remel

MicroTest™ M5™
Multi-Microbe Media EN

REF **R12515 M5 3mL**	Σ 72
REF **R12555 M5 Traditional Swab Kit 3mL**	Σ 100
REF **R12580 M5 Universal Swab Kit 3mL**	Σ 100

INTENDED USE
Remel MicroTest™ M5™ is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydiae, and mycoplasmas, which include *Mycoplasma* and *Ureaplasma* species. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.

The device is not automated, is for professional use only and is not a companion diagnostic.

SUMMARY AND EXPLANATION
Viruses, chlamydiae, and mycoplasmas 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
M5™ medium consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, protein stabilizers, sucrose, and glutamic acid. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Vancomycin, amphotericin B, and colistin 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	HEPES Buffer
Bovine Serum Albumin	Phenol Red
Protein Stabilizers	Vancomycin
Sucrose	Amphotericin B
L-Glutamic Acid	Colistin

pH 7.3 ± 0.2 @ 25°C

*Adjusted as required to meet performance standards.

PRODUCT VARIANTS AND PACKAGING CONFIGURATIONS
MicroTest™ M5™ media tubes are supplied in screw-cap tubes containing 3mL of transport medium plus glass beads (unless stated differently). 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.

Tubes may be supplied alone or with the following specimen collection options:

Swab Type	Product code
Polyester Tip Swab with Plastic Shaft	R12555
Polyester Tip applicator	R12580

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. Please refer to the Safety Data Sheet (SDS) on company website and product labeling for information on potentially hazardous components.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

In the event of malfunction, do not use the device

STORAGE
This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°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, AND TRANSPORT
Specimens should be collected and handled following recommended guidelines.[2,6] To maintain optimum viability, transport specimens to the laboratory as soon as possible. Although M5® 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.[1,5]

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. Use sterile pair of scissors if additional trimming is needed.
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 OF THE TEST
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™ M5™ 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-1540
Cytomegalovirus ATCC® VR-977
Chlamydia trachomatis ATCC® VR-880
Mycoplasma pneumoniae ATCC® 15531
Mycoplasma hominis ATCC® 23114
Ureaplasma urealyticum ATCC® 27618

LIMITATIONS
1. Specimens should be handled aseptically.
2. Condition, timing, and volume of specimen collected for culture can significantly impact culture and detection results. Follow recommended guidelines for specimen collection.[2,6]
3. M5™ is intended for use as a collection and transport medium for viral, chlamydial, and mycoplasmal agents only. This medium can serve as a cryoprotectant for clinical viruses, including cytomegalovirus and varicella-zoster 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- or polyester-tipped swabs are suitable when specimen collection by a swab is appropriate.
5. Specimens for isolation of mycoplasmas should be processed within 48 hours of specimen collection.

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

PERFORMANCE CHARACTERISTICS
M5™ transport medium was compared to commercial and standard transport media routinely used for the transport and maintenance of viral, chlamydial, and mycoplasmal 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	92%	68%	44%
Herpes Simplex Type 1 McIntyre		81%	71%
Cytomegalovirus (AD 169)		69%	40%
Influenza A H3N2 Shanghai 87		83%	76%
Chlamydia trachomatis	84%	67%	58%
Mycoplasma pneumoniae	Recovered	Recovered	Recovered
Mycoplasma hominis	Recovered	Recovered	Recovered
Ureaplasma urealyticum	Recovered	Recovered	Recovered

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Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LOT	Batch Code (Lot Number)
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
	Use By (Expiration Date)
Σ N	Contains sufficient for <n> tests
	Do not use if packaging damaged
EC REP	Authorized European Representative
	Manufacturer
UK CA	UK Conformity Assessment
CE	European Conformity Assessment

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