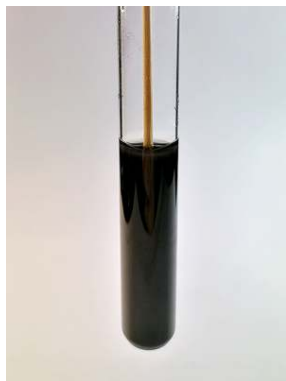


**INSTRUCTIONS FOR USE**

# AMIES TRANSPORT MEDIUM

## Dehydrated culture medium



Amies Transport Medium

**1 - INTENDED USE**

*In vitro* diagnostic. Medium for the transport of clinical swab specimens to the laboratory.

**2 - COMPOSITION - TYPICAL FORMULA \***

(AFTER RECONSTITUTION WITH 1 L OF WATER)

|                                |       |
|--------------------------------|-------|
| Charcoal                       | 10.00 |
| Sodium chloride                | 3.00  |
| Calcium chloride               | 0.10  |
| Potassium chloride             | 0.20  |
| Magnesium chloride             | 0.10  |
| Potassium dihydrogen phosphate | 0.20  |
| Disodium hydrogen phosphate    | 1.15  |
| Sodium thioglycollate          | 1.00  |
| Agar                           | 4.00  |

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

**3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE**

In 1967, C. R. Amies,<sup>1</sup> medical microbiologist for the Ontario Public Health Laboratories (PHL), published his modification of Stuart's transport medium<sup>2</sup> for improved recovery of gonococci from clinical specimens.

Amies modified Stuart's formulation by replacing glycerophosphate, that was an energy source that allowed contaminants to overgrow pathogens, with an inorganic phosphate buffer, adding sodium chloride and charcoal to the medium, omitting methylene blue and increasing agar concentration.

Amies Transport Medium is a non-nutritive semi-solid medium used for the transport and storage of specimens to be subjected to microbiological analysis.

Sodium chloride at a concentration of 0.3% is optimal for preserving *Neisseria gonorrhoeae*. Calcium and magnesium salts contribute to survival of gonococci by controlling cell permeability.<sup>1</sup> The medium provides a reduced environment due to presence of sodium thioglycollate and a small amount of agar; charcoal neutralizes materials which are toxic to pathogens survival.<sup>3</sup>

**4- DIRECTIONS FOR MEDIUM PREPARATION**

Suspend 20 g in 1000 mL of cold purified water. Heat to boiling with frequent agitation, distribute into small screw-cap tubes or bottles and sterilise by autoclaving at 121° for 15 minutes. The charcoal must be properly suspended in the medium; invert the bottles or the tubes when they are cool but the agar still liquid.

**5 - PHYSICAL CHARACTERISTICS**

|  |   |
|--|---|
| Dehydrated medium appearance           | black, fine, homogeneous, free-flowing powder |
| Solution and prepared tubes appearance | black, opaque                                 |
| Final pH at 20-25 °C                   | 7.2 ± 0.1                                     |

**6 - MATERIALS PROVIDED - PACKAGING**

| Product                | Type              | REF     | Pack  |
|------------------------|-------------------|---------|---|
| Amies Transport Medium | Dehydrated medium | 4010342 | 500 g (25 L)<br>CND W0104010101; EDMA: 14.01.01.01; RDM: 1851171 /R |

**7 - MATERIALS REQUIRED BUT NOT PROVIDED**

Autoclave, water-bath, sterile swabs, Erlenmeyer flasks, screw-cap tubes.

**8 - SPECIMENS**

Amies Transport Medium is suitable for the transport and storage of clinical specimens for the isolation of aerobic and anaerobic microorganisms, especially collected from the throat, urogenital system and from wounds; in particular, the medium was developed for the collection of samples on which detect gonococci. Good laboratory practices for collection, transport and storage of clinical specimens should be applied. Collect specimens before antimicrobial therapy where possible.

**9 - TEST PROCEDURE**

- Insert the swab into the medium to one-third of the medium depth.
- Cut or break the swab stick if longer than the tube.
- Screw the cap firmly.
- Transport to the laboratory as soon as possible or preferably within 6 hours (maximum up to 24 hours).
- Transfer to appropriate isolation media depending on specimen source.
- Incubate plated media using proper microbiological procedures for cultivation of the suspected pathogens.

**10 - READING AND INTERPRETATION**

The presence of microorganisms is indicated by the appearance of colonies of varying morphology and size on the isolation media. The characteristics of the growths are closely related to the type or types of cultivated microorganisms.

**11 - 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, it is responsibility of the end-user to perform Quality Control testing 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                                      |
|---------------------------------|-------------------------|---|
| <i>B.fragilis</i> ATCC 25285    | 20-25°C / 24h           | good recovery after subculture to Shaedler Blood Agar |
| <i>N.gonorrhoeae</i> ATCC 19424 | 20-25°C / 24h           | good recovery after subculture to Chocolate Agar      |

ATCC is a trademark of American Type Culture Collection

### 12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated Amies Transport Medium is tested for organisms recovery by comparing the results with a previously approved Reference Batch.

Recovery is tested by incubating at 20-25°C for 18-24 hours the inoculated Amies tubes with the following strains: *B.fragilis* ATCC 25285, *N.gonorrhoeae* ATCC 19424, *S.pyogenes* ATCC 19615, *H.influenzae* ATCC 10211. The inoculated tubes are sub-cultured on appropriate plating media by a semi-quantitative ecometric technique and incubated at 35-37°C for 18-24 hours with the appropriate atmosphere (aerobic, anaerobic, CO<sub>2</sub>). The bacterial recovery on plating media are observed and recorded. All inoculated Amies Transport Medium tubes, maintained at 20-25°C for 18-24 hours, originate a good growth on sub-cultured plated media.

### 13 - LIMITATIONS OF THE METHOD

- The tubes with Amies Transport Medium can be stored for not more than 9 months in a cool place (22-25°C) with caps tightly closed.<sup>3</sup>
- According to the data of Barry et al.<sup>4</sup>, survival of anaerobes is best if the sample is collected with a cotton swab rather than on calcium alginate swabs.
- The survival of bacteria in a transport medium depends on many factors, including the type and concentration of bacteria in the sample and the temperature during the transport. Optimal growth and typical morphology can only be predicted following direct inoculation of the specimen and the use of an adequate isolation medium. Amies Transport medium, however, provides an adequate level of microbial survival in clinical specimens that cannot be immediately forwarded to the laboratory.
- Cell viability may decrease during the storage period and some degree of multiplication of contaminating microorganisms may occur, especially for faecal specimens that contain a considerable number of coliforms.
- 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.

### 14 - 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.
- Dehydrated media must be handled with suitable protection. Before use, consult the Safety Data Sheet.
- 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 the unused medium and the sterilized plates inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website [www.biolifeitaliana.it](http://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.

### 15 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap were damaged or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

### 16 - REFERENCES






1. Amies CR. A modified formula for the preparation of Stuart's transport medium Can J Public Health 1967; 58:296-300.
2. Stuart RD, Toshach Sheila R, Patsula TM. The problem of transport of specimens for the culture of gonococci. Acta Pathol Microbiol Scand 1954; 74: 371-374.
3. MacFaddin JF. Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria. Baltimore: Williams & Wilkins; 1985.
4. Barry AL, Fay GH, Sauer RL, (1972) Efficiency of a transport medium for the recovery of aerobic and anaerobic bacteria in various transport media. Appl Microbiol 1972; 24(1): 31.

### TABLE OF APPLICABLE SYMBOLS

|  |                          |  |  |  |
|--|--------------------------|--|--|--|
| <b>REF</b><br>or REF<br>Catalogue number | <b>LOT</b><br>Batch code | <b>IVD</b><br>In vitro<br>Diagnostic<br>Medical Device |  Manufacturer |  Use by |
|--|--------------------------|--|--|--|





|  |   |  |  |  |
|--|---|--|--|--|
|  Temperature limitation |  Contents sufficient for <n> tests |  Consult Instructions for Use |  Keep away from direct light |  Store in a dry place |
|--|---|--|--|--|

#### REVISION HISTORY

| Version    | Description of changes     | Date    |
|------------|----------------------------|---------|
| Revision 1 | Updated layout and content | 2020/09 |

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

