remel

MicroTest[™] M4RT[®]

Multi-Microbe Media

INTENDED USE

Remel MicroTest[™] M4RT[®] is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral agents.

SUMMARY AND EXPLANATION

Viruses are susceptible to adverse environmental conditions and require specific transport media to maintain viability (and infectivity) while in transit to the laboratory. Formulations containing protein for stabilization, antibiotics to minimize bacterial and fungal contamination, and a buffer to maintain a neutral pH are ideal for this purpose.

PRINCIPLE

M4RT[®] medium consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, gelatin, sucrose, and glutamic acid. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Gentamicin and amphotericin B are incorporated in the medium to inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells enabling it to be used in shell vial procedures. Cryoprotectants are added to ensure organism viability during freeze-thaw. Because whole bovine serum may inhibit attachment and growth of myxoviruses and paramyxoviruses, it has not been included in this formulation.

REAGENTS (CLASSICAL FORMULA)*

Reactive Ingredients: Hank's Balanced Salts Bovine Serum Albumin Gelatin Sucrose L-Glutamic Acid

HEPES Buffer Phenol Red Gentamicin Amphotericin B

pH 7.3 ± 0.2 @ 25°C

*Adjusted as required to meet performance standards.

PRECAUTIONS

This product is for *In Vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at 2-30°C until used. Do not overheat. Do not incubate prior to use. Improper storage will result in a loss of antimicrobial activity.

PRODUCT DETERIORATION

This product should not be used if (1) there is evidence of contamination, (2) there is evidence of leakage, (3) the color has changed from light pink, (4) the expiration date has passed, or (5) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, TRANSPORT & DISPOSAL

Specimens should be collected and handled following recommended guidelines.^{2,4} To maintain optimum viability, transport specimens to

the laboratory as soon as possible. Although M4RT[®] can maintain even fragile organisms for relatively long periods of time at room temperature, specimens should be refrigerated at 2-8°C or kept on wet ice (or equivalent) following collection and while in transit. If there will be a delay in processing, freeze specimens at or below -70°C and transport on dry ice. Ship specimens in compliance with federal, state, and hospital guidelines. Specimens should be processed as soon as possible after being received in the laboratory. Dispose of all parts in accordance with national, federal and state laws and hospital and laboratory guidelines.

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Syringes, needles, (2) Sterile forceps, (3) Supplemental media, (4) Inoculating loop, loop sterilization device, (5) Incubators, alternative environmental systems, (6) Quality control organisms, and (7) Materials required for organism identification. Refer to appropriate references for necessary equipment required in specimen collection.^{1,3}

PROCEDURE

Proper specimen collection from the patient is critical for successful isolation and identification of infectious organisms. Specimens should be collected as soon as possible after onset of disease.

- 1. Aseptically remove cap from vial.
- 2. Insert swab into medium.
- 3. Break swab shaft evenly at the scored line.
- 4. Replace cap to vial and close tightly.
- 5. Label with appropriate patient information.
- 6. Send to the laboratory for processing with minimal delay.

INTERPRETATION

This transport medium serves as a vehicle for maintaining organism viability while transporting the specimen to the laboratory.

QUALITY CONTROL

All lot numbers of MicroTest[™] M4RT[®] have been tested for microbial contamination, toxicity to host cells, ability to maintain viability of desired agents (listed below) and have been 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

Herpes simplex type 2 ATCC[®] VR-734 Respiratory syncytial virus ATCC[®] VR-1302 Cytomegalovirus ATCC[®] VR-977

LIMITATIONS

- 1. Specimens should be handled aseptically.
- Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.^{2,4}
- M4RT[®] is intended for use as a collection and transport medium for viral agents only. This medium can serve as a cryoprotectant for clinical viruses, including cytomegalovirus and varicellazoster virus.
- 4. Because calcium alginate swabs are toxic for many enveloped viruses and may interfere with fluorescent antibody tests, they should not be used for specimen collection. Wooden shaft swabs may contain toxins and formaldehydes and should not be used. Cotton-, nylon- or polyester-tipped swabs are suitable when specimen collection by a swab is appropriate.

EXPECTED VALUES

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

ENGLISH

PERFORMANCE CHARACTERISTICS

Remel M4RT® transport medium was compared to commercial and standard transport media routinely used for the transport and maintenance of viral agents. The results were equivalent or superior to the media in the comparison. The percentage of recovery for each agent at 2-8°C was as follows:

| ORGANISM | 8 HOURS | 24 HOURS | 48 HOURS |
|--------------------------------|---------|----------|----------|
| Respiratory Syncytial Virus | 70% | 65% | 52% |
| Herpes Simplex Type 1 McIntyre | | 84% | 65% |
| Cytomegalovirus (AD 169) | | 65% | 38% |
| Influenzae A H3N2 Shanghai 87 | | 89% | 72% |

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Symbol Legend

| REF | Catalog Number | | |
|----------|--|--|--|
| IVD | In Vitro Diagnostic Medical Device | | |
| LAB | For Laboratory Use | | |
| []i | Consult Instructions for Use (IFU) | | |
| X | Temperature Limitation (Storage Temp.) | | |
| LOT | Batch Code (Lot Number) | | |
| Σ | Use By (Expiration Date) | | |
| EC REP | European Authorized Representative | | |

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PACKAGING CONFIGURATIONS

Remel MicroTest™ media are supplied in screw-cap tubes containing 1.5 ml or 3.0 ml of transport medium plus three glass beads (unless stated differently) or in glass dram vials containing 2 ml of transport medium. Tubes of MicroTest[™] media are supplied alone or with the following specimen collection options:

- Two regular size plastic-shaft, scored swabs with polyester fiber tips (Universal Kit)
- One regular size plastic-shaft, scored swab and one stainless steel-shaft, mini-tip swab, both with polyester fiber tips ٠
- One regular size plastic-shaft, scored swab with nylon flocked tip ٠
- One mini-tip plastic-shaft, scored swab with nylon flocked tip ٠
- One regular size plastic-shaft, scored swab and one aluminum wire-shaft mini-tip swab both with polyester fiber tips

Swabs with several applicator-shaft options are available to facilitate collection of specimens from various patient sites. Refer to individual product descriptions in the Remel catalog or visit www.thermofisher.com for specific information about the materials supplied.