HealthLink
800-638-2625

Product No. 1612
Revision No. 01

PRODUCT INFORMATION AND QUALITY CONTROL SHEET

URINE SCREEN

I. INTENDED USE

The HealthLink Urine Screen Kit contains the necessary culture media and ancillary equipment to perform screen cultures for bacteriuria in a laboratory setting. The kit includes: Urine Screen bi-plates (CNA 5%SB/MacConkey Agar), calibrated inoculation loops and patient results forms.

II. SUMMARY AND EXPLANATION

Infections of the urinary tract are often first detected in the urine. Growth obtained from specimens exhibiting bacteria and WBCs on microscopic examination can denote cystitis, pyelonephritis or can be the precursor or causative agent of septicemia. The diagnosis of a urinary tract infection is based on quantifying the total number of organisms present in a urine sample. Urine is a sterile body fluid but, because it is a good growth medium for bacteria, specimen collection technique is essential for meaningful culture results. Contamination most commonly arises from contact with resident skin flora or fecal material.

The combination of selective and differential media contained in the HealthLink Urine Screen provides useful preliminary information to the laboratorian in identifying the causative agent of a urinary tract infection as a gram positive or gram negative organism. This information is pertinent to the proper choice of antimicrobial therapy.

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. Colistin and nalidixic acid , 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.

The selective property of the MacConkey medium is due to the addition of bile salts and crystal violet which inhibit the growth of gram positive organisms. Differentiation of lactose fermenting versus non lactose fermenting is achieved with the indicator neutral red. Colonies will appear either colorless or pink to red based on the organisms ability to ferment this carbohydrate.

IV. TYPICAL FORMULA AND APPEARANCE

(Approximate formula* per liter of processed water)

CNA 5% AGAR

Appearance = opaque, cherry red

Pancreatic Digest of Casein	12.0g
Peptic Digest of Animal Tissue	5.0
Yeast Extract	3.0
Beef Extract	3.0
Corn Starch	1.0
Sodium Chloride	5.0
Agar	13.5
Colistin	10.0mg
Nalidixic Acid	10.0
Defibrinated Sheep Blood	5%

MacCONKEY AGAR

Appearance =pinkish-purple, slightly opalescent

Pancreatic Digest of Gelatin	17.0g
Pancreatic Digest of Casein	1.5
Peptic Digest of Animal Tissue	1.5
Lactose	10.0
Bile Salts	1.5
Sodium Chloride	5.0
Neutral Red	0.03
Crystal Violet	0.001
Agar	13.5

*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.

Three types of urine specimens may be evaluated for culture; the clean-catch midstream, a Foley-catheterized specimen and a suprapubic aspiration. If a delay in inoculation is inevitable, urine specimens may be refrigerated at 2-8°C for up to 24 hours prior to culture.[1,2]

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

VIII. MATERIALS PROVIDED

CNA 5% SB / MacConkey Agar Plates and lot specific Quality Control Certificate.
Calibrated inoculation loops
Patient report forms

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. (See "Specimen Collection" for additional information.) Dip the calibrated loop just below the surface of a well mixed or resuspended specimen. Withdraw the loop ensuring that a drop of specimen is contained within the loop portion (avoid bubbles). Inoculate one agar of the biplate by dispensing the drop with a straight line motion down the center of the agar. Without redipping the loop, make zig-zag motions across the straight line inoculation as tightly as possible to disperse the inoculum onto the enitre agar surface. Redip the loop into the specimen and repeat this procedure with the remaining agar.

Incubate the inoculated plates, media side up, at 33-37°C for 16 - 24 hours. Colonies observed after incubation may be selected for further biochemical testing or antimicrobial sensitivity studies. Reincubation for an additional 24 hours is needed only if there is a discrepancy between the culture and urinalysis or Gram stain result.

A non-selective medium, such as Tryptic Soy Agar with 5% sheep blood, should also be considered for inoculation to increase the chance of recovering gram negative bacteria present in low numbers.

XI. EXPECTED RESULTS

NCCLS Control Organisms (ATCC Strains)

CNA 5% AGAR	
Streptococcus pyogenes (ATCC 19615)	Growth, beta hemolysis
Streptococcus pneumoniae (ATCC 6305)	Growth, alpha hemolysis
Staphylococcus aureus (ATCC 25923)	Growth
Proteus mirabilis (ATCC 12453)	Inhibition (partial)
MacCONKEY AGAR	
Escherichia coli (ATCC 25922)	Growth, pink colonies
Proteus mirabilis (ATCC 12453)	Growth, colorless colonies, inhibition of swarming
Salmonella typhimurium (ATCC 14028)	Growth, colorless colonies
Enterococcus faecalis (ATCC 29212)	Inhibition (partial)

XII. LABORATORY RESULTS

Results should be reported as the number of bacterial colonies per milliliter of urine specimen (col/ml). After incubation, count the number of colonies present and multiply by the dilution factor of the inoculation loop. (Multiply the number of colonies by 100 (0.01ml) when using the calibrated loop provided in this kit. Example: 100 colonies isolated x 100 = 10,000 col/ml.) The significance of colony counts less than 10^5 col/ml is increased according to the type of specimen submitted for examination: catheterized or suprapubic aspirate. Patients asymptomatic for urinary tract infection with culture results of 10^5 col/ml or greater should by recultured for confirmation.[1]

Colonies of suspected pathogens may be selected for further biochemical testing and antimicrobial susceptibility studies if desired. If more than two organisms are observed and none clearly predominates, especially with the absence of leukocytes or the presence of large numbers of squamous epithelial cells, gross contamination should be suspected and a reculture performed.

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. Definitive identification of organisms and antimicrobial sensitivity determination requires additional testing which may include: Gram stain, oxidase, catalase, and other biochemical tests. Additional biochemical information may be obtained from reference microbiology texts.[2,3,4]

XIV. REFERENCES

1. Clarridge, J.E., M.T. Pezzlo, K.L. Vosti. March 1987. Cumitech 2A. Laboratory Diagnosis of Urinary Tract Infections. Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.
2. Lennette, E.H., ed. 1985. Manual of Clinical Microbiology, 4th ed. American Society for Microbiology, Washington, D.C.
3. Finegold, S.M. and W.S. Martin. 1982. Bailey and Scott's Diagnostic Microbiology, 6th ed. C.V. Mosby Company, St, Louis.
4. 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. Lippincot Company, Philadelphia.

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.

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