

SELENITE BROTH WITH SWAB

IVD in Class A, EU Reg. 2017/746

 For in vitro diagnostic use **IVD**

In vitro diagnostic device consisting of a swab and a test tube containing Selenite Broth.

DESCRIPTION

In vitro diagnostic device consisting of a swab and a test tube containing Selenite Broth, that is an enrichment liquid medium for the isolation of *Salmonella* spp. and some species of *Shigella* in clinical and nonclinical (food) samples. Selenite Broth is based on early works by Klett and Guth who demonstrated the selective inhibitory effects of selenite and used it for the culture of typhoid organisms. Twenty years later, Leifson utilized this information to fully investigate selenite activity, to formulate the liquid medium selenite broth and to promote its wide use as an enrichment medium for the isolation of *Salmonella* spp.

PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Lactose is the fermentable carbohydrate. Sodium phosphate is the buffer. Sodium selenite is the selective agent inhibiting many species of Gram-positive and Gram-negative bacteria including enterococci and coliforms.

Selenite Broth:

COMPOSITION	g/L
Enzymatic Digest of Casein	5.0
Lactose	4.0
Sodium Phosphate	10.0
Sodium Selenite	4.0

Final pH 7,0 ± 0,2 at 25°C

WARNING AND PRECAUTIONS

For in vitro diagnostic use.

Observe the precautions normally taken when handling laboratory reagents.

Prepared Medium: The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.

Safety Data Sheet is available on request for professional users.

Disposal of waste (hazardous waste with infectious risk) must be carried out according to national and local regulations in force.

STORAGE AND STABILITY

SELENITE BROTH WITH SWAB

2-8°C

SELENITE BROTH WITH SWAB is stable until the expiration date indicated on the label under the recommended storage conditions.

INSTRUCTIONS FOR USE

- Selenite Broth with Swab is intended to collect a rectal sample and promote *Salmonella*/*Shigella* growth. It can also be used to transfer a small quantity of sample from the primary stool collection container. In addition, Selenite Broth with Swab can also be used for surface sampling in the food sector.
- Do not deviate from the intended use. Do not use the product if it is expired or the package is opened/damaged. Sterility guaranteed if unopened.
- Use the device following aseptic procedures. Single-use device; do not reuse. Reusing the device could contaminate the sample and/or the patient.
- Keep the device away from heat sources.
- Store at a temperature between +2°C and +8°C. Do not freeze.
- After use, the device may contain infectious microorganisms. Use appropriate PPE and dispose of the test tube and swab according to current regulations for Medical waste.

HOW TO USE

- 1) Remove the swab and tube containing Selenite Broth from the box.
- 2) Open the blister pack and aseptically remove the swab from the pack.
- 3) Collect specimens. Good laboratory practices for collection of the clinical and nonclinical samples should be applied.
- 4) Unscrew the cap and insert the swab into the test tube.
- 5) Break the swab in the test tube. Discard the broken part of the shaft in accordance with current regulations for medical waste.
- 6) Firmly tighten the cap onto the test tube and label the test tube with the patient's data.
- 7) Incubate in aerobic conditions at 35±2°C for 12-24h (coliforms may overgrow the pathogens if incubated for longer than 24 hours).
- 8) After incubation, growth of organisms is indicated by turbidity and often by a colour change of the medium to pink-orange-red.
- 9) Subculture to a selective plated medium such as XLD Agar or *Salmonella* Chromogenic Agar. Examine for typical colony morphology. Confirm with further biochemical tests.

QUALITY CONTROL: Selenite Broth

Appearance: clear, very pale yellow

In accordance with the predefined Company Quality System, each lot of **SELENITE BROTH WITH SWAB** is tested against predetermined specifications to ensure consistent product quality.

Typical response after incubation at 35±2°C for 18-24 hours, in aerobiosis:

MICROORGANISM	GROWTH
<i>Salmonella</i> Typhimurium ATCC® 14028	Good
<i>Shigella sonnei</i> ATCC® 25931	Good
<i>Escherichia coli</i> ATCC® 25922	Partially to completely inhibited



REFERENCES

- Leifson, E. 1936. New selenite selective enrichment medium for the isolation of typhoid and paratyphoid (*Salmonella*) bacilli. *Am. J. Hyg.*, 24.
- Banffer, J. 1971. Comparison of the isolation of *Salmonellae* from human faeces by enrichment at 37°C and at 43°C. *Zentrabl. Bakt.I.Orig.*, 217: 35- 40 - Dif.








PRESENTATION	Packaging	REF.
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SELENITE BROTH WITH SWAB	100 pcs	32222
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The kit includes:
 n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 2 mL of Selenite Broth;
 n. 100 Swab (sterile, in single blister);
 n. 100 Labels for a correct identification of the sample.

CND: W0104010206

SYMBOLS

-  Read the instructions
-  Biological hazard
-  CE Mark (product complies with the requirements of Regulation (EU) 746/2017)
-  Temperature limitation
-  Use by
-  For in vitro diagnostic use
-  Manufacturer