IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

GBS DETECT™

Cat. no. A300	GBS Detect™, 15x100mm Plate, 17ml	10 plates/bag
Cat. no. A300BX	GBS Detect™, 15x100mm Plate, 17ml	100 plates/box
Cat. no. GA300	GBS Detect™, 15x100mm Plate, 17ml (reduced stacking ring)	10 plates/bag

INTENDED USE

Hardy Diagnostics GBS Detect™ is recommended for the isolation and differentiation by enhanced hemolysis of detection of gamma-hemolytic (non-hemolytic) Group B Streptococcus from GBS enrichment broth procedures.

SUMMARY

Approximately 10-35% of women are asymptomatic carriers of group B streptococci (GBS) in the genital and gastrointestinal tracts.[7] GBS remains a leading cause of serious illness and death in newborn populations and, therefore, the detection of GBS in the vaginal-anorectal area is critical to the prevention of neonatal GBS disease. Several surveys have been conducted that show the incidence of neonatal sepsis and meningitis due to GBS is currently 0.5-3 cases per 1,000 live births, although there are substantial geographical and racial differences.[8] The case-fatality ratios are now declining due to prompt recognition and proper treatment.[9]

The Centers for Disease Control and Prevention (CDC) recommends the screening of all pregnant women for vaginal and rectal GBS colonization between 35 and 37 weeks of gestation using an enrichment broth followed by subculture to a Blood Agar plate (Cat. no. A10) or other appropriate media.[10] The use of a selective enrichment broth incorporating chromogenic pigments, such as Strep B Carrot Broth™, has recently been included in CDC's Recommendations for the Prevention of Group B Streptococcal Disease.[27] Strep B Carrot Broth™ demonstrates increased sensitivity and specificity, reduced incubation time, reduced need for additional plated media, and elimination of the need to confirm positives with additional testing.[11-15,20-23]

A small percentage of GBS may not produce beta-hemolysis. GBS detection with Strep B Carrot Broth™ enrichment procedures is only possible with beta-hemolytic colonies. However, there is evidence of a direct genetic linkage between pigment production in Strep B Carrot Broth™ and hemolysin production by GBS bacteria. Beta-hemolytic, pigment producing GBS occurs with 95.3 to 99.5% of all GBS strains isolated from clinical specimens.[17-19]

Subcultures from enrichment broths may contain non-hemolytic or gamma strains of GBS that may be missed by normal plating procedures, because non-hemolytic GBS is not readily distinguishable from other small non-hemolytic colonies. Therefore, all LIM Broth cultures and negative Strep B Carrot Broth™ cultures should be subcultured to GBS Detect™ plates for detection of gamma-hemolytic GBS. GBS Detect plates contain special supplements that cause otherwise non-hemolytic strains of GBS to appear as beta-hemolytic, thus increasing the sensitivity of detection methods used to detect GBS colonization in pregnant women. Selective agents are added to suppress coliforms, staphylococci, and other organisms that might be present as normal flora.

GBS Detect™ eliminates needless steps in screening for non-hemolytic group B streptococci and makes Strep B Carrot Broth™ a more sensitive method for all strains of GBS.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	15.0gm
Peptic Digest of Soybean Meal	5.0gm
Sodium Chloride	5.0gm
Nucleic Acid	3.0gm
Selective Agents	15.3gm
Hemolysis Inducing Agents	20.0ml
Sheep Blood	50.0ml
Agar	15.0gm

Final pH 7.3 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), hemolysis, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended quality control incubation times.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

PROCEDURE

Method of Use: Medium should be brought to room temperature prior to inoculation. Inoculate according to standard microbiological procedures.

1. Using a vaginal-rectal specimen, inoculate a suitable GBS enrichment broth, either non-chromogenic such as LIM Broth or a chromogenic broth such as one of the Strep B Carrot Broth™ formats, according to the procedures in the technical information sheets.

2. Subculture all non-chromogenic broths (such as LIM Broth) or color negative chromogenic enrichment broths (such as one of the Strep B Carrot Broth™ formats) to a GBS Detect™ plate. Streak inoculum in four quadrants to obtain isolated colonies. **Note:** Isolated colonies must be obtained.

3. Incubate the GBS Detect™ plate for 18-24 hours at 35 +/- 2ºC. in an aerobic atmosphere.

4. After 18-24 hours, observe for growth of beta-hemolytic gram-positive, catalase-negative colonies. Gamma-hemolytic GBS will produce large, transparent zones of hemolysis, with a soft edge on GBS Detect™.

5. Using isolated colonies from the GBS Detect™ plate described in step 4, perform latex particle agglutination test (StrepPRO™ Grouping Kit, Cat. no. PL030HD) or other tests recommended for the detection of group B streptococci antigen following the procedure specified by the manufacturer.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Organisms other than GBS can produce faint or incomplete zones of hemolysis.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, enrichment broths such as LIM Broth (Cat. no. L57), Strep B Carrot Broth™ kit formats, StrepPRO™ Grouping Kit (Cat. no. PL030HD), other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method	Incubation			Results
		Time	Temperature	Atmosphere	
Streptococcus agalactiae ATCC® 13813	A	24hr	35°C	Aerobic	Growth; beta-hemolysis
Streptococcus agalactiae Clinical Strain	A	24hr	35°C	Aerobic	Growth; beta-hemolysis
Enterococcus faecalis ATCC® 29212	A	24hr	35°C	Aerobic	Growth; gamma hemolysis

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

GBS Detect™ should appear opaque, and cherry red in color.

REFERENCES

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Streptococcus agalactiae (ATCC® 13813) colonies growing on GBS Detect™ (Cat. no. A300) showing beta-hemolytic colonies. This strain is not hemolytic on a regular blood agar plate. Incubated aerobically for 24 hours at 35ºC.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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