

TandemPlex®

Respiratory pathogens are difficult to distinguish due to overlapping clinical presentation. A multiplexed approach is advantageous in efficient symptomatic screening of common respiratory viruses, bacteria, and fungi. Molecular methods are also ideal for genotyping of Influenza A and determination of SARS-CoV-2 lineages.

TandemPlex® panels features our proprietary multiplextandem PCR (MT-PCR) technology, a highly multiplexed molecular method that empowers users with the added capability to detect DNA and RNA viruses, bacteria, fungi and genotypes in a single run. MT-PCR enables comprehensive syndromic diagnosis and earlier medical intervention. In addition, a comprehensive test allows the detection of multiple pathogens that are responsible for a symptom.

The patented 2-step process mitigates competition during amplification, ensuring reliable detection of targets with differing concentration levels in the specimen.

Multiplexed molecular methods are becoming the gold standard for the detection of respiratory 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.

- 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

- TandemPlex® panel compatible with HighPlex instrument
- TandemPlex® panel compatible with UltraPlex 3 instrument
- 8-well TandemPlex® panel
- 12-well TandemPlex® panel
- 16-well TandemPlex® panel
- 24-well TandemPlex® panel

Respiratory Pathogens TandemPlex® Panels

SARS-CoV-2, Influenza & RSV

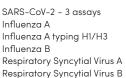
Panels for the detection and typing of important respiratory viruses for efficient screening, optimised for high-throughput workflows.

SARS-CoV-2, Influenza and RSV 8-well **REF 80081**









SARS-CoV-2 Typing Panel 24-well (RUO) **REF 80082**







SARS-CoV-2	SARS	E484Q
SARS-CoV-2 - 3 assays	SARS	P681R
utations	SARS	P681H
Mulations	SARS	I 452R
SARS N501Y SARS HV 69-70del	SARS	P151S
SARS K417N	SARS	D3N
SARS K417T	SARS	V1887I
SARS E484K		

Comprehensive Testing

The broadest panel for the detection of a wide range of pathogens that cause upper and lower respiratory tract infections.

Respiratory Pathogens 24-well **REF 80617**







Viruses

SARS-CoV-2 - 2 assays

Influenza A

Influenza A typing H1/H3

Influenza B

Respiratory Syncytial Virus A

Respiratory Syncytial Virus B

Parainfluenza 1

Parainfluenza 2

Parainfluenza 3

Parainfluenza 4

Metapneumovirus A

Metapneumovirus B

Adenovirus groups B, C, E, partially

A. D

Rhinovirus and Enterovirus Enterovirus

Parechovirus

Seasonal Coronavirus

Bacteria

Mycoplasma pneumoniae Chlamydophila pneumoniae Chlamvdophila psittaci Bordetella IS481 (B. pertussis, partially B. homlesii) Bordetella pertussis Bordetella IS1001 (B. parapertussis, partially B. bronchiseptica) Legionella pneumophila Legionella longbeachae

Pneumocystis jirovecii (PJP)

Prevalent Pathogens

Panels designed in collaboration with our healthcare partners to meet the need for efficient symptomatic coverage, including the most common bacterial and viral respiratory pathogens.

Metapneumovirus A

Metapneumovirus B

Seasonal Coronavirus

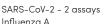
Enterovirus

Bocavirus

Parechovirus

Rhinovirus and Enterovirus

Respiratory Viruses 16-well REF 20602



Influenza A typing H1/H3

Influenza B Respiratory Syncytial Virus A

Respiratory Syncytial Virus B

Parainfluenza 1 Parainfluenza 2

Parainfluenza 3

Parainfluenza 4



Tactical selection of respiratory targets for efficient screening of the 10 most common viruses and Bordetella.

Respiratory Pathogens 12-well **REF 80618**









SARS-CoV-2 - 2 assays Influenza A Influenza B Respiratory Syncytial Virus A

Respiratory Syncytial Virus B Parainfluenza 1

Parainfluenza 2 Parainfluenza 3

Parainfluenza 4

Pneumonia

expedited patient treatment.

Pneumonia 16-well

Mycoplasma pneumoniae

Metapneumovirus A Metapneumovirus B Adenovirus groups B, C, E, partially A, D Rhinovirus and Enterovirus

Differential diagnosis of pathogens who are common candidates

of pneumonia and atypical pneumonia clinical profiles, allowing

Bordetella IS481 (B. pertussis, partially B. homlesii)

Respiratory Pathogens 16-well REF 20620







Viruses

SARS-CoV-2 - 2 assays Influenza A Influenza B

Respiratory Syncytial Virus A Respiratory Syncytial Virus B Parainfluenza 1

Parainfluenza 2 Parainfluenza 3 Parainfluenza 4

Metapneumovirus A Metapneumovirus B Adenovirus groups B, C, E, partially A, D Rhinovirus and Enterovirus Enterovirus

Adenovirus groups B, C, E, partially A, D

Bacteria

Mycoplasma pneumoniae Bordetella IS481 (B. pertussis, partially B. homlesii)

Parechovirus

Respiratory Pathogens B 16-well **REF 20612**







Bacteria

Bacteria

REF 20631

Chlamydophila pneumoniae Chlamydophila psittaci Bordetella IS481 (B. pertussis, partially B. homlesii) Bordetella IS1001 (B. parapertussis, partially B. bronchiseptica) Legionella pneumophila Legionella longbeachae Coxiella burnetti

Haemophilus influenzae Mycobacterium tuberculosis complex Staphylococcus aureus Streptococcus pneumoniae

Pneumocystis jirovecii (PJP) Aspergillus fumigatus Cryptococcus neoformans and C. gattii







Viruses SARS-CoV-2 - 2 assays

Influenza A Influenza B Respiratory Syncytial Virus A Respiratory Syncytial Virus B Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4

Metapneumovirus A

Metapneumovirus B

Adenovirus groups B, C, E, partially A, D Rhinovirus and Enterovirus

Bacteria

Mycoplasma pneumoniae Chlamydophila pneumoniae Bordetella IS481 (B. pertussis, partially B homlesii) Bordetella IS1001 (B. parapertussis, partially B. bronchiseptica) Legionella pneumophila Legionella longbeachae

Atypical Pneumonia 8-well **REF 20632**

Mycoplasma pneumoniae

Chlamydophila psittaci

Legionella pneumophila Legionella longbeachae

Chlamydophila pneumoniae





Respiratory Pathogens C 16-well **REF 20613**







Viruses

Parainfluenza 4

SARS-CoV-2 - 2 assays Influenza A Influenza A typing H1/H3 Influenza B Respiratory Syncytial Virus A Respiratory Syncytial Virus B Parainfluenza 1 Parainfluenza 2 Parainfluenza 3

Metapneumovirus A Metapneumovirus B Adenovirus groups B, C, E, partially A, D Rhinovirus and Enterovirus

Bacteria

Mycoplasma pneumoniae Bordetella IS481 (B. pertussis, partially B. homlesii) Bordetella pertussis Legionella pneumophila Legionella longbeachae

Pneumocystis jirovecii (PJP) Cryptococcus neoformans and C. gattii

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.

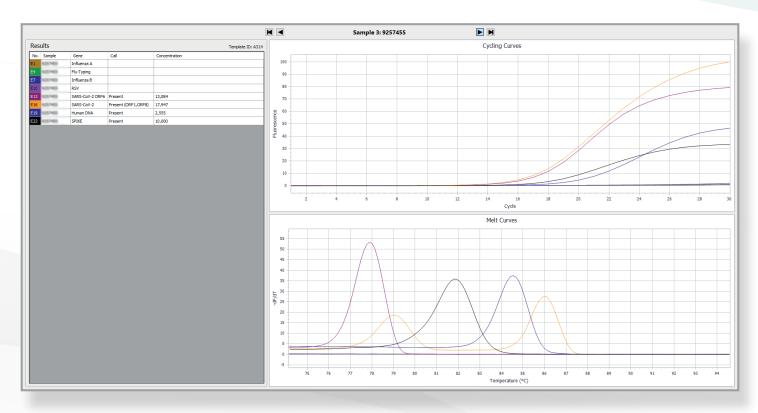
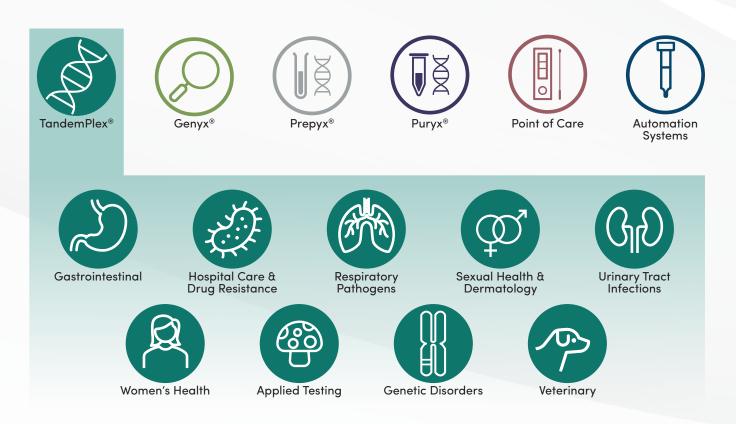


Figure 1: Sample results for SARS-CoV-2, Influenza & RSV 8-well panel (REF 80081)

Product Portfolio



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.

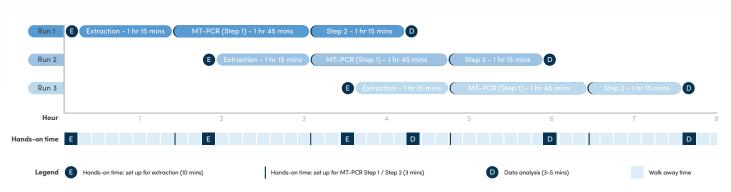
UltraPlex Alliance™

High throughput

MT-Prep™ XL sample purification with UltraPlex 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 $^{\odot}$ panels can run up to 96 samples; 24-well panels up to 48 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.

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. 80081S)
- 2. Step 2 Plates (e.g. 80081P)
- 3. Reagent Cassette for HighPlex or Reagent Reservoir for UltraPlex instruments
- 4. A synthetic positive control



Key reagents

key reage	51115			
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	
91011	Synthetic Positive Controls for Respiratory Pathogens	HP 24	UP 96	
91071	Synthetic Positive Controls for Atypical Pneumonia	HP 24	UP 96	
91520	Synthetic Positive Controls for SARS-CoV-2 Typing	HP 24	UP 96	
HighPlex	HP 24			
93100	MT-Prep [™] 24			
90501	HighPlex			
UltraPlex Alliance™				
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

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

© 2023 AusDiagnostics Pty Ltd. AusDiagnostics, TandemPlex, UltraPlex Alliance, and HighPlex Alliance are trademarks of AusDiagnostics Pty Ltd. Unless otherwise indicated, TandemPlex® MT-PCR panels, and devices included in the HighPlex Alliance and UltraPlex Alliance are intended for in vitro diagnostics use by authorised clinical testing laboratories in Australia, New Zealand, and the European Economic Area and is included on the Australian Register of Therapeutic Goods (ARTG), and compliant with the European IVD Directive 98/79/EC. All products for research use only in USA. PB_RESP-GE02. 2023 AUG.

AusDiagnostics Pty Ltd

290–292 Coward Street, Mascot NSW 2020, Australia | Tel: +61 2 9698 8030

AusDiagnostics UK Ltd

Unit 3, Anglo Business Park, Asheridge Rd, Chesham, Bucks, HP5 2QA, United Kingdom Tel: +44 0 1494 300 121

AusDiagnostics NZ Ltd

156B Bush Road, Albany, Auckland 0632, New Zealand | Tel: +64 9 886 9717

AusDiagnostics USA Inc

Building 2, 1367 Brumlow Ave, Southlake TX 76092, USA | Tel: +1 817 912 1448



Authorized Distributor

Nuclear Laser Medicine srl Viale delle Industrie, 3 20049 Settala (Milan), ITALY Tel. 02 952451 – Fax 02 95245237–8 VAT 08763060152 segreteria@nlm.it – www.nlm.it

² For UltraPlex 3: Low Reagent Reservoirs are for 8-well universal panels; medium for 12-well, 16-well, and 24-well