

#### **TECHNICAL SHEET**

# IVD in Class A, EU Reg. 2017/746

For in vitro diagnostic use **IVD** 

In vitro diagnostic and screening device consisting of a swab and a test tube containing XLD (Xylose Lysine Desoxycholate) Agar.

#### **DESCRIPTION**

**XLD AGAR WITH SWAB** 

In vitro diagnostic and screening device consisting of a swab and a test tube containing XLD (Xylose Lysine Desoxycholate) Agar, that is a selective medium for the isolation and identification of Salmonella and Shigella from from food, environmental samples and clinical specimens.

### **PRINCIPLE**

Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Xylose, lactose and sucrose are the fermentable carbohydrates. Lysine is the decarboxylase substrate. Sodium thiosulfate and ferric ammonium serve as indicators of hydrogen sulphide production under alkaline conditions. Phenol red is the pH indicator. Sodium deoxycholate is the selective agent inhibiting most Gram-positive bacteria. Agar is the solidifying agent.

### XLD Agar:

COMPOSITION	g/L
Estratto di Lievito	3.0
Sodio Cloruro	5.0
Xilosio	3.75
Lattosio	7.5
Saccarosio	7.5
L-Lisina	5.0
Sodio Tiosolfato	6.8
Ferro(III) Ammonio Citrato	0.8
Rosso Fenolo	0.08
Sodio Desossicolato	1.0
Agar	13.5

### Final pH 7,4 ± 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

### **XLD AGAR WITH SWAB**

10-25°C

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

## **INSTRUCTIONS FOR USE**

- XLD Agar with Swab is intended to collect a rectal sample and isolate Salmonella/Shigella growth. It can also be used to transfer a small quantity of sample from the primary stool collection container. In addition, XLD Agar 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 in a cool, dry place at a temperature between +10°C and +25°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**

- Remove the swab and tube containing XLD Agar from the box. 1)
  - 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.
- Unscrew the cap and insert the swab into the test tube.
- Break the swab in the test tube. Discard the broken part of the shaft 5) in accordance with current regulations for medical waste.
- Firmly tighten the cap onto  $\bar{\text{the}}$  test tube and label the test tube with the patient's data.
- Incubate aerobically at  $37 \pm 1^{\circ}$ C for up to 48 hours.
- 8) Generally, after incubation, growth of Salmonella, is indicated by a colour change of the medium to black.
- 9) Confirm with further diagnostic tests.

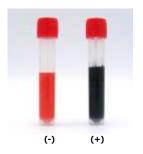
# **QUALITY CONTROL: XLD Agar**

Appearance: slightly opalescent, red

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

Typical response after incubation at 37±1°C for 24±3 hours, in aerobiosis:

MICROORGANISM	GROWTH	
Salmonella Typhimurium ATCC 14028	Red with black center	
Salmonella Enteritidis ATCC 13076		
	Red with black center	
Enterococcus faecalis ATCC 19433	Total inhibition	
Escherichia coli ATCC 25922	Yellow colonies	



### REFERENCES

- Taylor W. 1. (1965) Am. J. Clin. Path. 44, 471 ~475.
- McCarthy M. D. (1966) N. Z J. Med. Lab. Technol. 20, 127-131. Isenberg H. D., Kominos S. & Siegal M. (1 969)Appl. Microbiol. 18,656 659.
- Taylor W. I. & Harris B. (1965) Am. J. Clin. Path. 44, 476-479.
   Taylor W. I. & Harris B. (1967) Am. J. Clin. Path. 48, 350-355. Ox
   ISO 6579-1:2017 Microbiology of food and animal feeding stuffs. Horizontal method for the
- detection of Salmonella spp.
   ISO 6579-1:2020 Microbiologia della catena alimentare Metodo orizzontale per la ricerca.
- la conta e la sierotipizzazione di Salmonella Parte 1: Metodo orizzontale per la ricerca di Salmonella spp.



**TECHNICAL SHEET** 

**PRESENTATION** REF. Packaging

# XLD AGAR WITH SWAB

## 100 pcs 10268/SWAB

The kit includes:

n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 3,5 mL of XLD Agar;

n. 100 Swab (sterile, in single blister);

n. 100 Labels for a correct identification of the sample.

CE Mark (product complies with the requirements of Regulation (EU) 746/2017)

### CND: W0104010206

### **SYMBOLS**

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Read the instructions



Biological hazard



**Temperature limitation** 



Use by

IVD

For in vitro diagnostic use