

BUFFERED GLYCEROL SALINE

INTENDED USE

Remel Buffered Glycerol Saline is recommended for use in qualitative procedures for collection, transportation, and preservation of clinical specimens.

SUMMARY AND EXPLANATION

Certain enteric pathogens rapidly lose viability in stool specimens unless cultured immediately after collection.^{1,2} Support media, such as Buffered Glycerol Saline, were developed to maintain viability of bacteria during transport to the laboratory. Buffered Glycerol Saline is one of the earliest media developed for transport of stool specimens. It is especially suitable for preserving the viability of *Shigella* species.³

PRINCIPLE

Buffered Glycerol Saline contains a glycerol-phosphate buffer to maintain a near neutral pH. This is necessary to preserve certain enteric pathogens in stool specimens. Phenol Red is a pH indicator which changes the medium to a yellow color if an acid condition exists. An acidic environment is detrimental to bacterial viability.

REAGENTS (CLASSICAL FORMULA)*

| | | |
|-------------------------------------|-------|----|
| Sodium Chloride | 4.2 | g |
| Dibasic Potassium Phosphate | 3.1 | g |
| Monobasic Potassium Phosphate | 1.0 | g |
| Phenol Red Sodium Salt..... | 0.05 | g |
| Glycerin..... | 298.5 | ml |
| Ethanol..... | 2.5 | ml |
| Demineralized Water | 800.0 | ml |

pH 7.2 ± 0.2 @ 25°C

*Adjusted as required to meet performance standards.

PRECAUTIONS

CAUTION! May cause irritation to skin, eyes, and respiratory tract. Avoid breathing vapor and eye/skin contact.

This product is for *In Vitro* diagnostic use and should be used by properly trained individuals. Take precautions against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully. Refer to Material Safety Data Sheet for additional information.

STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at room temperature until used. Do not freeze or overheat.

PRODUCT DETERIORATION

This product should not be used if (1) the color has changed from red, (2) the expiration date has passed, (3) there is evidence of dehydration, or (4) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Refer to the collection instruction sheet included with this product. Specimens should be collected and handled following recommended guidelines.^{5,6}

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms.

PROCEDURE

Swab Specimens:

1. Remove transport vial cap and immerse swab into the medium.
2. Break swab shaft evenly with the lip of the vial.
3. Replace vial cap and tighten.
4. Label with patient/specimen information.
5. Transport to the laboratory at room temperature for processing.

Fecal Specimens:

1. Place approximately 1 gram of stool into the transport vial.
2. Replace vial cap and tighten.
3. Shake vial to mix stool with transport medium.
4. Label with patient/specimen information.
5. Transport to the laboratory at room temperature for processing.

Specimen Processing:

1. Mix specimen thoroughly by shaking the vial.
2. Subculture to appropriate isolation media depending on source and suspected organisms.
3. If specimen cannot be processed immediately, maintain the transport vial at refrigerator or freezer temperatures.

QUALITY CONTROL

All lot numbers of Buffered Glycerol Saline have been tested using the following quality control organisms and found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

| CONTROL | INCUBATION | RESULTS |
|--|------------------------|-----------------------------|
| <i>Salmonella enterica</i> serovar Typhimurium ATCC® 14028 | Ambient, 24h @ 15-30°C | Good recovery on subculture |
| <i>Shigella flexneri</i> ATCC® 12022 | Ambient, 24h @ 15-30°C | Good recovery on subculture |

LIMITATIONS

1. Buffered Glycerol Saline is not satisfactory for the preservation of *Campylobacter* spp. or *Vibrio parahaemolyticus*, these organisms require an enriched medium for transport.^{1,2,4}
2. Patients should not have been on antibiotic therapy for 72 hours prior to specimen collection.
3. Some stool specimens may be highly acidic and will overcome the buffering capacity of this medium. This will cause the red indicator to shift to a yellow color. Discard the vial if it has turned yellow. Inoculate a fresh vial using a smaller volume of stool specimen.

BIBLIOGRAPHY

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PACKAGING

Buffered Glycerol Saline:
REF R21650, 15 ml/Vial 12 Vials/Pk

Symbol Legend

| REF | Catalog Number |
|---|--|
| IVD | In Vitro Diagnostic Medical Device |
| LAB | For Laboratory Use |
|  | Consult Instructions for Use (IFU) |
|  | Temperature Limitation (Storage Temp.) |
| LOT | Batch Code (Lot Number) |
|  | Use By (Expiration Date) |

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