

PRODUCT INFORMATION AND QUALITY CONTROL SHEET

STREP SCREEN

I. INTENDED USE

The HealthLink Strep Screen contains culture media and ancillary items to perform screening cultures for Streptococci, especially beta hemolytic Strep group A. This kit includes: Strep Select agar plates, specimen swabs, disposable carbon dioxide generating systems, Taxo A® differentiation discs and patient result forms.

Strep Select Agar is a selective media for use in the isolation of *Streptococci sp.* from clinical specimens; especially beta hemolytic Strep group A.

II. SUMMARY AND EXPLANATION

Although viruses are the most common causative agent of pharyngitis, streptococcal pharyngitis is by far the most common type of upper respiratory tract pathogen that can be effectively treated. Diagnosis and treatment of streptococcal pharyngitis is important to prevent the occurrence of rheumatic fever and limit epidemiological spread.¹ To aid in the isolation of group A streptococci (*S. pyogenes*) from specimens that contain large amounts of normal flora, antimicrobial agents have been combined into a highly nutritious general purpose medium supplemented with sheep blood. These antimicrobial agents (neomycin and polymyxin B) suppress the growth of normal flora and other organisms which could prevent detection of group A streptococci.

III. PRINCIPLES OF THE PROCEDURE

Growth support characteristics of Columbia Agar are derived from the presence of peptones prepared from pancreatic digest of casein, peptic digest of animal tissue and beef extract. Yeast extract and corn starch are included as energy sources. Sheep blood provides both X factor (hemin) and a visualization of hemolytic reactions. Neomycin and Polymyxin B, antimicrobial agents, create a selective environment for gram positive organisms by either disrupting the cell membrane or blocking DNA replication of susceptible gram negative organisms.

IV. TYPICAL FORMULA AND APPEARANCE

Appearance = opaque, cherry red

(Approximate formula* per liter of processed water)

Casein Peptone	10.0g
Beef extract	6.7
Nucleic acid	6.0
Sodium Chloride	5.0
Agar	13.5
Maltose	0.25
Neomycin	0.002
Polymyxin B	200,000 units
Defibrinated Sheep Blood	50 ml

*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 and procedural techniques must be followed to ensure the most accurate culture results possible. Specimens should be collected prior to the initiation of anti-infective therapy. Sterile collection containers should be used.

A properly collected throat swab is essential. Under adequate lighting, depress the tongue and rub a sterile swab vigorously over each tonsillar area and posterior pharynx. Any exudate should be touched, and care should be taken to avoid areas containing large amounts of normal respiratory flora (i.e., tongue, uvula, cheeks, lips, etc.).

Plates should be inoculated promptly after specimen collection. If a delay in inoculation of more than 1-2 hours is unavoidable, transport medium such as Stuart's or Amies should be used. Every effort should be made at prompt specimen inoculation. Extended delays in processing permit overgrowth of potential pathogens by normal respiratory flora.

VIII. MATERIALS PROVIDED

Strep Select Agar Plates
Specimen swabs
CO₂ generators and zip-lock bags
Taxo® A discs
Patient Report Pad

IX. MATERIALS REQUIRED BUT NOT PROVIDED

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

X. PROCEDURE

DAY ONE

1. Remove Strep Select Agar Plate from refrigerated storage and allow to warm to room temperature. Agar surface should be free of excessive moisture which could cause confluent organism growth. Label plate with specimen identification number and inoculation date.

2. Roll the specimen swab, or swab immersed in purulent material, over the initial one third of the plate to ensure contact with all swab surfaces.

Note: If additional test procedures are to be performed (i.e., Gram stain etc.), it is recommended that multiple specimen swabs be collected.

3. Using a plastic sterile disposable inoculating loop, streak in a zig-zag fashion over swabbed area and continue over the entire plate surface for isolation of colonies. Avoid applying excess pressure to the agar surface during inoculation to prevent gouging and splitting of the agar medium. (See Diagram 1.)

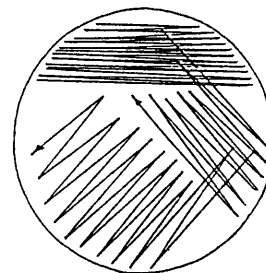


Diagram 1

4. If testing with differentiation discs (i.e., Taxo A®) is desired on primary inoculum, aseptically place a disc onto the initial inoculum area ensuring complete contact with the agar surface. See Diagram 2. (See also Section XIII. LIMITATIONS)

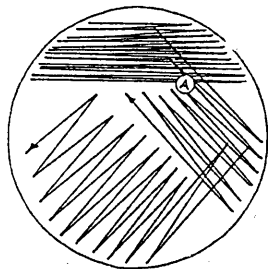


Diagram 2

5. Insert the inoculated plate and a CO₂ generator into a zip-lock bag. Seal the bag, crush the generator in an upright position and allow the liquid contained in the vial to contact the pellets. When effervescing has stopped, place the unopened zip-lock bag into the incubator media side up.

5. Incubate the plates at 33-37°C for 18 - 48 hours.

6. Pathogens may be detected as early as 18 hours however, it is recommended that inoculated plates be incubated for a total of 48 hours before reporting a culture as "normal flora".

DAY TWO

1. Remove the plate from the incubator. (Note: The CO₂ atmosphere within the zip lock bag will dissipate upon opening the bag. Examination of culture results prior to detection of organism growth or 48 hours of incubation may be accomplished by; 1) examining the plate through the unopened bag or 2) using an additional CO₂ generator upon reincubating the opened and examined culture plate. (Catalog #3425)

2. Presumptively identify the suspected pathogenic organism(s) present by comparing the growth reactions to the β Strep Screen Color Identification Chart.

3. Interpretation of Taxo A® Zones of Inhibition

3.1 Taxo A®: Observe the agar plate for growth of beta hemolytic streptococci. Any zone of inhibition of beta hemolytic streptococci around the disc should be interpreted as positive.⁴ Interpretation is as follows: Zone present = "beta hemolytic *Streptococci*, presumptive group A by bacitracin"

Zone absent = "beta hemolytic *Streptococci* species, presumptively not group A by bacitracin.

XI. EXPECTED RESULTS

NCCLS CONTROL ORGANISMS (ATCC STRAINS)

<i>Streptococcus pyogenes</i> (ATCC 19615)	Growth, beta hemolysis, sensitive to Taxo A®
<i>Streptococcus group B</i> (ATCC 12386)	Growth, beta hemolysis, not sensitive to Taxo A®
<i>Staphylococcus aureus</i> (ATCC 25923)	Inhibition (partial)
<i>Streptococcus mitis</i> (ATCC 6249)	Inhibition (partial to complete)
<i>Neisseria sicca</i> (ATCC 9913)	Inhibition (partial to complete)
<i>Proteus mirabilis</i> (ATCC 12453)	Inhibition (partial)
<i>Escherichia coli</i> (ATCC 25922)	Inhibition (partial to complete)

XII. LABORATORY RESULTS

Growth should be evident after 18-48 hours of incubation. Beta hemolytic Streptococci may be presumptively identified as small, translucent to opaque colonies surrounded by zones of beta hemolysis. The presence of a zone of inhibition surrounding the Taxo A® disc is a presumptive identification of beta hemolytic Strep group A. Definitive identification of beta hemolytic Strep group A requires further testing using serologic or antigen based test procedures.

Most *Neisseria* sp., viridans Streptococci, and non group A streptococci are inhibited on this medium. Small colonies of alpha hemolytic streptococci and non hemolytic streptococci may grow but should not interfere with interpretation of culture results. Some staphylococci and *Pseudomonas* species may not be inhibited.

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 anti-infective 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

- Bannatyne, R.M., C. Clausen, L.R. McCarthy. 1979. Cumitech 10. Laboratory Diagnosis of Upper Respiratory Tract Infections. Coordinating ed., I.B.R. Duncan. American Society for Microbiology, Washington, D.C.
- Gunn, B.A., D.K. Onashi, C.A. Gaydos, and E.S. Holt. 1977. Selective and enhanced recovery of Group A and B streptococci from throat cultures with sheep blood agar containing sulfamethoxazole and trimethoprim. J. of Clinical Microbiology Vol 5:650-655.
- Finegold, S.M. and W.S. Martin. 1982. Bailey and Scott's Diagnostic Microbiology, 6th ed. C.V. Mosby Company, St. Louis.
- Koneman, E.S., S.D. Allen, V.R. Dowell, Jr. and H. M. Sommers. 1983. Color Atlas and Textbook of Microbiology, 2nd ed. J.B. Lippincott Company, Philadelphia.
- Lennette, E.H., ed. 1985. Manual of Clinical Microbiology, 4th ed. American Society for Microbiology, Washington, D.C.

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. For general information pertaining to CLIA and its requirements for your laboratory, see the *Federal Register/ Vol. 57, No. 40/ Friday, February 28, 1992* and subsequent published updates and revisions or call HealthLink's Technical Service Department.

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:

- Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8°C.
- Daily, document that laboratory incubator maintains temperature within the recommended range: 33-37°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 HealthLink "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.

End users performing differential disc method procedures (i.e. Taxo® A disc for differentiation of group A beta Streptococcus, Taxo® P disc for differentiation of *Streptococcus pneumoniae*) must document and complete appropriate quality control procedures for these discs. These procedures must be performed weekly according to the *Federal Register Vol 57, No. 40, February 28, 1992, Section 493.1227 a), 2. p. 7167.* (Quality Control Kit catalog #s 3137 and 3139 can be ordered by contacting our customer service department.)

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

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