Instructions for Use

REF - BM1682 **Faecal Transport Solution**

Bottled Media

1. Intended Use

For *in vitro* diagnostic use. BM1682 Faecal Transport Solution is recommended for the transport of clinical specimens, especially those associated with enteric pathogens [1]. This formulation allows for transport at chilled or ambient temperatures.

2. Composition*

Ingredient	g/L
Disodium phosphate	6.0
Sodium thioglycolate	1.5
Sodium chloride	5.0
Calcium chloride	0.09
Agar	0.2

*Adjusted/supplemented as needed to meet performance requirements

3. Summary and Explanation

BM1682 Faecal Transport Solution is a modified Cary Blair Transport Medium [2], designed for the transportation and preservation of clinical specimens, primarily stool and rectal swabs. The product is designed to maintain the viability of enteric bacterial pathogens during transport and subsequent storage at chilled or ambient temperatures.

4. Principle

Faecal Transport Solution is an isotonic, buffered, and nonnutritive medium with a carefully balanced composition. It includes agar to help reduce oxygen diffusion, sodium thioglycolate to impede oxidation, and disodium phosphate to help maintain pH. The relatively high pH of the medium helps to minimises overgrowth of non-target organisms and prevent acid formation in the specimen.

5. Physical Characteristics

	Appearance and Colour	pH
Medium	Colourless liquid	8.5 ± 0.2

6. Materials Provided

BM1682 is available in 6.5ml plastic, screw-top tube containing 2ml of Faecal Transport Solution (Product Code BM1682-M054-2). Each tube is labelled with product name, product code, lot number and expiry date.

7. Materials Needed but not Provided

Sterile swab with a 78mm break point. Standard microbiological laboratory materials e.g., sterile loops or swabs, collection containers, incubators, media for isolation and quality control organisms.

8. Specimens

BM1682 Faecal Transport Solution is suitable for the testing of the following specimens:

- Clinical: Stool samples and rectal swabs

Follow local guidelines for specimen collection. Use a BM1682 compatible sterile swab with a 78mm break point.

9. Test Procedures and Interpretation of results

Refer to appropriate standard method or local guidance on specimen collection & subsequent processing.

Stool specimens: place approximately 1g of specimen into the Faecal Transport Solution. Close cap tightly and label with appropriate patient information. Transport to the laboratory at chilled or ambient temperatures and process as soon as possible. Mix thoroughly before inoculation to appropriate enrichment or selective media.

Rectal swabs: Collect swab specimen following local guidance, place the swab into the Faecal Transport Solution and snap the swab at the breakpoint. Close the cap tightly and the swab shaft will lock into the swab cap capture device. Label with appropriate patient information. Transport to the laboratory at chilled or ambient temperatures and process as soon as possible. Mix thoroughly before inoculation to appropriate enrichment or selective media.

Alternatively, use PCR techniques to confirm the presence of suspected pathogens (follow local guidelines).

After subculture incubation, examine selective agar for colonies (typical colony appearance will depend on selective medium used – see relevant supplier IFU). Perform further biochemical, serological, molecular, or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

10. Quality Control

Organism	Incubation	Result (Specificity)
E. coli NCTC 12241	Inoculate the Productivity bottles with the stated dilution and immediately subculture 200µl of each bottle onto a separate E&O PP0120 Columbia Agar with 5% Horse Blood plate (Before plates). Incubate the inoculated bottles at 20-25°C aerobically for 24 hours. After incubation, subculture 200µl of each bottle onto a separate E&O PP0120 Columbia Agar with 5% Horse Blood plate (After plates). Incubate E&O PP0120 Columbia Agar with 5% Horse Blood plates at 37 ± 1°C for 18-24 hours.	Stable viability (≤2 $\log_{10}$ difference) Subplate: Grey colonies
S. typhimurium NCTC 12023		Stable viability (≤2 $\log_{10}$ difference) Subplate: Grey colonies
S. sonnei ATCC 9290		Stable viability (≤2 $\log_{10}$ difference) Subplate: Grey colonies

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 BM1682 Faecal Transport Solution performance, samples were tested to assess maintenance of stable viability, where an acceptable recovery range after a holding period is ≤2 $\log_{10}$ difference, when subcultured on E&O PP0120 Columbia Agar with 5% Horse Blood. Samples were inoculated with 25-250cfu and incubated at 20-25°C for 24 hours during the test. All samples showed expected recovery and morphology of the required test organisms: *Escherichia coli* (NCTC 12241), *Salmonella typhimurium* (NCTC 12023) and *Shigella sonnei* (ATCC 9290). Therefore, it can be concluded that BM1682 Faecal Transport Solution meets performance criteria when used according to the instructions outlined above. Trend analysis data available upon request.

For extended verification of BM1682, samples were tested with subculturing after incubation times of 24, 48, and 72 hours aerobically at 2-8°C and at 22 ± 1°C. At each time point, 200µl of each of the BM1682 samples in triplicate were subcultured to Columbia Blood Agar (E&O PP0120) and incubated as follows -

Campylobacter jejuni: 41.5°C in microaerophilic conditions for 48 hours.

Clostridium difficile: 37°C in anaerobic conditions for 48 hours.

All other organisms: 37°C in aerobic conditions for 18-24 hours.

Results are summarised in the table below:

Organism	**Incubation temp (°C)**	**Time***
Campylobacter jejuni NCTC 11322	2-8	72h
	20-25	24h
Clostridium difficile NCTC 11204	2-8	72h
	20-25	72h
Enterococcus faecalis (VRE-B) ATCC 51299	2-8	72h
	20-25	72h
Escherichia coli NCTC 12241	2-8	72h
	20-25	72h
Escherichia coli (O157) NCTC 12900	2-8	72h
	20-25	72h
Salmonella typhimurium NCTC 12023	2-8	72h
	20-25	48h
Yersinia enterocolitica NCTC 12982	2-8	72h
	20-25	72h
Shigella flexneri ATCC 12022	2-8	72h
	20-25	72h
Shigella sonnei NCTC 8574	2-8	72h
	20-25	72h

* Incubation time required (up to 72 hours) until the difference between before and after counts was greater than 2 $\log_{10}$.

All organisms, except *Campylobacter jejuni* NCTC 11322 and *Salmonella typhimurium* NCTC 12023, remained within the 2 $\log_{10}$ difference up to the end of the 72hr incubation period at both room temperature and in cold storage. *Campylobacter jejuni* NCTC 11322 incubated at 22°C remained within this specification at 24 hours but not at 48 hours so it is recommended that, if the sample is stored at room temperature, testing for suspected *Campylobacter* infection should be conducted within 24 hours of sample collection. At 22°C, *S. typhimurium* NCTC 12023 remained in specification at 48 hours but was outside the 2 $\log_{10}$ difference at 72 hours due to overgrowth. It is recommended that, if the sample is stored at room temperature, testing for

suspected *Salmonella* infection should be conducted within 48 hours of sample collection. Both organisms remained within specification for up to 72 hours when stored at 2-8°C.

12. Limitations of the Medium

- Volume and condition of specimen, transit time and type of bacterial species are all factors that can affect bacterial survival and recovery via culture.
- Delay in specimen processing from BM1682 Faecal Transport Solution may affect results. If delay is unavoidable then storage at 2-8°C is recommended or process the specimen within 24 hours to allow recovery of *Campylobacter* spp. and 48 hours for *Salmonella* species.
- Anti-diarrheal or antibiotic treatment before sampling may affect culture of target organisms.
- This medium is for transport of specimens and should not be used for enrichment of target organisms.
- This medium is not validated for storage of samples for more than 72 hours (refer to Section 11).

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 BM1682 Bottled Media Material Safety Data Sheet.

14. Storage conditions and Shelf life

Store BM1682 in the original container with the lid tightly closed at between 2 and 30°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 medium 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.

15. References

1. CLSI M40-A2. (2014). Quality control of microbiological transport systems; Approved standard – second edition. CLSI document M40-A2. Wayne, PA: Clinical and Laboratory Standards Institute.
2. Cary, S.G. and Blair, E.B. (1964). New Transport Medium for Shipment of Clinical Specimens. J. Bact, 88:96-98.

Version History*

001 24/01/24 - New Document Created
002 02/03/26 – Updated QC strains and elaborated procedures in Sections 10 and 11. Separated routine QC procedure and extended verification procedure in Section 11.

*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	Σ Contents sufficient for <n> tests	Consult Instructions for Use	Keep away from direct light	Store in a dry place