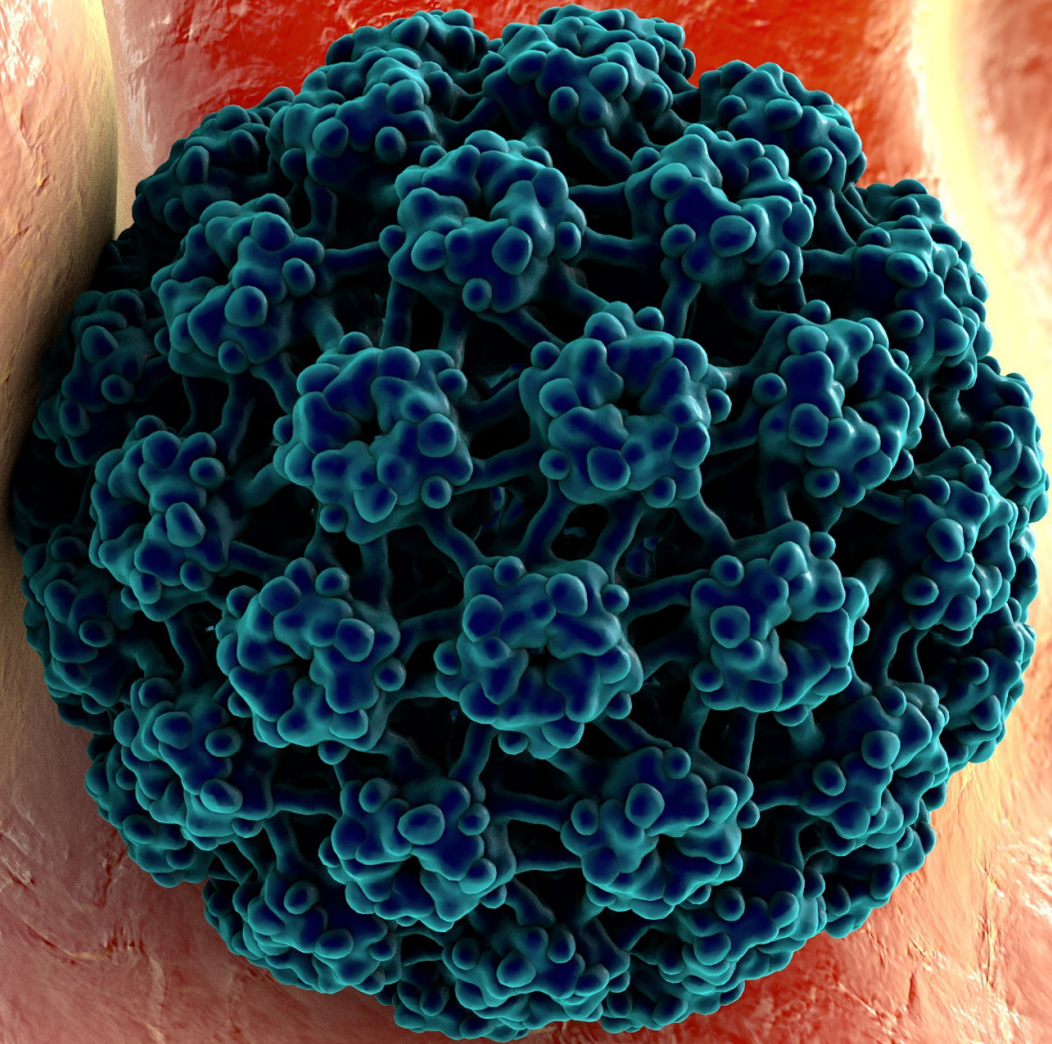


AusDiagnostics



**Genital Infections
& STI**

TandemPlex®

TandemPlex® panels feature multiplex tandem PCR, or MT-PCR, a multiplexed molecular method that provides the added capability to detect viruses, bacteria, protozoa and yeasts in one go, bringing great benefits for differential diagnosis. This is important in an era of syndromic diagnosis when patients often present with symptoms that are analogous in viral and bacterial infections.

Having the ability to detect and differentiate between multiple pathogens is critical for deciding medical interventions for best patient outcomes.

Multiplexed molecular methods are becoming the gold standard for the detection of genital pathogens due to their superior sensitivity, rapid turnaround time, simplicity, and ability to identify multiple pathogens, some of which are slow growing or difficult to culture.

Benefits of TandemPlex® panels

- Detect up to 40 targets with a single panel
- High specificity for reliable results
- Separated 2-step process that allows parallel processing for greater efficiency
- Low amount of sample required so you can retain some for further analysis
- Low number of multiplexed amplification cycles which limits competition and preserves relative quantitation

Genital Infections & STI TandemPlex® Panels

Urinogenital & Resistance

Comprehensive detection of pathogens that cause the most common sexually-transmitted infections (STI), conditionally pathogenic flora, and associated resistance genes.

Chlamydia trachomatis

Intracellular obligatory pathogenic bacteria that are one of the most common causes of STI. Frequently asymptomatic but can cause severe complications if not properly treated.

Neisseria gonorrhoeae

Diplococcal intracellular obligatory pathogenic bacteria that are rarer than Chlamydia, but also associated with severe long-term complications if not properly treated.

Urinogenital and Resistance 12-well Urinogenital and Resistance 12-well, Universal REF 27123 / 87123 (Universal)

12
well

HP
24

UP
96

Major STI

Chlamydia trachomatis
Chlamydia trachomatis LGV
Mycoplasma genitalium *Neisseria gonorrhoeae opaJ*
Neisseria gonorrhoeae opaH
Trichomonas vaginalis

Resistance genes

M. genitalium parC
fluoroquinolone resistance
M. genitalium 23S macrolide resistance
N. gonorrhoeae ceftriaxone resistance
resistance mosaic *penA*

Conditionally pathogenic flora

Mycoplasma hominis
Ureaplasma parvum
Ureaplasma urealyticum

Urinogenital 8-well REF 27113

8
well

HP
24

Major STI

Chlamydia trachomatis
Mycoplasma genitalium
Neisseria gonorrhoeae
Trichomonas vaginalis

Conditionally pathogenic flora

Mycoplasma hominis
Ureaplasma parvum
Ureaplasma urealyticum

HP
24

TandemPlex® panel compatible with Highplex instrument

UP
96

TandemPlex® panel compatible with Ultrplex 3 instrument

8
well

8-well TandemPlex® panel

12
well

12-well TandemPlex® panel

16
well

16-well TandemPlex® panel

24
well

24-well TandemPlex® panel

Symptomatic Urinogenital Infections

Detect four main obligatory pathogenic genital infections (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma genitalium*) along with conditionally pathogenic mycoplasmas.

Syphilis

While molecular methods are not very informative for systemic syphilis, detection of *Treponema pallidum* in the initial stage of the disease (syphilis ulcer) allows early diagnosis and differentiation from herpes and HPV.

Genital Herpes

Neurotropic virus causing lesions and ulcers of genitalia. Should be differentiated with *Treponema* and HPV, so diagnosis is crucial.

HPV

Detection and genotyping of the most important high cancerogenic risk Human Papillomaviruses (HPV).

STI 16-well REF 27112



STI screening

Chlamydia trachomatis
Mycoplasma genitalium
Neisseria gonorrhoeae (2 targets)
Trichomonas vaginalis

Conditionally pathogenic bacteria

Mycoplasma hominis
Streptococcus agalactiae (GBS)
Ureaplasma urealyticum
Ureaplasma parvum

Thrush

Candida albicans
Candida glabrata
Candida krusei (*Pichia kudriavzevii*)

Genital ulcers

Chlamydia trachomatis LGV
Haemophilus ducreyi
HSV 1 (Human herpesvirus 1)
HSV 2 (Human herpesvirus 2)
Treponema pallidum

Viral and Syphilis 12-well REF 87095



HSV 1 (Human herpesvirus 1)
HSV 2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
EBV (Human herpesvirus 4)
CMV (Human herpesvirus 5)
HHV 6 (Human herpesvirus 6)

Treponema pallidum
Enterovirus
Parechovirus types 1-8
Adenovirus group B, C, and E

High-Risk HPV Genotyping 8-well REF 23201



HPV16	HPV35	HPV52	HPV66
HPV18	HPV39	HPV56	HPV68
HPV31	HPV45	HPV58	
HPV33	HPV51	HPV59	

High and Low-Risk HPV Genotyping 16-well REF 23202 (coming soon)



HPV6	HPV33	HPV44	HPV58
HPV11	HPV35	HPV45	HPV59
HPV16	HPV39	HPV51	HPV66
HPV18	HPV42	HPV52	HPV68
HPV31	HPV43	HPV56	HPV82

Women's Health

Selection of pathogens causing gynaecologic infectious diseases.

Candidiasis

Conditionally pathogenic *Candida* yeast may cause inflammation and unpleasant symptoms if their concentration is high enough. Diagnosis helps ensure proper treatment.

Bacterial vaginosis

Imbalance between anaerobic bacteria and normal vaginal flora leading to unpleasant clinical symptoms.

Trichomonas vaginalis

Sexually transmitted obligatory pathogenic parasite not sensitive to standard *Chlamydia* and *Neisseria* treatment, so differential diagnostics is crucial.

Vaginitis and Vaginosis 12-well (Universal) REF 87124



Candidiasis

Candida albicans
Candida tropicalis
Candida glabrata
Candida krusei (*Pichia kudriavzevii*)
Candida parapsilosis

Bacterial vaginosis

Gardnerella vaginalis
Atopobium vaginae
Lactobacillus crispatus
Lactobacillus iners
Lactobacillus jensenii
Lactobacillus gasser

Trichomonas vaginalis

Trichomonas vaginalis

Sample Results

Presence of a target gene is represented by the fluorescence detected during the MT-PCR process.

These results (Figure 1) are also presented as MELT curves and gene targets detected in the sample are automatically called for clear diagnosis.

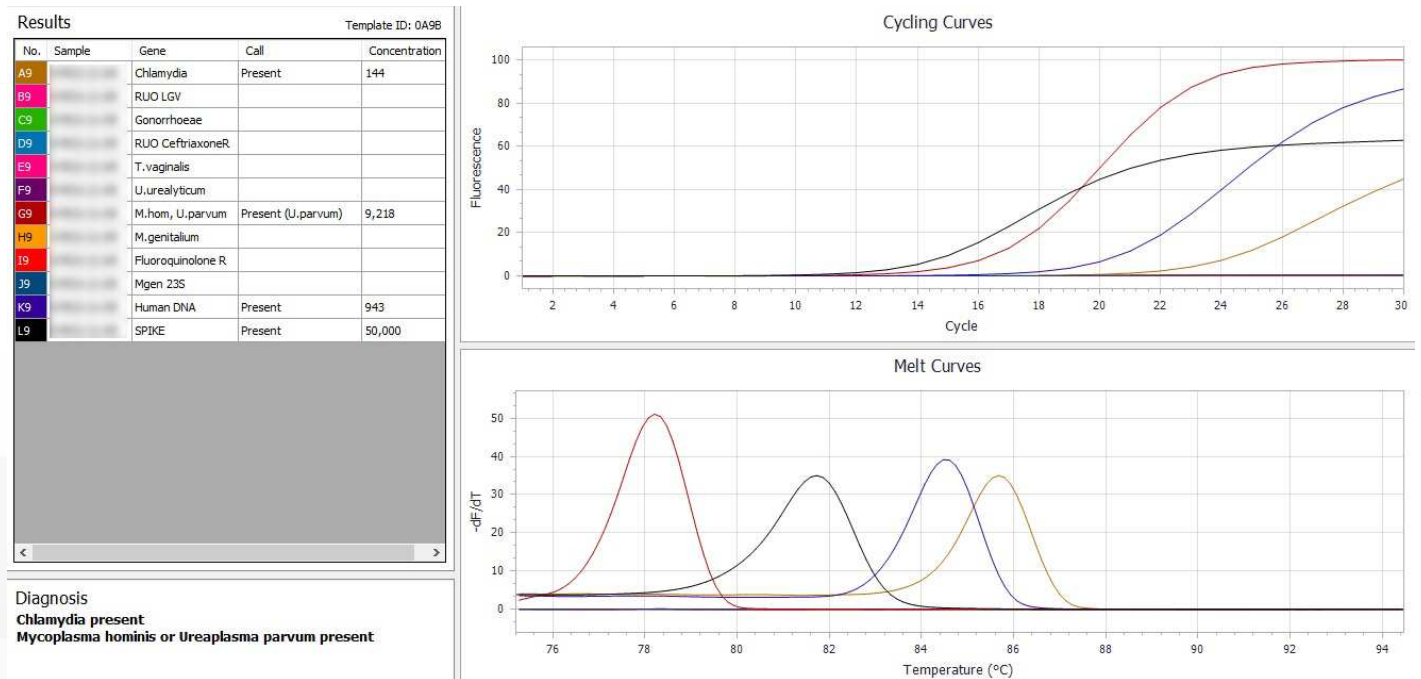


Figure 1: Sample results for Urinogenital & Resistance 12-well Panel (REF 87123)

Automation

Diagnostic testing using TandemPlex® panels is effortless with automation solutions for any workflow, ranging from low and versatile throughput to high throughput and screening applications.

Highplex Alliance™

Low-medium throughput

MT-Prep™ 24 sample purification with Highplex MT-PCR processing

- Sample to results from up to 24 samples¹ in 4 hrs 30 mins
Extraction: 35 – 55 mins² | MT-PCR: 3 hrs 30 mins
- Quick and easy setup in less than 2 mins
- Ready-to-use reagents and key plastic consumables
- Small footprint – requires less than 2m of bench space
- UV deck sterilisation to prevent cross contamination
- Automatic results calling
- LIMS compatible



¹ 8-well, 12-well and 16-well TandemPlex® panels can run up to 24 samples; 24-well panels up to 16 samples.

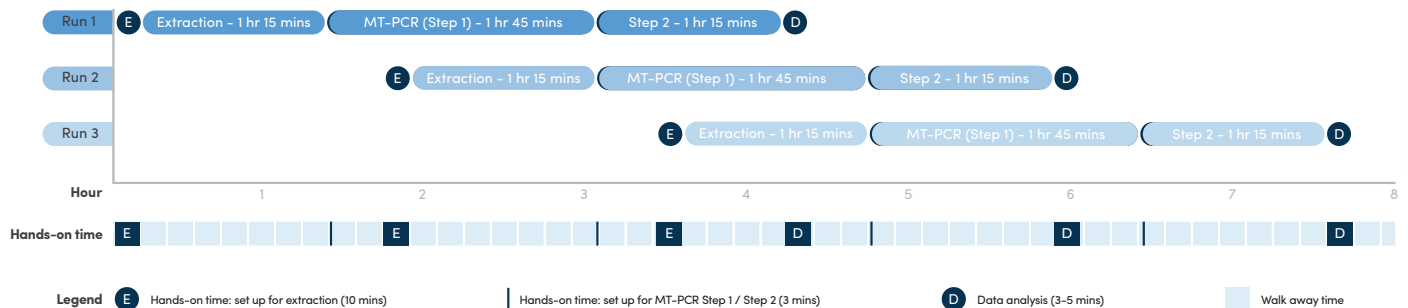
² using MT-Prep™ Viral/Pathogen Nucleic Acids Extraction Kit B. 35-minute rapid protocol, 55-minute standard protocol for up to 24 samples.

Ultrplex Alliance™

High throughput

MT-Prep™ XL sample purification with Ultrplex 3 MT-PCR processing

- Sample to results from up to 96 primary samples³ in 4 hrs 15 mins
Extraction: 1 hr 15 mins⁴ | MT-PCR: 3 hrs 30 mins
- Set up in as little as 2 mins
- Ready-to-use reagents and key plastic consumables
- Multi-channel pipetting for efficient processing
- Use with universal TandemPlex® panels
- Automatic results calling
- LIMS compatible



³ 8-well and 12-well TandemPlex® panels can run up to 96 samples; 24-well panels up to 48 samples.

⁴ Sample purification using Puryx® Comprehensive DNA/RNA Extraction kit.

Ordering information

Each TandemPlex® panel requires the following to run:

1. Step 1 Tubes (e.g. 87123S)
2. Step 2 Plates (e.g. 87123P)
3. Reagent Cassette for Highplex or Reagent Reservoir for Ultraplex instruments
4. Synthetic positive controls



Learn more

Key reagents

xxxxxS	Step 1 Tubes for the relevant panel	HP ₂₄	UP ₉₆
xxxxxP	Step 2 Plates for the relevant panel	HP ₂₄	UP ₉₆
40231	Low DNA Reagent Cassette ¹	HP ₂₄	
40241	Demi DNA Reagent Cassette ¹	HP ₂₄	
40331	Low RNA Reagent Cassette ¹	HP ₂₄	
40341	Demi RNA Reagent Cassette ¹	HP ₂₄	
40421	Medium DNA Reagent Reservoir ²	UP ₉₆	
40431	Low DNA Reagent Reservoir ²	UP ₉₆	
40521	Medium RNA Reagent Reservoir ²	UP ₉₆	
40531	Low RNA Reagent Reservoir ²	UP ₉₆	
91151	Synthetic Positive Controls for Bacteria and Bacterial Resistance	HP ₂₄	UP ₉₆
91021	Synthetic Positive Controls for STDs and Herpes	HP ₂₄	UP ₉₆
Highplex Alliance™		HP ₂₄	
93100	MT-Prep™ 24		
90501	Highplex		
Ultraplex Alliance™			UP ₉₆
93600	MT-Prep™ XL		
94601	Ultraplex 3		

¹ For Highplex: Demi Reagent Cassettes are for 8-well panels; Low for 12-well, 16-well, and 24-well

² For Ultraplex 3: Low Reagent Reservoirs are for 8-well universal panels; medium for 12-well and 24-well

Ordering information on consumables for the Highplex Alliance™ and Ultraplex Alliance™ is available from your local AusDiagnostics representative.

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