QUALITY CONTROL PROCEDURES (Optional)

I INTRODUCTION
BD BBL™ GC-Lect™ Agar is a selective medium providing enhanced growth and recovery of *Neisseria gonorrhoeae* and better inhibition of contaminating organisms.

II PERFORMANCE TEST PROCEDURE
1. Inoculate representative samples with dilutions of the cultures listed below.
   a. For *Neisseria gonorrhoeae* cultures: using a volumetric pipettor or equivalent method, deliver 0.1 mL of a dilution yielding 30–300 CFU to each plate and spread-inoculate using a sterile glass spreader. For all other organisms: using a volumetric pipettor or equivalent method, deliver 0.1 mL of a dilution yielding $10^4$–$10^5$ per 0.1 mL inoculum to each plate and spread-inoculate using a sterile glass spreader.
   b. Incubate at 35 ± 2 °C in an aerobic atmosphere supplemented with carbon dioxide.
   c. Include Chocolate II Agar plates as nonselective controls for all organisms.
2. Examine plates after 18–24 and 42–48 h for growth, colony size and selectivity.
3. Expected Results

<table>
<thead>
<tr>
<th>CLSI Organisms</th>
<th>ATCC®</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Neisseria gonorrhoeae</em></td>
<td>43069</td>
<td>Growth</td>
</tr>
<tr>
<td><em>Neisseria meningitidis</em></td>
<td>13090</td>
<td>Growth</td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
<td>43071</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td><em>Neisseria sicca</em></td>
<td>9913</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td><em>Candida albicans</em></td>
<td>60193</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td>12228</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>25922</td>
<td>Inhibition (partial to complete)</td>
</tr>
</tbody>
</table>

Additional Organisms
- *Neisseria gonorrhoeae* 35201 Growth
- *Capnocytophaga ochracea* 33595 Inhibition (complete)

*Recommended organism strain for User Quality Control.*

NOTE: User QC testing of exempt media for *N. gonorrhoeae* is strongly recommended by CLSI M22-A3.

III ADDITIONAL QUALITY CONTROL
1. Examine plates as described under “Product Deterioration.”
2. Visually examine representative plates to assure that any existing physical defects will not interfere with use.
3. Determine the pH potentiometrically at room temperature for adherence to the specification of 7.2 ± 0.2.
4. Note the firmness of plates during the inoculation procedure.
5. Incubate uninoculated representative plates at 35 ± 2 °C in an aerobic atmosphere supplemented with carbon dioxide for 72 h and examine for microbial contamination.

PRODUCT INFORMATION

IV INTENDED USE
BD BBL GC-Lect Agar is a selective plated medium providing enhanced growth and recovery of *Neisseria gonorrhoeae* and better inhibition of contaminating bacteria and fungi, including *Capnocytophaga* species in oropharyngeal specimens.

V SUMMARY AND EXPLANATION
A succession of media have been developed for the isolation of the pathogenic *Neisseria* from specimens containing mixed flora [Thayer-Martin Selective Agar, Modified Thayer-Martin (MTM) Agar, Martin-Lewis Agar]. Each provides greater inhibition of contaminating organisms than the preceding formulation but each is, to varying degrees, inhibitory to certain strains that it is designed to recover. BD Diagnostics developed GC II Agar Base as an improved base for Chocolate II Agar which is utilized in these selective media. The superior growth-promotion achieved for pathogenic *Neisseria* also enabled growth of strains of *Capnocytophaga* on the selective medium when inoculated with oropharyngeal specimens.

BD BBL GC-Lect Agar was developed and patented by BD Diagnostics to provide the additional inhibition required to prevent overgrowth of the pathogenic *Neisseria* in specimens containing *Capnocytophaga* species and other strains resistant to the inhibitors in MTM Agar; i.e., vancomycin-resistant contaminants, including certain strains of *Staphylococcus epidermidis*. As with MTM, *N. lactamica*, which is resistant to colistin, is not inhibited by BD BBL GC-Lect Agar.

BD BBL GC-Lect Agar contains a decreased concentration of vancomycin for improved recovery of *N. gonorrhoeae* strains that are sensitive to this antibiotic.
VI PRINCIPLES OF THE PROCEDURE

BD BBL GC-Lect Agar is based on BD BBL Chocolate II Agar that contains the improved GC II Agar Base, achieved through careful selection and pretesting of raw materials, bovine hemoglobin and BD IsoVitaleX™ Enrichment. The GC II Agar Base contains nitrogenous nutrients in the form of casein and meat peptones, phosphate buffer to maintain pH and corn starch, which neutralizes toxic fatty acids that may be present in the agar. X (hemin) and V (nicotinamide adenine dinucleotide) factors are provided by hemoglobin and BD IsoVitaleX Enrichment. BD IsoVitaleX Enrichment also provides vitamins, amino acids, co-enzymes, dextrose, ferric ion and other factors that improve the growth of pathogenic Neisseria. In addition, BD BBL GC-Lect Agar permits the growth of some vancomycin-sensitive gonococcal strains which are inhibited on standard MMT Agar.

To improve the selectivity of BD BBL GC-Lect Agar, BD Diagnostics developed a combination of five antimicrobial agents to inhibit gram-positive bacteria, including vancomycin-resistant S. epidermidis, gram-negative species, including Proteus and Capnocytophaga, as well as fungi, including Candida albicans.

VII REAGENTS

BD BBL GC-Lect Agar

Approximate Formula* Per Liter Purified Water

Pancreatic Digest of Casein ________________________________ 7.5 g
Selected Meat Peptone ____________________________________ 7.5 g
Corn Starch ___________________________________________________________________________ 1.0 g
Dipotassium Phosphate ___________________________________ 4.0 g
Monopotassium Phosphate __________________________________ 1.0 g

Sodium Chloride ________________________________________ 5.0 g
Agar ___________________________________________________ 12.0 g
Hemoglobin _____________________________________________ 10.0 g
Selective Agents _________________________________________ 17.0 mg
BD IsoVitaleX Enrichment __________________________________ 10.0 mL

BD IsoVitaleX Enrichment

Approximate Formula* Per Liter Purified Water

Vitamin B12____________________________________________________________________________ 0.01 g
L-Glutamine ____________________________________________________________ 10.0 g
Adenine _______________________________________________________________________________ 1.0 g
Guanine Hydrochloride _________________________________________________________ 0.03 g
p-Aminobenzoic Acid ___________________________________________________________ 0.013 g
Nicotinamide Adenine Dinucleotide ________________________________ 0.25 g

Thiamine Pyrophosphate ________________________________________________ 0.1 g
Ferric Nitrate ___________________________________________________________ 0.02 g
Thiamine Hydrochloride _____________________________________________ 0.003 g
L-Cysteine Hydrochloride __________________________________________ 25.9 g
L-Cysteine ___________________________________________________________ 1.1 g
Dextrose ____________________________________________________________ 100.0 g

Storage Instructions:

On receipt, store plates in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Prepared plates stored in their original sleeve wrapping at 2–8 °C until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation. Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

VIII SPECIMEN COLLECTION AND HANDLING

Specimens suitable for culture may be handled using various techniques. For detailed information, consult appropriate texts. Specimens should be obtained before antimicrobial therapy has been administered. Provision must be made for prompt delivery to the laboratory.

IX PROCEDURE

Material Provided: BD BBL GC-Lect Agar

Material Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.

Test Procedure: Observe aseptic techniques.

The agar surface should be smooth and moist, but without excessive moisture.

Streak the specimen as soon as possible after it is received in the laboratory. Alternatively, if material is being cultured directly from a swab, proceed as follows:

1. Roll swab directly on the medium in a large "Z" to provide adequate exposure of swab to the medium for transfer of organisms.
2. Cross-streak the "Z" pattern with a sterile wire loop, preferably in the clinic. If not done previously, cross-streaking should be done in the laboratory.
3. Place the culture as soon as possible in an aerobic environment enriched with carbon dioxide.

User Quality Control: See “Quality Control Procedures.”

Each lot of media has been tested using appropriate quality control organisms and this testing meets product specifications and CLSI standards, where relevant. As always, QC testing should be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory's standard quality control procedures.

X RESULTS

After a minimum of 18 h of incubation, the plates should show isolated colonies in streaked areas and confluent growth in areas of heavy inoculation. Some strains may require up to 72 h of incubation before visible colonies appear. Neisseria gonorrhoeae appears as small, grayish-white to colorless mucoid colonies. N. meningitidis forms a colony similar to N. gonorrhoeae, but larger and bluish-gray.

A presumptive identification may be made by performing a Gram stain and an oxidase test. Biochemical tests and other identification procedures should be performed to confirm findings.
XI LIMITATIONS OF THE PROCEDURE
For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.\textsuperscript{15,16,20-23}
A single medium is rarely adequate for detecting all organisms of potential significance in a specimen. The agents in selective media may inhibit some strains of the desired species or permit growth of a species they were designed to inhibit, especially if the species is present in large numbers. Specimens cultured on selective media should, therefore, also be cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

XII PERFORMANCE CHARACTERISTICS\textsuperscript{16}
In a clinical study with 500 specimens, visible growth of \textit{N. gonorrhoeae} occurred within 24 h in 72\% of the positive cultures on \textbf{BD BBL GC-Lect} Agar, compared with only 52\% on the reference medium, MTM Agar. A total of 50 positive cultures were obtained with \textbf{BD BBL GC-Lect} Agar, compared with 49 obtained with MTM. The selectivity of \textbf{BD BBL GC-Lect} Agar was superior, with only 19 cultures producing growth of normal flora, compared with 78 cultures on MTM after 24 h of incubation. The selectivity was especially improved on \textbf{BD BBL GC-Lect} Agar with regard to yeasts (2 versus 30 cultures) and gram-positive cocci (5 versus 31 cultures).

XIII AVAILABILITY

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>297715</td>
<td>\textbf{BD BBL}™ \textbf{GC-Lect}™ Agar, Pkg. of 20 plates</td>
</tr>
<tr>
<td>297928</td>
<td>\textbf{BD BBL}™ \textbf{GC-Lect}™ Agar, Ctn. of 100 plates</td>
</tr>
</tbody>
</table>

XIV REFERENCES


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