Instructions for Use

REF - BM0453 **Group B Streptococcus Selective Broth**

Bottled Media

1. Intended Use

For *in vitro* diagnostic use. BM0453 Group B Streptococcus Selective Broth is a selective medium for the isolation of Group B *Streptococci* (GBS).

2. Composition*

Ingredient	Amt/L
Beef extract	1.0g
Yeast extract	2.0g
Peptone	5.0g
Sodium chloride	5.0g
Nalidixic acid	0.015g
Gentamicin	0.00064g
Defibrinated horse blood	50.0ml

*Adjusted/supplemented as needed to meet performance requirements

3. Summary and Explanation

Group B Streptococci, also known under the name of *Streptococcus agalactiae*, are the cause of numerous infections in adults but mostly an important cause of serious neonatal infections, occurring in the three first weeks of life. Studies indicate that approximately 12-27 % of pregnant women are colonised by GBS. (WHO, Infectious diseases, Group B *Streptococcus*). Detecting vaginal (and in some countries also rectal) colonisation by GBS in pregnant women is the most effective strategy to prevent infection transmission during baby delivery.

Worldwide, official guidelines recommend prenatal screening of GBS in the last month of pregnancy. In GBS-carrying women, this screening allows determining the need of intrapartum antibiotic prophylaxis, which has proved effective in preventing the infections occurring in the first week of life (known as early-onset GBS infections).

4. Principle

The beef extract, peptone and yeast extract act as carbon, nitrogen, and vitamin sources in this medium. Sodium chloride maintains osmotic balance. addition of sheep blood to the medium promotes luxuriant growth of *streptococci*.

5. Physical Characteristics

	Appearance and Colour	pH
Medium	Cherry red liquid	7.2 ± 0.2

6. Materials Provided

BM0453 Group B Streptococcus Selective Broth can be provided in 50 x 3ml in Thin Wall Bijous (product code: BM0453-M003-3). Each bottle is ink-jet printed or labelled with (abbreviated) product name, product code, lot number and expiry date.

7. Materials Needed but not Provided

Standard microbiological laboratory materials e.g., sterile loops or swabs, collection containers, incubators, media for isolation and quality control organisms.

8. Specimens

BM0453 Group B Streptococcus Selective Broth is suitable for the testing of the following specimens:

- Clinical Specimens: urine, rectal and vaginal specimens.

Sampling and transport equipment must be used in accordance with the end user's suppliers' recommendations. Refer to appropriate standard method or local guidance on sample collection and subsequent processing.

9. Test Procedures and Interpretation of results

Clinical Specimens:

Add no more than 1g or 1ml of specimen to the vial of broth and incubate at 37 ± 1°C aerobically for 18-24 hours.

After initial incubation, subculture 1ml onto a suitable agar and incubate further at 37 ± 1°C aerobically for 18-24 hours.

After incubation, examine agar for colonies (typical colony appearance outlined in Quality Control table below). Perform further biochemical, serological, or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

10. Quality Control

Organism	Incubation	Result (Specificity)
S. agalactiae (ATCC 12386)	37 ± 1°C aerobically for 18-24 hours	Growth: White colonies with β-haemolysis
E. coli (NCTC 12241)	37 ± 1°C aerobically for 18-24 hours	Inhibited
	Subculture 10µl of the productivity broth onto E&O PP0120 Columbia Blood Agar. Subculture 10µl of the selectivity broth onto E&O PP0280 Tryptone Soya agar and incubate both at 37 ± 1°C aerobically for 18-24 hours.	

It is the responsibility of the user to perform Quality Control testing taking into consideration the intended use of the medium and in agreement with any local relevant guidelines (e.g., frequency, strains used, atmosphere, incubation temperature).

11. Performance

To fully verify BM0453 Group B Streptococcus Selective Broth performance, samples were tested to assess colony morphology and recovery level when incubated at 37 ± 1°C aerobically for 18-24 hours, before being subcultured on the medium stated in the QC table above, and incubated at 37 ± 1°C aerobically for 18-24 hours. All samples grew and showed good recovery and the correct morphology of the required test organism: *Streptococcus agalactiae* (ATCC 12386) and no recovery of the non-target test organism: *Escherichia coli* (NCTC 12241). Therefore, it can be concluded that BM0453 Group B Streptococcus Selective Broth, meets performance criteria when used according to the instructions outlined above. Trend analysis data available upon request.

12. Limitations of the Media

- Additional biochemical, serological, or molecular tests should be performed on sub-culture isolates to confirm identity.
- Due to natural variation, some strains may grow poorly on this medium.

13. Precautions and Warnings

This product is considered non-hazardous under CLP regulations. Wear such PPE as recommended by laboratory COSHH assessment. During and after use, always handle all materials in a manner conforming to Good Laboratory Practices and consider that material under test should be regarded as a potential biohazard if mishandled.

Refer to E&O BM0453 Bottled Media Material Safety Data Sheet.

14. Storage conditions and Shelf life

Store BM0453 in the original bottle with the lid tightly closed at between 2 and 8°C. Kept under these conditions it may be used up to date of expiry shown on product label.

Dispose of in accordance with local and national authority requirements. Do not use media if it is contaminated, discoloured or out of date. Additionally, do not use medium if it has been stored inappropriately or the packaging has been damaged.

Version History*

001 01/05/24 - New Document Created

*Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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TABLE OF APPLICABLE SYMBOLS

REF o REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	Keep away from direct light	Store in a dry place