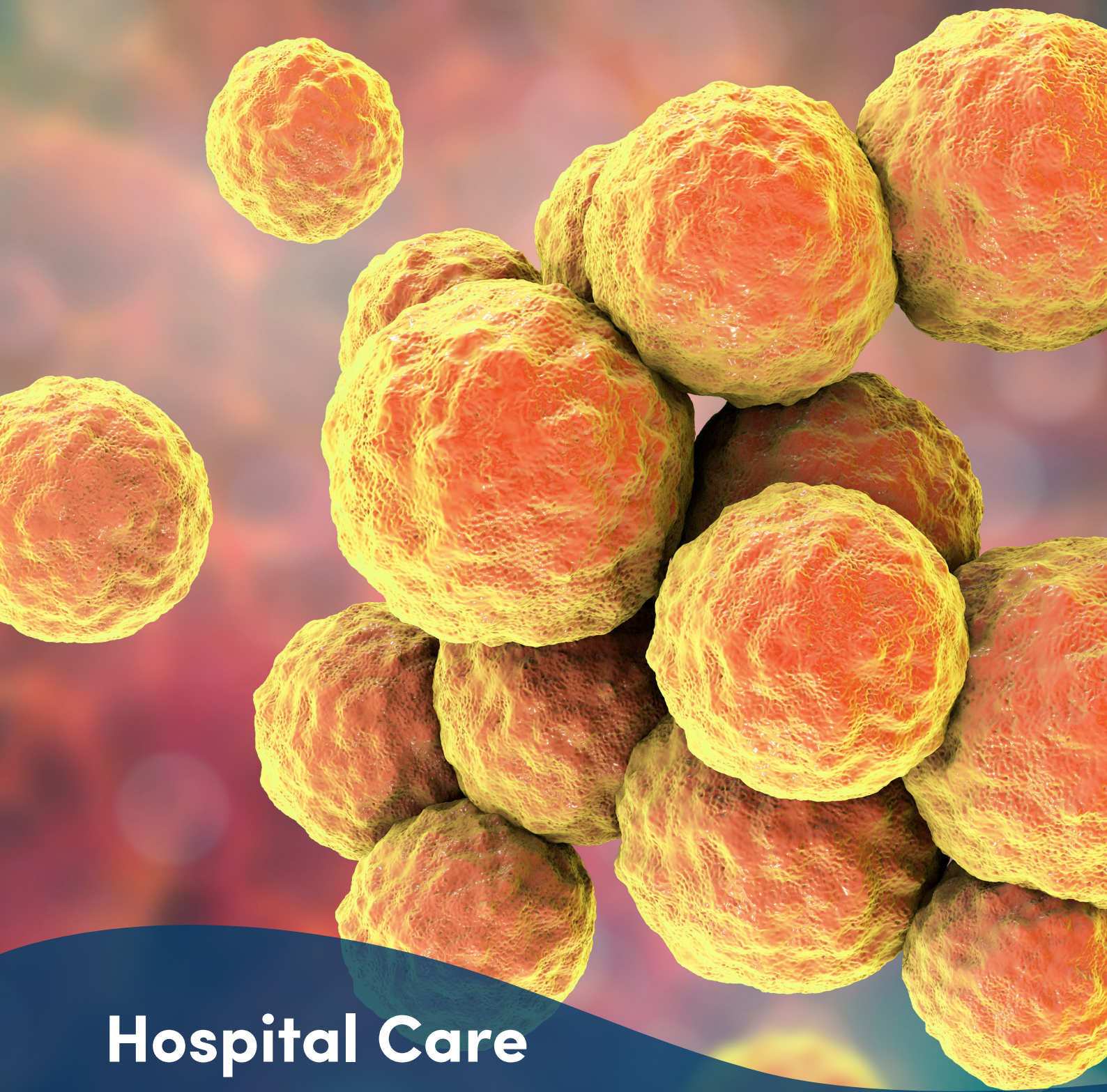
AusDiagnostics



Hospital Care & Drug Resistance

TandemPlex®

Combined differentiation of pathogens and detection of resistance genes is critical for rapidly determining the most appropriate medical interventions in a hospital or community setting.

TandemPlex® panels features our proprietary multiplex-tandem PCR (MT-PCR) technology, a highly multiplexed molecular method that empowers users with the added capability to detect multiple pathogens and antimicrobial resistance genes in a single run. MT-PCR enables comprehensive syndromic diagnosis and earlier medical intervention. This is important in the global fight against antimicrobial resistance and improving antimicrobial stewardship.

Multiplexed molecular methods are becoming the gold standard for drug resistance and critical testing 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 volume of sample required, allowing for further analysis on the remainder of the sample
- Low number of multiplexed amplification cycles which limits competition and preserves relative quantitation

HP 24 TandemPlex® panel compatible with HighPlex instrument

UP 96 TandemPlex® panel compatible with UltraPlex 3 instrument

8 8-well TandemPlex® panel

12 12-well TandemPlex® panel

16 16-well TandemPlex® panel

24 24-well TandemPlex® panel

Hospital Care & Drug Resistance Panels

CRE & ESBL

A selection of clinically relevant panels that detect resistance markers of *enterobacteriaceae* which commonly cause infections within healthcare and community settings. High spread levels of extended spectrum β-lactamases (ESBL) make testing for resistance increasingly necessary, since carbapenems are one of the few remaining antibiotics that can combat ESBL-producing pathogens. Although mostly effective, resistance enzymes (carbapenemases) that destroy these antibiotics pose serious public health concern.

These panels detect a representative selection of simple β-lactamases, extended spectrum β-lactamases (ESBL) and carbapenemases. The selection of targets in each panel reflects the prevalence of ESBL or CRE in different geographical regions.

CRE 16-well
REF 21098

16 well | HP 24 | UP 96

Carbapenemases

NDM
KPC
IMP (1, 4, 5, 6, 10, 14a)
VIM
OXA-23-like
OXA-48-like
OXA-51-like
OXA-58-like
IMI
SME

Extended Spectrum β-lactamases (ESBL's)

CMY
GES
CTX-M group 1
CTX-M group 9

Internal control

Bacteria 16S RNA

CRE EU 16-well
REF 21099

16 well | HP 24 | UP 96

Carbapenemases

NDM
KPC
IMP (1, 4, 5, 6, 8, 10, 14a)
VIM
OXA-48-like
IMI
SME
GIM-1
FRI-1
SIM-1
SPM-1

Extended Spectrum β-lactamases (ESBL's)

GES

Other resistance markers

Colistin resistance MCR-1

CRE Reference 24-well
REF 81099

24 well | HP 24 | UP 96

Carbapenemases

NDM
KPC
IMP (1, 4, 5, 6, 8, 10, 14a)
VIM
OXA-23-like
OXA-24/40-like
OXA-48-like
OXA-51-like
OXA-58-like
IMI
SME
DIM-1
GIM-1
FRI-1
SIM-1
SPM-1

Extended Spectrum β-lactamases (ESBL's)

GES
PER-1
VEB-1

Other resistance markers

Colistin resistance MCR-1
KPC mutation D179Y

ESBL 16-well
REF 21093

16 well · HP 24 · UP 96

β-lactamases

pan-SHV
pan-TEM
pan-CMY

Extended Spectrum β-lactamases (ESBL's)

DHA-1
CTX-M group 1
CTX-M group 9

Carbapenemases

NDM
KPC
IMP (1, 4, 5, 6, 10, 14a)
VIM
OXA-1-like
OXA-48-like
VEB-1

Internal control

Bacteria 16S RNA

Fungal Identification

Detailed screening of 17 fungal candidates associated with systemic fungal infections, skin infection, osteomyelitis, fungemia, and endophthalmitis.

Fungal ID 16-well (RUO)
REF 24110

16 well · HP 24 · UP 96

Candida albicans
Candida glabrata
Candida parapsilosis
Pichia kudriavzevii (Candida krusei)
Candida dubliniensis
Meyerozyma guiliermondii (Candida guiliermondii)
Debaryomyces hansenii (Candida famata)
Candida auris
Candida tropicalis
Candida kefyr
Fusarium spp.
Fusarium solani
Lomentospora prolificans (Scedosporium prolificans)
Cryptococcus neoformans and *C. gattii*
Saccharomyces cerevisiae
Yarrowia lipolytica
Aspergillus spp.

Encephalitis, Meningitis, & Herpes

Analysis of cerebrospinal fluid (CSF) is crucial for the diagnosis and management of central nervous system (CNS) infections. Molecular methods for the detection and identification of bacterial and viral pathogens have demonstrated value for patients with clinical symptoms consistent with CNS infection.

Syndromic testing panels that detect bacteria which are likely to infect the CNS such as *Haemophilus influenzae, Streptococcus pneumoniae, Neisseria meningitidis, Listeria monocytogenes* or *Escherichia coli* are recommended.

PCR has also become the standard for detecting viruses associated with aseptic meningitis or encephalitis, especially for Enterovirus and Parechovirus. Depending on the age and immune status of the patient, there are many other viruses which can cause infection. These include Herpes Simplex Virus (HSV), Varicella Zoster Virus (VZV), Cytomegalovirus (CMV), Human Herpesvirus 6 (HHV-6), Epstein-Barr Virus (EBV), Enterovirus (EV), and human Parechovirus (HPeV).

Viral 12-well
REF 27095

12 well · HP 24

Herpes virus

HSV-1 (Human herpesvirus 1)
HSV-2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
EBV (Human Herpesvirus 4)
CMV (Human herpes Virus 5)
HHV-6 (Human herpes Virus 6)
HHV-7 (Human herpes Virus 7)

Other viruses

Adenovirus group B, C, E
Enterovirus
Parechovirus

CSF 16-well
REF 27050

16 well · HP 24 · UP 96

Bacteria

Haemophilus influenzae
Neisseria meningitidis -2 assays
Streptococcus pneumoniae
Listeria monocytogenes (LMO)
Leptospira interrogans
Mycobacterium tuberculosis complex

Viruses

HSV-1 (Human herpesvirus 1)
HSV-2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
EBV (Human herpesvirus 4)
Enterovirus
Parechovirus

Fungi

Cryptococcus neoformans and *C. gatti*

Herpes, Enterovirus and Adenovirus 8-well
REF 27091

8 well · HP 24

Herpes virus

HSV-1 (Human herpesvirus 1)
HSV-2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
CMV (Human herpesvirus 5)

Other viruses

Adenovirus group B, C, E
Enterovirus

CSF 24-well (RUO)
REF 87024

24 well · HP 24 · UP 96

Bacteria

Neisseria meningitidis - 2 assays
Haemophilus influenzae
Streptococcus pneumoniae
Streptococcus agalactiae
Escherichia coli
Listeria monocytogenes (LMO)
Leptospira interrogans
Mycobacterium tuberculosis complex
Staphylococcus aureus
Staphylococcus spp.
Kingella kingae

Viruses

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)
Enterovirus
Parechovirus

Fungi

Cryptococcus neoformans and *C. gatti*

Resistance genes

Methicillin resistance mecA
Methicillin resistance femA

Gram Positive Resistance

A select panel of gram-positive pathogens that are a common cause of wound infections, urinary tract infections (UTIs), and sepsis in addition to their antimicrobial resistance markers.

Staphylococcus + VRE 8-well
REF 21340

8 well · HP 24

Gram Positive Bacteria

Enterococcus faecium
Enterococcus faecalis
Staphylococcus aureus

Methicillin resistance

mecA
femA

Vancomycin resistance

vanA
vanB

Resistance Screening

A dedicated panel to detect the most common and important antibiotic resistance markers. This includes the most prevalent CRE and ESBL targets along with vancomycin resistance of *Enterococcus*, MRSA and *Candida auris*.

Resistance Screening 16-well *(coming soon)*
REF 21091

16 well · HP 24 · UP 96

Carbapenemases

NDM
KPC
IMP (1, 4, 5, 6, 10, 8, 14a)
VIM
OXA-23-like
OXA-48-like

Extended Spectrum β-lactamases (ESBL's)

CTX-M group 1
CTX-M group 2
CTX-M group 8
CTX-M group 9

Bacteria

Staphylococcus aureus

Critical fungal infection

Candida auris

Methicillin resistance

mecA
femA

Vancomycin resistance

vanA
vanB
vanC
vanM

Colistin resistance

MCR-1
MCR-3
MCR-9

Internal control

Bacteria 16S RNA

Sample TandemPlex® 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.

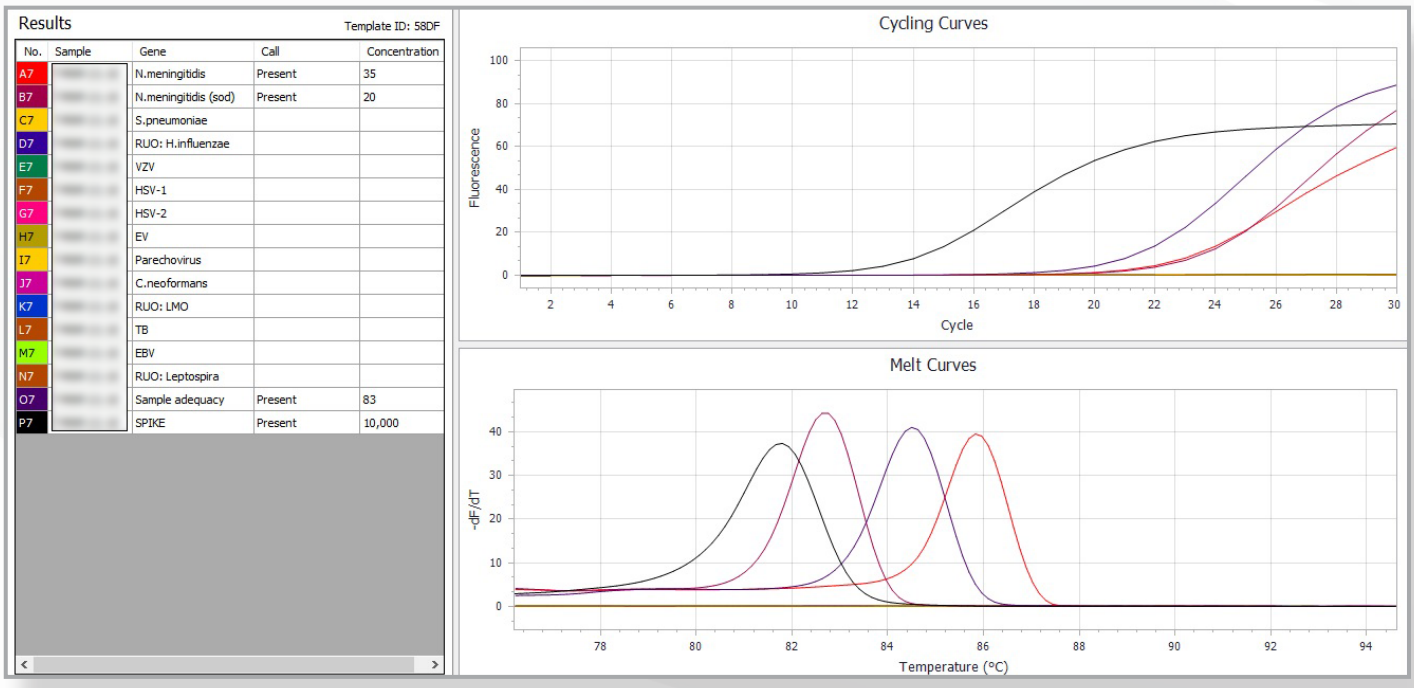


Figure 1: Sample results for CSF 16-well Panel (REF 27050)

Automation

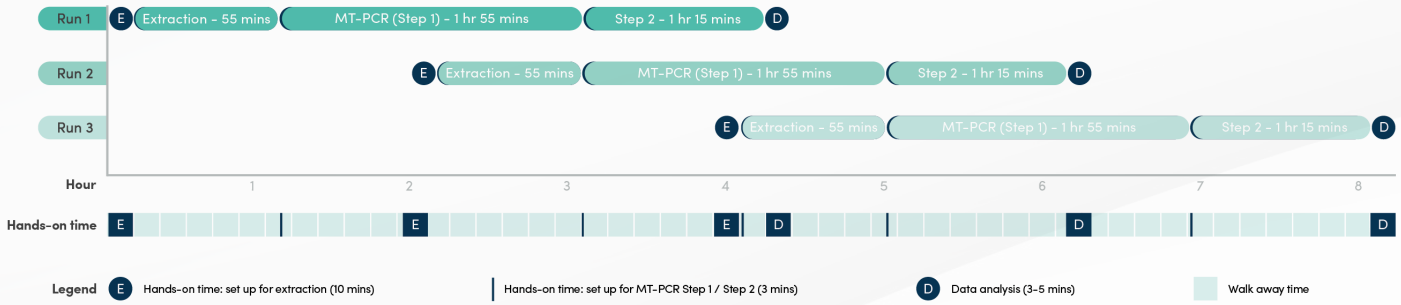
Diagnostic testing using TandemPlex® panels is effortless with automation solutions for any workflow, ranging from low and versatile throughput to high throughput and screening applications.

HighPlex Alliance™

Low-medium throughput

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

- Sample to results from up to 24 samples[1] in 4 hrs 30 mins
  Extraction: 35 – 55 mins[2] | 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



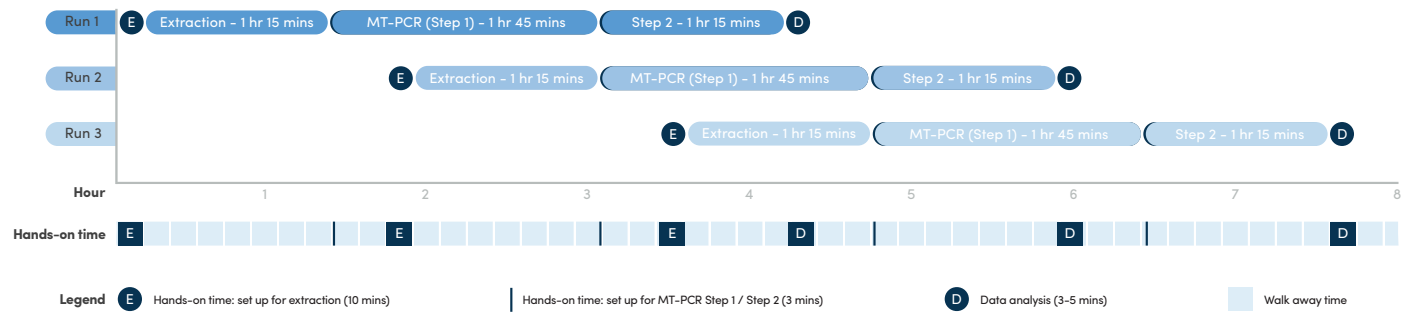
[1] *8-well, 12-well and 16-well TandemPlex® panels can run up to 24 samples; 24-well panels up to 16 samples.*
[2] *using MT-Prep™ Viral/Pathogen Nucleic Acids Extraction Kit B. 35-minute rapid protocol, 55-minute standard protocol for up to 24 samples.*

UltraPlex Alliance™

High throughput

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

- Sample to results from up to 96 primary samples[3] in 4 hrs 15 mins
  Extraction: 1 hr 15 mins[4] | 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 purificatoin using Puryx® Comprehensive DNA/RNA Extraction kit.*

Ordering information

Each TandemPlex® panel requires the following to run:

1. Step 1 Tubes (e.g. 21098S)
2. Step 2 Plates (e.g. 21098P)
3. Reagent Cassette for HighPlex or Reagent Reservoir for UltraPlex instruments
4. A synthetic positive control

Learn more

Key reagents			
xxxxxS	Step 1 Tubes for the desired panel	HP 24	UP 96
xxxxxP	Step 2 Plates for the desired 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 & Bacterial Resistance	HP 24	UP 96
91021	Synthetic Positive Controls for STDs and Herpes	HP 24	UP 96
91081	Synthetic Positive Control for CSF	HP 24	
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, 16-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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