INSTRUCTIONS FOR USE

WURTZ AGAR

Ready-to-use plates

Wurtz Agar: lactose fermenting *E.coli* (yellow colonies)

1 - INTENDED USE

In vitro diagnostic device. Culture medium for isolation and differentiation of enterobacteria from clinical and non-clinical specimens.

2- COMPOSITION - TYPICAL FORMULA *

Peptone	5.000 g
Beef extract	3.000 g
Sodium chloride	5.000 g
Lactose	10.000 g
Bromothymol blue	0.075 g
Agar	15.000 g
Purified water	1000 mL

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Wurtz agar is intended for the isolation, enumeration and differentiation of enterobacteria from samples of clinical and non-clinical origin.[1,2] Animal peptones provide carbon, nitrogen, vitamins and trace elements for microbial growth. Sodium chloride maintains the osmotic balance while agar is the solidifying agent. Lactose and bromothymol blue differentiate lactose-fermenting from lactose non-fermenting bacteria: lactose-fermenting isolates acidify the medium with a colour change of bromothymol blue from green to yellow. Non-fermenting lactose bacteria grow with blue colonies because of alkalinisation of the medium due to the decomposition of peptones with production of ammonia.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	dark green, limpid
Final pH at 20-25°C	7.1 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Wurtz Agar	Ready-to-use plates	542200	2 x 10 plates ø 90 mm primary packaging: 2 cellophane sachets secondary packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

Wurtz Agar is intended for the microbiological processing of clinical and non-clinical specimens when the differentiation of lactose fermenting and non-fermenting bacteria is required. Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of clinical specimens should be applied.

8- TEST PROCEDURE

Allow plates to come to room temperature and to dry the surface of the medium.
Inoculate and streak the specimen with a sterile loop over the four quadrants of the plate to obtain well isolated colonies, ensuring that sections 1 and 4 do not overlap. 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.
Replace the lid and then incubate the streaked agar plate in aerobic atmosphere, at 35-37°C for 18-24 hours, in an inverted position to prevent condensation.

9 - READING AND INTERPRETATION

After incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of isolated colonies.
The lactose fermenting bacteria grow on Wurtz Agar with yellow colonies of different sizes, with a more or less extensive yellow colour of the medium. Non-lactose fermenting bacteria grow with colourless to blue colonies.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the 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 the quality control.

CONTROL STRAINS		INCUBATION T°/ T / ATM	EXPECTED RESULTS
E.coli	ATCC 25922	35-37°C / 18-24H / A	good growth, large yellow colonies

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P.vulgaris	ATCC 6380	35-37°C / 18-24H / A	good growth, blue colonies

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready-to-use plates of Wurtz Agar and of the raw material used for the production of prepared plates (dehydrated Wurtz Agar REF 402200) are tested for productivity by comparing the results with a previously approved Reference Batch. The productivity characteristics are tested by semi-quantitative ecometric technique with the following strains: *E.coli* ATCC 25922, *P.vulgaris* ATCC 6380, *E.aerogenes* ATCC 13048, S.Enteritidis ATCC 13076 and *E.faecalis* ATCC 29212. After incubation, the colonies, medium colour and the amount of growth are evaluated and recorded. All strains show a good growth with typical colours. Lactose-fermenters: *E.coli* and *E.aerogenes*: yellow colonies and medium, *E.faecalis*: small yellow colonies; lactose non-fermenters: *P.vulgaris* and S.Enteritidis: blue colonies and medium.

12 - LIMITATIONS OF THE METHOD

- Due to the inclusion of sodium chloride in the formulation, *Proteus* swarming is not limited on Wurtz Agar.
- 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 required and 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.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use plates be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization, but a product with controlled bio contamination, within the limits of defined specifications reported on the Quality Control Certificate.
- Sterilize all biohazard waste before disposal. Dispose 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 on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store plates in their original pack at 2-8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at 2-8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g., microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

15 - REFERENCES

1. Mazzone C, Rizzi M, Tauro L. Etiology and Incidence of positive Microbiological tests in the Department of Pneumology. Microbiologia Medica 2010; 25 (2):101
2. Corry JEL, Curtis GDW and Baird R M., (Eds.), Culture Media for Food Microbiology, Vol. 34, Progress in Industrial Microbiology, 1995, Elsevier, Amsterdam

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	For single use only	Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 1	Updated layout and content in compliance with IVDR 2017/746	2021/01
Instructions for Use (IFU) - Revision 2	Removal of obsolete classification	2023/03

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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