HealthLink
800-638-2625

Product No. 1176
Revision No. 01

PRODUCT INFORMATION AND QUALITY CONTROL SHEET

V AGAR

I. INTENDED USE

v agar is used for the isolation of *Gardnerella vaginalis* and serves to differentiate it from other genioturinary flora by the hemolytic reaction.

II. SUMMARY AND EXPLANATION

Gardner and Dukes recovered a gram negative pleomorphic bacillus from 127 of 138 cases of bacterial vaginitis and assigned it the name *Haemophilus vaginalis* (3). Numerous other authors associated *H. vaginalis* with bacterial vaginitis (1,2). In 1980, Greenwood and Pickett recommended transferring the organism to a new genus, *Gardnerella* (4).

G. vaginalis is a gram negative to gram variable pleomorphic rod. Colonies on V Agar are about 0.3mm in diameter and surrounded by a zone of beta hemolysis (6). Organisms resembling *G. vaginalis* are rarely hemolytic.

III. PRINCIPLES OF THE PROCEDURE

V agar contains peptones, beef extract and yeast extract, which supply the nutrients required for the growth of G. vaginalis strains. The peptones and beef and yeast extracts are sources of the nitrogenous compounds, carbon, sulfur and trace ingredients. The yeast extract and corn starch serve as energy sources with the yeast extract and corn starch serve as energy sources with the yeast extract being a supplier of the B-complex vitamins.

The human blood aids in the identification of G. vaginalis since the small size of the colonies and the diffuse hemolysis is distinctive compared to other hemolytic colonies.

IV. TYPICAL FORMULA AND APPEARANCE

Appearance = opaque, cherry red
(Approximate formula* per liter of processed water)

Columbia agar	44g
Proteose peptone #3	10
Human blood w/CPD	50ml

*adjusted and/or supplemented to meet performance criteria.

V. PRECAUTIONS

This product is for IN VITRO diagnostic use only. Culture specimens may contain microorganisms which can be potentially infectious to the user. Strict adherence to aseptic techniques and established precautions against microbiological hazards should be followed throughout the procedure. Carefully dispose of all items which contact patient specimens or isolated bacteria.

VI. STORAGE/SHELF LIFE

Plated media should be stored at 2-8°C (36-46°F), media side up, in the unopened or resealed package protected from light. DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow unopened plates to warm to room temperature prior to inoculation. Prior to and during inoculation procedures, plates should be handled in a manner that minimizes product exposure to the environment. Product which has exceeded the assigned expiration date noted on the label should not be used.
Do not use plates that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration. The presence of excessive condensate may indicate plates which have been damaged by exposure to temperature extremes.

VII. SPECIMEN COLLECTION

The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination. Proper specimen collection techniques must be followed to ensure the most accurate culture results. Sterile swabs and collection containers should be used. Plates should be inoculated promptly after specimen collection. If a delay in inoculation is unavoidable, transport medium should be employed. Specimens should be collected prior to the initiation of antimicrobial therapy.

Detailed information on proper specimen collection may be obtained from microbiology reference materials.

VIII. MATERIALS PROVIDED

V Agar plates

IX. MATERIALS REQUIRED BUT NOT PROVIDED

Incubator maintaining 33-37°C.
Ancillary culture media, reagents and laboratory equipment as required.

X. PROCEDURE

Inoculate the specimen as soon as possible after it is received in the laboratory. The streak plate method is used primarily to isolate pure cultures from specimens containing mixed flora. If material is being cultured directly from a swab, roll the swab over a small area of the plate surface at the edge (approximately 1/4 to 1/3 of the plate); then streak in a zig-zag fashion with a sterile loop from this inoculated area in two sections to cover the entire agar surface; flaming or flipping loop between sections. Avoid applying excessive pressure to the agar surface during inoculation to prevent gouging and splitting of the agar media. Incubate plates media side up at 33-37°C for 18-24 hours. (Note: Agar surfaces should be smooth and moist but free of excessive moisture which could cause confluent growth patterns.)

XI. EXPECTED RESULTS

NCCLS CONTROL ORGANISMS (ATCC STRAINS)

G. vaginalis (ATCC 14018)	Growth, Beta hemolysis

XII. LABORATORY RESULTS

This medium is intended to be used as a primary isolation medium. Presumptive identification of organisms may be made on the basis of typical organism morphology and Gram stain.

Definitive identification of organisms requires further testing. Additional biochemical information may be obtained from reference microbiology texts.[1,2,3]

XIII. LIMITATIONS

The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media.

XIV. REFERENCES

1. Bergman, S. 1965. *Haemophilus vaginalis* in vaginitis. Acta Obset. Gyne. Scand. 44:8-17
2. Edmunds, P.N. 1959. *Haemophilus vaginalis:* its association with puerperal pyrexia and leucorrhoeae. J. Obset. Gynec. (Britain). 66:917
3. Gardner, H.L. and C.D. Dukes. 1995. *Haemophilus vaginalis* vaginitis. A newly defined specific infection previously classified "non-specific" vaginitis. Am. J. Obset. Gynecol. 69:962-976
4. Greenwood, J.R. and M.J. Pickett. 1980. Transfer of *Haemophilus vaginalis* Gardner and Dukes to a new genus. *Gardnerella, G. vaginalis* (Gardner and Dukes) comb. nov. Int. J. Syst. Bacteriol. 30:170-178

5. Lennette, E.H., et al. 1985. Manual of Clinical Microbiology. 4th Ed. ASM. Washington, DC
6. Piof, P., et al. 1982. Identification of *Garderella (Haemophilus) vaginalis*. J. Clin. Microbiol. 15:19-24

USER QUALITY ASSURANCE/ QUALITY CONTROL PROCEDURES AND INFORMATION

HealthLink recommends that the following quality assurance and quality control procedures be performed on each batch of product.

I. QUALITY ASSURANCE
The following quality assurance procedures must be performed to assure the product will perform according to its intended use within the assigned expiry date:

1. Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8°C.
2. Daily, document that laboratory incubator maintains temperature within the recommended range: 22-35°C.

II. QUALITY CONTROL
The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory :

1. Inspect plates according to instructions contained on the "Quality Control Log Sheet." (See also Section VI "STORAGE/SHELF LIFE")
2. Peel off the lower portion of a product bag label (Quality Control Certificate) for the lot being accepted into the laboratory and affix it to the Quality Control Log Sheet.
3. Initial and date the Quality Control Log Sheet.

Note: Notify Technical Service immediately if media does not meet the inspection criteria.

TECHNICAL SERVICE

HealthLink provides a toll free technical service line (1-800-638-2625) to assist with product usage. To receive additional product information, procedural instructions, QA/QC log sheets, Material Safety Data Sheets, or to have technical questions answered; please call between the hours of 9:00 am to 5:00 pm EST.

HealthLink
7779 Bayberry Road
Jacksonville, FL 32256

1-800-638-2625

January, 1997

Product No. 1176 Rev. No. 01