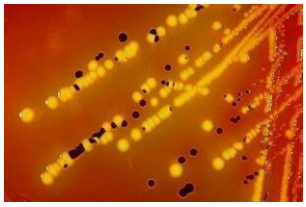
XYLOSE LYSINE DESOXYCHOLATE (XLD) AGAR
(Ready Plated Media) - INSTRUCTIONS FOR USE

1. INTENDED USE

In vitro diagnostic. XLD Agar is a selective and differential medium intended for the isolation of Gram-negative enteric pathogens, especially Salmonella and Shigella from clinical specimens. It is recommended for the detection of Salmonella in non-sterile pharmaceutical products according to harmonized EP, USP, JP method and by FDA-BAM for detection of Salmonella in food.

2. PRINCIPLE



XLD Agar: Salmonella colonies with large black centre and *E. aerogenes* with yellow colonies

Shigella and Salmonella bacteria are inherently pathogenic to humans. These bacteria can be ingested from contaminated food, contaminated water via the faecal-oral route will invade the gastrointestinal tract and cause enteric infection, with diarrhea as the most common symptom. XLD Agar is the complete Xylose Lysine Desoxycholate Agar, a moderately selective medium recommended for isolation and differentiation of these enteric pathogens, especially Shigella species. Peptones in the media provide essential growth factors such as nitrogen, carbon, vitamins, and trace elements necessary for bacterial growth. Sucrose is added as a carbon source. The addition of Xylose, Lysine and Deoxycholate allows for differentiation of Salmonella spp. and Shigella spp. Xylose is incorporated into the medium because it is fermented by practically all enterics except for the Shigellae. This property enables the differentiation of Shigella species. Lysine is included to enable the Salmonella group to be differentiated from the non-pathogens. Without lysine, Salmonellae would ferment the xylose and be indistinguishable from nonpathogenic species. After the salmonella exhausts the supply of xylose, the lysine is attacked via the enzyme lysine decarboxylase, with reversion to an alkaline pH, that mimics the Shigella reaction. To prevent similar reversion by lysine-positive coliforms, lactose and sucrose (saccharose) are added to produce acid in excess. Degradation of xylose, lactose and sucrose generates acid products, which in the presence of the pH indicator phenol red, causes a color change in the medium from red to yellow.

3. MATERIALS PROVIDED

PRODUCT	TYPE	REF	PACK
XLD Agar plate	Ready Plated Media	AG/XLD/22/01	10 plates in a pack

4. MATERIALS REQUIRED BUT NOT PROVIDED:

Water bath, Sterile loops, incubator, and laboratory equipment as required.

5. SPECIMENS:

The sample consists of bacterial colonies isolated from clinical specimens such as faeces, rectal swab, urine, bile, non-sterile pharmaceutical products, and food by the usual techniques.

6. TEST PROCEDURE, READING AND INTERPRETATION

- Allow plates to come to room temperature and to dry the surface of the medium.
- Inoculate and streak the specimen with a loop over the four quadrants of the plate. Alternatively, if the material is being cultured directly from a swab, roll the swab over a small area of the surface at the edge; then streak from this inoculated area.
- Maximal recovery of *Salmonella* from faecal specimens is obtained by using the enrichment step in Selenite Broth followed by subculture to XLD Agar and to a second plating medium.
- For *Shigella* isolation from faecal specimens, enrichment in GN Broth is advised, followed by subculture on two different selective media: XLD Agar and a second less selective medium (Mac Conkey Agar).
- Incubate inoculated XLD Agar plates with the specimen or with a specimen enriched in liquid medium, in aerobic conditions at 35-37°C for 18-24 hours.
- Colonies on XLD agar may require 48 hours incubation for full colour and black precipitate development.

7. USER QUALITY CONTROL

All manufactured lots of the product are released for sale after Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for quality control.

CONTROL STRAINS	INCUBATION	EXPECTED RESULTS
S. typhimurium ATCC 14028	37°C /18-24H-Aerobic	good growth, red colonies with black centre
S. flexneri ATCC 12022	37°C /18-24H-Aerobic	good growth, red colonies
E. faecalis ATCC 29212	37°C /18-24H-Aerobic	inhibited
E.coli ATCC 25922	37°C /18-24H-Aerobic	partially inhibited, yellow colonies

Key: ATCC is a trademark of American Type Culture Collection

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8. LIMITATIONS OF THE METHOD

- A single medium is only rarely useful to recover all pathogens contained in a specimen. Therefore, additional media for the isolation of Salmonella and/or Shigella, with lower selectivity such as Mac Conkey Agar and with higher selectivity such as SS Agar, should be used; it is suggested to inoculate additional media for the isolation of other enteric pathogens with the specimen.
- Non-enteric organisms such as Pseudomonas may grow; Pseudomonas and *Providencia rettgeri* may both exhibit red colonies. Some Proteus spp. may develop black centres. *S.Parathyphi A, S.Cholerae-suis, S.Pullorum* and *S.Gallinarum* may form red colonies without black centre, thus resembling Shigella spp.
- Incubation exceeding 48 hours may lead to false positive results.
- Even if the microbial colonies on the plates are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

9. PRECAUTIONS AND WARNINGS

- This product is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose of the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available with AstraGene and can be provided on request.

10. STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store at +2 - 8°C away from direct light in a cool, dry place. Storage below 2°C may lead to crystallization of media components. If properly stored, it may be used up to the expiration date. Do not use it beyond this date. The user is responsible for the storage method (temperature) of the medium.

11. SYMBOLS

	Date of manufacture		Use-by-date		Do not use if package is damaged		Manufacturer
	Batch Code		Refer to the instructions		ISO		GMP
	*In-Vitro* diagnostic Medical devices		Mark of conformity				

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