



## XLD Agar (Special)

REF PO0931A

EN

### Intended Use

XLD Agar (Special) (PO0931A) is a selective media for the isolation of *Salmonella* and *Shigella* species from faecal samples. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having *Salmonella* and *Shigella* bacterial infections.

The device is for professional use only, is not automated, nor is it a companion diagnostic.

### Summary and Explanation

*Shigella* and *Salmonella* bacteria are inherently pathogenic to humans. These bacteria can be ingested from contaminated food and contaminated water via the faecal-oral route and will invade the gastrointestinal tract and cause enteric infection, with diarrhoea as the most common symptom. *Salmonella* infections can become particularly invasive in infants, older adults and both *Shigella* and *Salmonella* infections can be serious in immunocompromised individuals<sup>1,2</sup>. Resistance to antibiotics is a concern with most *Shigella* possessing multidrug resistance to ampicillin, trimethoprim-sulfamethoxazole, fluoroquinolones and third and fourth generation cephalosporins. *Salmonella* has also been found to have rising resistance to fluoroquinolones and azithromycin, with invasive strains emerging in some areas with multi-drug resistance to chloramphenicol, ampicillin, trimethoprim-sulfamethoxazole and cephalosporins. The emergence of this resistance, and the prospect of invasive disease during infection can further complicate treatment protocols and impact patient outcomes.

It is important to distinguish between *Salmonella* and *Shigella* organisms in clinical samples to ensure that the correct diagnosis is achieved, and a suitable treatment protocol can be implemented for the patient. Gram-negative bacteria are easily identifiable following Gram stain where the crystal violet stain will not bind to the thick peptidoglycan layer present in the bacterial cell wall and bacteria will present red/pink under the microscope. Following a Gram stain, a morphological analysis of the bacteria can help to further differentiate genus and species. In addition to this, both bacteria are able to metabolise xylose, but only *Salmonella* spp. are able to produce hydrogen sulfide, resulting in the black centres seen when grown on XLD Agar<sup>3,4</sup>. Thus, growth on XLD agar can help to further differentiate species of *Salmonella* and *Shigella* and should be incorporated into clinical diagnostic workflows.

### Principle of Method

The XLD Agar relies on xylose fermentation, lysine decarboxylation (XLD) and the production of hydrogen sulphide for the primary differentiation of shigellae and salmonellae from non-pathogenic bacteria. Rapid xylose fermentation is almost universal amongst enteric bacteria, except for members of the *Shigella*, *Providencia* and *Edwardsiella* genera. Xylose is present so that *Shigella* species may be identified by a negative reaction. Salmonellae are differentiated from non-pathogenic xylose fermenters by the incorporation of lysine in the medium. Salmonellae exhaust the xylose and decarboxylate the lysine, thus altering the pH to alkaline and mimicking the *Shigella* reaction. Phenol red is included as a pH indicator. The presence of salmonellae and *Edwardsiella* species is differentiated from that of shigellae by a hydrogen sulphide indicator. The high acid level produced by fermentation of lactose and sucrose prevents lysine positive coliforms from reverting the pH to an alkaline value and non-pathogenic hydrogen sulphide producers do not decarboxylate lysine. The acid level also prevents blackening by these microorganisms until after the 24-hour examination for pathogens. Sodium desoxycholate is incorporated as an inhibitor in the medium. The concentration used inhibits Gram-positive bacteria and allows for the inhibition of coliforms without decreasing the ability to support shigellae and salmonellae. Yeast extract is present as a nutrient source.

### Typical Formula

	grams per litre
Xylose	3.75
L-lysine	5.0
Lactose	7.5
Sucrose	7.5
Sodium chloride	5.0
Yeast extract	3.0
Phenol red	0.08
Sodium deoxycholate	1.0
Sodium thiosulphate	6.8
Ferric ammonium citrate	0.8
Agar	13.0

### Physical Appearance

Colour	Red
Clarity	Clear
Fill weight	19.0 ± 2.0g
pH	7.4 ± 0.2

### Materials Provided

PO0931A: 10 x 90mm XLD agar plates.

Each plate should only be used once.

### Materials Required but Not Supplied

- Inoculating loops.
- Swabs.
- Collection containers.
- Incubators.
- Quality control organisms.

### Storage

- Store product in its original packaging at 2–10°C.
- The product may be used until the expiry date stated on the label.
- Store away from light.
- Allow product to equilibrate to room temperature before use.
- Do not incubate prior to use.

### Warnings and Precautions

- For in vitro diagnostic use only.
- For professional use only.
- Inspect the product packaging before first use.
- Do not use the product if there is any visible damage to the packaging or plates.
- Do not use the product beyond the stated expiry date.
- Do not use the device if signs of contamination are present.
- Do not use the device if the colour has changed or there are other signs of deterioration.
- It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations. Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product ([www.thermofisher.com](http://www.thermofisher.com)).

### Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

### Specimen Collection, Handling and Storage

Specimens should be collected and handled following local recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI), ID 20 and ID 24.

### Procedure

- Allow product to equilibrate to room temperature.
- Inoculate and streak the specimen onto the medium using a standard loop.
- Incubate plates aerobically for 18–24 hours at 37 ± 2°C.
- Visually inspect plates to assess colony growth and colour under good lighting.

### Interpretation

The presence of colony growth indicates the presence of gram-negative enteric pathogens. Suspected *Shigella* colonies will appear as red due to their inability to ferment xylose. Suspected *Salmonella* colonies will be differentiated from *Shigella* by their black centres due to hydrogen sulfide production.

### Quality Control

It is the responsibility of the user to perform Quality Control testing taking into account the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature etc.).

The performance of this medium can be verified by testing the following reference strains.

#### PO0931A:

Incubation Conditions: 18–24 hours at 37 + 2°C. aerobic

<b>Positive Controls</b> Inoculum level: 10-100 cfu Colony count is ≥ 50% of the control medium count.	
<i>Salmonella Typhimurium</i> ATCC® 14028™	Red colonies, black centres.
<i>Shigella sonnei</i> ATCC® 25931™	Irregular red colonies.

<i>Shigella flexneri</i> ATCC® 12022™	Irregular red colonies.
<b>Negative Controls</b> Inoculum level: 100-1000 cfu	
<i>Escherichia coli</i> ATCC® 25922™	No growth or yellow colonies.

### Limitations

Identifications are presumptive and should be confirmed using appropriate biochemical/serological methods. *Pseudomonas* may grow on XLD medium and may appear as red colonies, i.e. false positives, although the oxidase reaction can be used to differentiate them. Some strains of *Proteus* species may also appear as false positives and some may develop black centres.

Other non-target organisms may also be able to grow. Some serotypes such as *Salmonella gallinarum*, *Salmonella paratyphi* and *Salmonella pullorum* may not develop black centres.

Lactose positive *Salmonella* may appear as yellow colonies with or without black centres.

Due to variation in nutritional requirements or sensitivity to selective agents some strains of the target organisms may be encountered that grow poorly or fail to grow on this medium.

### Performance Characteristics









Accuracy has been demonstrated through review of the QC data. Correct detection of *Salmonella* and *Shigella* strains is confirmed by the inclusion of a well-characterised isolates in the QC processes performed as part of the manufacture of each batch of the devices, which must meet the defined acceptance criteria. The precision of the XLD Agar (special) (PO0931A) was demonstrated by an overall pass rate of 100% obtained for the product over five months of testing (2021 – 2022; 10 batches).










The device is tested in-house as part of the QC process. QC data shows that when using target and non-target organisms and following manufacturer instructions, users can repeatedly recover organisms with colony size and morphology as described in this document.

### Bibliography

1. CDC. 2020a. "Salmonellosis (Nontyphoidal) - Chapter 4 - 2020 Yellow Book | Travelers' Health | CDC." 2020. <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/salmonellosis-nontyphoidal>.
2. CDC. 2020b. "Shigellosis - Chapter 4 - 2020 Yellow Book | Travelers' Health | CDC." 2020. <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/shigellosis>.
3. Public Health England. 2021. "UK SMI ID 24: Identification of Salmonella Species - GOV.UK." 2021. <https://www.gov.uk/government/publications/smi-id-24-identification-of-salmonella-species>.
4. Public Health England. 2014. "SMI ID 20: Identification of Shigella Species - GOV.UK." 2014. <https://www.gov.uk/government/publications/smi-id-20-identification-of-shigella-species>.

### Symbol Legend

Symbol	Definition
	Catalogue number
	In Vitro Diagnostic Medical Device
	Batch code
	Temperature limit
	Use-by date
	Keep away from sunlight
	Do not re-use
	Consult instructions for use

	Contains sufficient for <n> tests
	Do not use if packaging damaged and consult instructions for use
	Manufacturer
	Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union
	Authorized representative in the European Community/European Union
	European Conformity Assessment
	UK Conformity Assessment
	Unique device identifier
	Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union
Made in the United Kingdom	Made in United Kingdom



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For technical assistance please contact your local distributor.

**Revision Information**

Version	Date of Issue and Modifications Introduced
2.0	2024-03-19