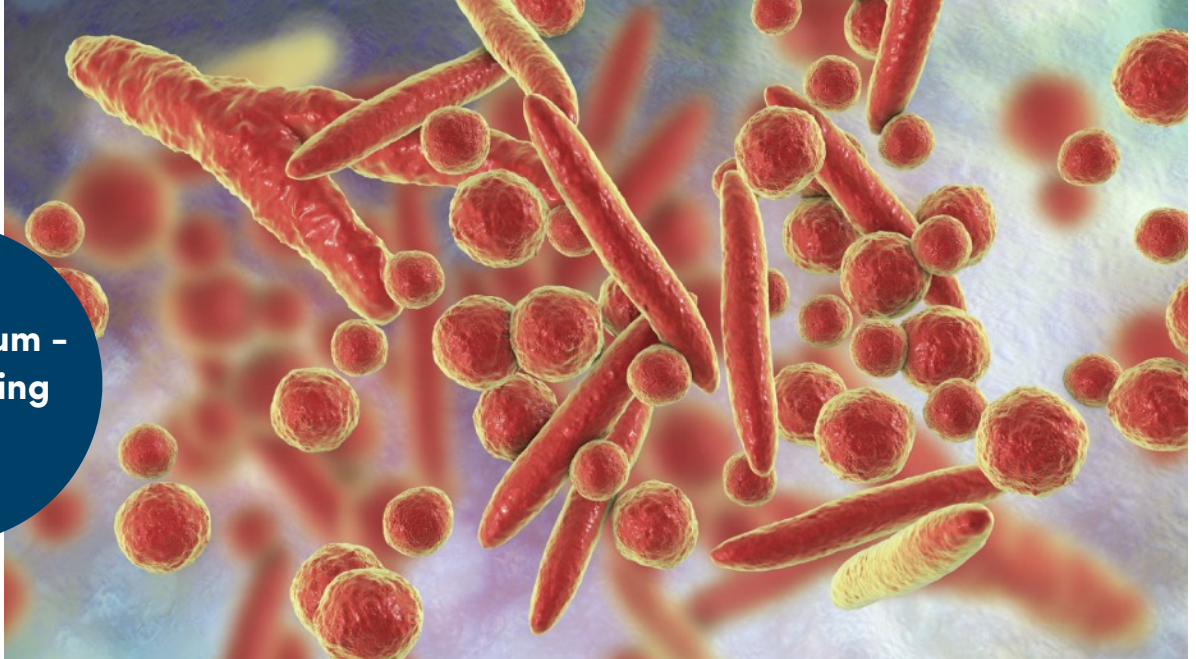


AusDiagnostics TODAY



**M.genitalium -
an emerging
threat**

STI TESTING: M. GENITALIUM AND RESISTANCE

AusDiagnostics product tests for five STIs including *Mycoplasma genitalium* and its resistance genes

While most laboratories routinely test only for Chlamydia and Gonorrhoea, the two most pathogenic STIs, the AusDiagnostics test panel **Urinogenital and resistance (12-well), REF27123** can identify others such as *Mycoplasma genitalium*, *Trichomonas* and *Ureaplasma*.

Mycoplasma genitalium - a relatively unknown STI which is causing concern among doctors and health professionals around the world - can be tested by a AusDiagnostics molecular test kit.

Mycoplasma genitalium was identified as a bacteria in the 1980s and is spread through unprotected intercourse. It is now becoming resistant to antibiotics and if left untreated it can cause cervicitis and pelvic inflammatory disease, leading to infertility. However, many patients are asymptomatic and don't know they're infected

In a study performed at a hospital in Australia, samples that had previously been analysed for Chlamydia and Gonorrhoea were re-analysed on the AusDiagnostics test kit.

Three out of 72 were found to contain *Mycoplasma genitalium* and seven contained *Ureaplasma urealyticum*. This means that the traditional testing missed 14 per cent of the STIs.

Although the jury is still out on the severity of *Ureaplasma* in STI infections, this is still useful information for the treating doctor.

In another study, four *Trichomonas* positives were found in 200 samples that had previously been declared free of STIs using tests that only measured Chlamydia and Gonorrhoea

Still the most important advantage of the panel is that certain STI organisms can be measured along with their resistance genes at one time.

For *Neisseria gonorrhoea* the panel can help identify resistance for two mainstream antibiotics widely used for gonorrhoea treatment - Azithromycin and Cephtriaxone.

(continued on the next page).

PANEL CONTENT

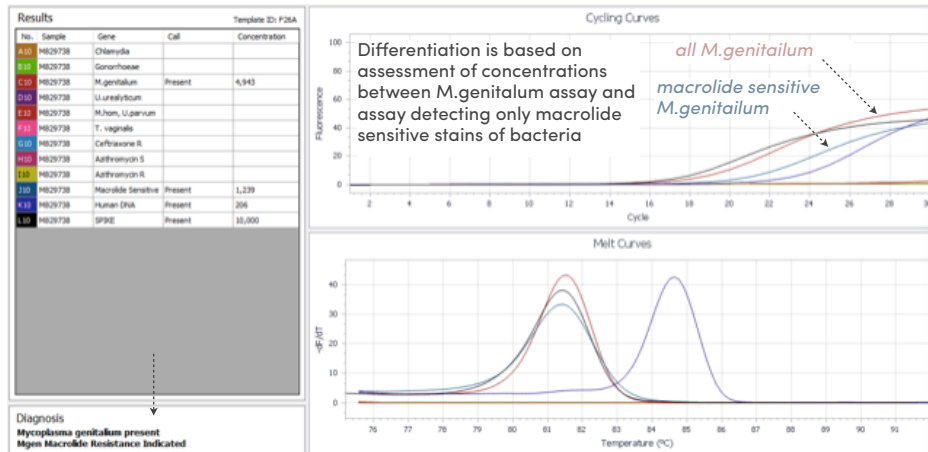
Urinogenital and resistance (12-well) REF27123

1	Chlamydia trachomatis
2	Neisseria gonorrhoeae (2 targets)
3	Mycoplasma genitalium
4	Trichomonas vaginalis
5	Mycoplasma hominis
	Ureaplasma parvum
6	Ureaplasma urealyticum
7	Ceftriaxon resistant N.gonorrhoeae
8	Azythromycin resistance of N. gonorrhoeae
9	
10	Azythromycin resistance of M.genitalium
11	Sample adequacy (Human DNA)
12	SPIKE, Extraction control

STI TESTING: M. GENITALIUM AND RESISTANCE (CONT.)

For *Mycoplasma genitalium* the product identifies resistance towards macrolides including azythromycin. As long as *M.genitalium* could have a few variants of resistance mutations the differentiation method is based on the comparison of concentrations reported by *M.genitalium*

assay which detects all stains of bacteria and the assay detecting strains which are macrolide sensitive. This method was evaluated in clinical studies and was shown to be accurate and economical allowing inclusion on *M.genitalium* resistance testing into the STI multiplex product.



QUICK MDX DETECTION OF DERMATOPHYTES AND OTHER SKIN FUNGAL INVASIONS

Dermatophytes are a common label for a group of three types of fungus that commonly causes skin disease in animals and humans. These anamorphic genera are *Microsporum*, *Epidermophyton* and *Trichophyton*.

There are about 40 species in these three genera. The most common dermatophytes are *Trichophyton rubrum* (70-80% of cases), *Trichophyton mentagrophytes* (20-30%), *Trichophyton verrucosum* (5-10%) and *Trichophyton tonsurans* (2-5%). Infrequently isolated (less than 1%) are *Epidermophyton floccosum*, *Microsporum canis* and other *Microsporum* (*Microsporum audouinii*, *Microsporum equinum*, *Microsporum nanum*, *Microsporum versicolor*). Less rare are other members of *Trichophyton* family (*Trichophyton equinum*, *Trichophyton kanei*, *Trichophyton raubitschekii*, and *Trichophyton violaceum*)

Importantly, Dermatophytes invasions should be discriminated from other fungal invasions as it determines the proper treatment. The most common types of yeasts found in skin lesions belong to genera *Candida*, *Scopulariopsis* and *Aspergillus*.

The new AusDiagnostics product can detect all of the pathogenic families of dermatophytes. It also identifies the most common species and helps with differential

diagnostics to recognise the most common skin yeasts. Validations performed in a few hospitals in Australia has shown that AusDiagnostics molecular method has a similar sensitivity to classical assays based on culturing while saving up to four weeks of culture. First customers has called the product "exciting and bringing a valuable improvement into traditional laboratory workflow for dermatophytes diagnostics"

Dermatophyte and other fungi (12-well) REF 24115	
1	Trichophyton spp.
2	Trichophyton rubrum complex
3	Trichophyton interdigitale
4	Microsporum spp.
5	Microsporidium canis
6	Nannizzia gypseum
7	Epidermophyton floccosum
8	Scopulariopsis spp.
9	Aspergillus spp.
10	Candida albicans, C.guilliermondii
11	C. parapsylosis, C. glabrata
12	SPIKE, Extraction control

RECENTLY UPDATED

Influenza A and Influenza A typing targets has been changed to accommodate new variants of the virus.

- ✓ New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome in order to increase assay sensitivity and to overcome the effects of recent mutations in the matrix gene.
- ✓ New HA-H3 assay - this assay was redesigned to increase differentiation from H1(2009).

These changes of assay were made in the following products:

- ✓ Respiratory Pathogens B (16-well) REF 20612 VER 08
 - ✓ Upper Respiratory Pathogens (16-well) Formerly Paediatric Respiratory Pathogens (16-well) REF 20616 VER 03
 - ✓ Respiratory Pathogens C (16-well) REF 20613 VER 06
 - ✓ Respiratory Viruses (Ultraplex) REF 80614 VER 06
 - ✓ Respiratory Viruses (16-well) REF 20602 VER 16
- New product versions were released on June 22nd.**

HEA (8-well) REF 27091 VER 9 panel was updated to perform 18 cycles in a step 1 amplification to improve the sensitivity of EV detection.

If you use this product please download and install the new template.

COMING SOON

The new generation of 12-well products is pending IVD release:

- ▶ **Viral (12-well) REF 27095 VER.6** will be ARTG listed and CE IVD marked
- ▶ **Faecal bacteria and parasites (12-well) REF. 25041 VER.1** will be ARTG listed and CE IVD marked

COMPANY NEWS

AusDiagnostics is continuing to grow, and our staff numbers are increasing accordingly. Please welcome new members of staff who have joined us in 2018:

- Bethany Maynard** - Production Assistant (AU)
- Justin Snyder** - Production Assistant (AU)
- Tiziana Figus** - Validation specialist (AU)
- Eva Upfold** - Regulatory Affairs Assistant (AU)
- Arlene Javines** - Administrative assistant (AU)
- Brenda Szymkiewicz** - Territory Manager (The Netherlands)
- Firat Kartal** - Territory Manager (UK)
- Mandy Netherton** - Application Specialist (US)