remove the swab from the sampling bag and attach it to the handle. Pass it over the desired surface according to the adopted sampling plan. At the end of the collection, return the swab to the sampling bag and close it. Send the sample to the laboratory and proceed with the analysis according to the methodology adopted by the laboratory.

Quality Control

Test	Result
Sterility	Absence of microbial growth
Salmonella enterica ATCC 14028	Good growth with turbidity of the medium
Escherichia coli ATCC 25922	Good growth with turbidity of the medium
Staphylococcus aureus ATCC 25923	Good growth with turbidity of the medium
Visual appearance	Sponge: yellow to orange-yellow, free of impurities, may contain dark spots. Medium: liquid, medium amber, clear.
pH at 25°C	7.2 ± 0.2

Results interpretation
Microbial growth is evidenced by the cloudiness of the medium. If growth is observed, perform microscopic analysis, subculture on selective media, and biochemical tests to identify isolated genera and species, if necessary. Perform the reading according to official compendia or internal laboratory methodology.

Precautions and special care
Product intended for *in vitro* diagnostic use only.
Restricted for use by professionals. Do not inhale or ingest.
Do not use the product beyond the expiration date, with signs of contamination, or if it has changed color. In the presence of contamination, the product should be immediately discarded.
Do not use the product if the packaging is damaged or tampered with.

Storage
Store between 2-35°C in a dry place and protect from light.

Shelf-life
1 year.

Disposal of the product
After use, the product must be handled at the generating unit before environmentally appropriate final disposal, in accordance with official regulations.

Quality Guarantee
bioBoaVista guarantees the quality of its products as long as they are used according to their respective instructions and in accordance with national and international references. bioBoaVista does not take responsibility for the use of its products for purposes other than those described and approved by the company. All clinical diagnoses should be analyzed in conjunction with clinical evidence and not solely based on laboratory results.

References
1. Becton, Dickinson and Company. Difco & BBL Manual. Manual of Microbiological Culture Media, 2nd ed., 2009.
2. Merck Microbiology Manual. 12th ed.

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