Transport of urogenital mycoplasmas

UMMt *RevolutioN*

50 tests (REF 00061)

CPB 0386_EN-2025-08_V3

For *in vitro* diagnostic only, for professional use only.

Single use test.

CE

1 - AIM

The UMMt *RevolutioN* kit (REF 00061) is a supplement of UMMt medium (3 mL) for the MYCOFAST *RevolutioN* 2 (REF 00080) and MYCOFAST *RevolutioN* ATB+ (REF 00070) kits. It is also required for the MYCOFAST Screening *RevolutioN* (REF 00063), COMPLEMENT MYCOFAST *RevolutioN* 2 (REF 00082), COMPLEMENT MYCOFAST RevolutioN ATB+ (REF 00073) and A7 AGAR (REF 00090) kits.

UMMt medium (3 mL) allows the transport and preservation of *Ureaplasma urealyticum* / *Ureaplasma parvum* (U.u.) and *Mycoplasma hominis* (M.h.) from various clinical samples, for any patient with suspected infection.

2 - PRINCIPLE

Mycoplasmas, that include several species identified in humans to date, belong to the mollicutes class. They differ from other bacteria in numerous ways, including the lack of a cell wall which gives them natural resistance to ß-lactams, as well as a membrane rich in sterols derived from the membranes of the eukaryotic cells to which they are attached. Mycoplasmas are relatively fragile organisms, which only grow in acellular culture in the presence of several growth factors and at an optimum temperature of 37°C (1). They are also sensitive to variations in osmotic pressure. The sample must be discharged into an isotonic medium containing sodium chloride, such as UMMt transport medium (3 mL) (2). Inoculation into a liquid medium produces a dilution effect.

Most human mycoplasmas are simple commensals. Species isolated from the urogenital tract, *U. urealyticum* and *M. hominis*, are the most commonly encountered. *U. urealyticum* species is divided into two biovars: *U. urealyticum* and *U. parvum* (U.u.).

U.u. or M.h. can be pathogenic. They are responsible for male genital infections (non-gonococcal urethritis, epididymitis, prostatitis, infertility); gynaecological infections (bacterial vaginosis, endometritis, salpingitis); fertility problems (chorioamniotitis, post-partum endometritis, prematurity, spontaneous abortion) ; neonatal problems (low birth weight, respiratory and neurological infections, bacteraemia, abscesses); extragenital infections (septic arthritis, reactive arthritis, other localisations) (3).

3 - REAGENT

UMMt (3 mL): Vial of liquid medium containing Mycoplasma broth, antibiotics and a preservative (pH: 6.0 ± 0.1).

4 - PRECAUTIONS

- The reagents in this kit are intended for *in vitro* use only and must be handled by authorised personnel.
- The tests are for single use only.
- Samples and inoculated reagents are potentially infectious, they must be handled with caution in accordance with the hygiene rules and regulations in force in the country of use for this type of product.
- Reagents containing raw materials of animal origin must be handled with caution.
- Do not use reagents after their expiry date.
- Do not use reagents that have been damaged or incorrectly stored before use.
- Do not use reagents showing signs of contamination.

5 - SAMPLE COLLECTION AND HANDLING

5.1 Sample collection

Cervico-vaginal samples: Use a Dacron swab only. The cervix should be carefully cleaned using a first swab to remove secretions before collecting the sample.

As mycoplasmas have a strong affinity for the mucosal cells to which they adhere, it is essential to scrape the mucosa thoroughly in order to obtain a good yield.

Urethral samples: Clean the meatus and swab or scrape the cells.

Urine: Collect the first stream of urine in a sterile vial without additive. Store urine for 2 hours at room temperature or for less than 12 hours at 5 ± 3°C (2).

Semen: Collect semen in a sterile bottle. The sample should be sent within 2 hours at room temperature and transferred rapidly to UMMt medium (2).

Gastric secretions from newborns: Under aseptic conditions, aspirate the gastric contents of the newborn at birth into a sterile aspirator or tube. The sample should be sent within half a day at room temperature.

5.2 Sample transport in UMMt medium

Swab samples: Discharge the swab into a vial of UMMt medium (3 mL).

Liquid samples: Inoculate a vial of UMMt medium (3 mL) with 300 µL of homogenized liquid.

5.3 Sample conservation in UMMt medium

Once inoculated, UMMt medium (3 mL) may be stored at room temperature (18-25°C) for 20 hours, or at 2-8°C for 56 hours.
For storage during 3 days at -20°C (-20°C to -22°C), first add 2 drops of MYCOPLASMA Stabilizer.

6 - PREPARATION AND STORAGE OF REAGENTS

Stored at 2-8°C in their original state, UMMt mediums (3 mL) are stable until the expiry date indicated on the box.
UMMt mediums (3 mL) can be stored temporarily (3 months) at room temperature but are more stable at 2-8°C. UMMt mediums (3 mL) are ready to use.

7 - MATERIAL REQUIRED BUT NOT PROVIDED

- Sample collection (Dacron swab, sterile vial without additive for liquid samples)
- MYCOPLASMA Stabilizer (REF 00064)
- Pipettes and tips
- Freezer at -20°C
- Incubator at 37 ± 1°C
- Container for contaminated waste

8 - QUALITY CONTROL

Quality control can be carried out from the *U. urealyticum* or *M. hominis* strains in the MYCOPLASMA CONTROL kit (REF 00900) or from lyophilized collection strains (*U. urealyticum* ATCC 33175 or *M. hominis* ATCC 23114) previously calibrated at 10^4 - 10^5 UCC/mL.
Inoculate the UMMt medium (3 mL) with the strain, then perform a counting with a liquid microdilution or a MYCOFAST tray. Add 2 drops of MYCOPLASMA Stabilizer to the UMMt and freeze during 3 days at -20°C (-20°C to -22°C). After freezing, re-count the UMMt inoculated with the strain.
The result of the counting obtained after freezing should be:

- +/- 1 log of the starting counting for ATCC strains
- ≥ 10^4 UCC/mL for MYCOPLASMA CONTROL strains.

9 - PERFORMANCES

9.1 Preservation performances

The preservation performances of UMMt *RevolutioN* mediums were tested using UMMt (3 mL) stored at 2-8°C or room temperature (RT) for 3 months. The results of preservation performances obtained using 2 U.u. strains at 2 dilutions and 2 M.h. strains at 2 dilutions are as follows:

- Mycoplasma preservation performances at +/- 1 log, for 20h at RT, are 92.9%.
- Mycoplasma preservation performances at +/- 1 log, for 56h at 2-8°C, are 96.4%.
- Mycoplasma preservation performances at +/- 1 log, for 72h at -20°C, are 89.3%.

9.2 Repeatability

Repeatability of mycoplasma preservation in UMMt *RevolutioN* medium was tested using 2 U.u. and 2 M.h. strains at 2 concentrations each. The pool of each inoculum was counted, separated into 10 inocula and stored. Each inoculum was counted after storage.
The repeatability of mycoplasma preservation, at +/- 1 log, in UMMt *RevolutioN* medium is 100%.

9.3 Reproducibility

The reproducibility of mycoplasma preservation in UMMt *RevolutioN* medium was tested using 4 concentrations of U.u. and M.h. strains. Each concentration was counted 10 times before and after storage.
The reproducibility of mycoplasma preservation, at +/- 1 log, in UMMt *RevolutioN* medium is 100%.

9.4 Interferences

In this study, we tested 9 bacterial species (*Enterococcus faecalis*, *Escherichia coli*, *Streptococcus D, Streptococcus pneumoniae, Streptococcus B/agalactiae, Bacteroïdes fragilis, Staphylococcus saprophyticus*, *Proteus mirabilis* and *Corynebacterium urealyticum)* and 2 yeast species (*Candida albicans* and *Cryptococcus neoformans*) that are likely to be found in urogenital samples.
Strains were tested at concentrations of 10^6 CFU/mL in UMMt medium with absence then presence of U.u. and M.h. at concentrations of ≥ 10^4 UCC/mL. For each UMMt vial (3 mL) previously inoculated, a liquid microdilution was carried out before and after storage. These counting were compared with those obtained with UMMt inoculated only with U.u. and M.h. strains with no germs likely to be found in urogenital samples.
The tests revealed no interference with the mycoplasma preservation in UMMt *RevolutioN* medium.

10 - WASTE ELIMINATION

Waste should be disposed of in accordance with the hygiene rules and current regulations for this kind of product in the country of use.

11 - BIBLIOGRAPHY

1. **TAYLOR-ROBINSON D., 1995.** *Ureaplasma urealyticum* (T-strain Mycoplasma) and *Mycoplasma hominis*, p. 1713-1718. Dans MANDELL G. L., BENNET J. E. and DOLIN R. (ed.). Principles and Practices of Infectious Diseases, 4th ed., vol. 2, Churchill Livingstone, New York.
2. **Rémic 2022** - Référentiel en Microbiologie Médicale (Société Française de Microbiologie) - (7ème édition).
3. **BEBEAR C., BEBEAR C.M., 2007.** Infections humaines à mycoplasmes. Revue Francophone des Laboratoires, N°391, 63-69.

Any serious incident related to the device shall be notified to the manufacturer and to the Competent Authority of the Member State in which the user is established.

The changes from the previous version are highlighted in grey.

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