Respiratory

Viral Respiratory Tract Infections (VRI) *In Development*

The Viral Respiratory Tract Infections (VRI) test cartridge detects 10 viral respiratory infections including SARS-CoV-2 in 2 hours 30 minutes. The panel provides a comprehensive respiratory screen detecting co-infections, enabling informed treatment decisions to be made.

Sample Type: Nasopharyngeal or Oropharyngeal Swab
Sample Volume: 300 µL
Detection Method: Randox Biochip Technology (end-point PCR)
Time to Result: 2 hours 30 minutes

VIRUSES	
SARS-CoV-2	Influenza A
Adenovirus A/B/C/D/E	Coronavirus OC43/HKUI
Sarbecovirus (SARS, SARS Like, SARS-CoV-2)	Influenza B
Enterovirus A/B/C/D / Rhinovirus A/B/C	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
Coronavirus 229E/NL63	Respiratory Syncytial Virus A/B (RSV)

SARS-CoV-2 Rapid Test CE

SARS-CoV-2 is a rapid real time PCR test cartridge, providing a clear and concise result in a timely manner. This enables the patient to take the recommended safety precautions.

Sample Type: Nasopharyngeal or Oropharyngeal Swab
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Time to Result: 39 minutes

VIRUS
SARS-CoV-2 (E gene sequence)

SARS-CoV-2 Rapid Pooling Test CE

The test provides a reliable SARS-CoV-2 result in 44 minutes and is currently one of the fastest PCR tests in the world. Pooling Cartridge can test up to 15 patient samples at one time.

Rapid SARS-CoV-2 pooling

Sample Type: Nasopharyngeal or Oropharyngeal Swab
Sample Volume: (150 µL per-patient sample. If less than 5 patient samples, supplement the remaining volume with eNAT solution).
Detection Method: Real-Time PCR
Time to Result: 44 minutes

15-fold lollipop pooling

Sample Type: Saliva using lollipop swab collection
Sample Volume: 750 µL (3 transport tubes of 250µl, each containing 5 lollipop swabs combined)
Detection Method: Real-Time PCR
Time to Result: 44 minutes

VIRUS
SARS-CoV-2 (E gene sequence)

SARS-CoV-2 Dual Target CE

SARS-CoV-2 dual target real time PCR cartridge provides clear and concise results in a timely manner, direct at the point of care. This enables individuals to take the recommended safety precautions without delay. The SARS-CoV-2 dual target rapid test allows for detection of both the E-gene and N-gene sequence.

Sample Type: Nasopharyngeal or Oropharyngeal Swab
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Time to Result: 49 minutes

VIRUS
SARS-CoV-2 (E gene and N gene sequence)

SARS-CoV-2 Dual Target, Flu A/B, and RSV CE

Patients infected with SARS-CoV-2, Influenza A (Flu A), Influenza B (Flu B) and/or Respiratory Syncytial Virus (RSV) have overlapping symptoms, but the approaches to patient management of infections caused by the viruses are different. SARS-CoV-2, Flu A/B, and RSV is a qualitative test for the rapid triage to support targeted treatment. The combination of these tests additionally reduces costs whilst addressing the challenge of respiratory infections at the point of care, facilitating infection control and risk assessment.

Sample Type: Nasopharyngeal or Oropharyngeal Swab
Sample Volume: 300 µL Clinical Sample
Detection Method: Real-Time PCR
Time to Result: <1 hour

VIRUSES		
SARS-CoV-2 (E gene and N gene)	Influenza A and Influenza B	Human Respiratory Syncytial Virus

Respiratory Tract Infections (RTI) *Planned Panel*

The Respiratory Tract Infection (RTI) test cartridge is the most comprehensive screening test for infections of both the upper and lower respiratory tracts. It simultaneously detects 14 viral and 8 bacterial infections.

VIRUSES		
Influenza A	Coronavirus OC43/HKU1	Parainfluenza virus 3
Influenza B	Enterovirus A/B/C	Parainfluenza virus 4
Adenovirus A/B/C/D/E	Metapneumovirus	Respiratory syncytial virus A/B
Bocavirus 1/2/3	Parainfluenza virus 1	Rhinovirus A/B/C
Coronavirus 229E/NL63	Parainfluenza virus 2	
BACTERIA		
Bordetella parapertussis	*Haemophilus influenzae*	*Mycoplasma pneumoniae*
Bordetella pertussis	*Legionella pneumophila*	*Streptococcus pneumoniae*
Chlamydophila pneumoniae	*Moraxella catarrhalis*	

Chronic Lung Disease (CLD) *Planned Panel

The Chronic Lung Disease (CLD) cartridge is a world leading multiplex test, detecting 131 species associated with long term lung disease e.g. Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD). The 131 species are simultaneously detected across this 31-plex array and includes bacterial, viral, fungal targets and an antibiotic resistance marker from a single sputum sample. Furthermore, the MecA antibiotic resistance marker is included to assist antibiotic stewardship.

VIRUSES	
Adenovirus	Respiratory syncytial virus A
Influenza virus A	Respiratory syncytial virus B
Influenza virus B	Rhinovirus A/B/C

BACTERIA		
Achromobacter xylosoxidans	*Moraxella catarrhalis*	*Pseudomonas aeruginosa*
Bordetella pertussis	*Mycoplasma pneumoniae*	*Staphylococcus aureus*
Burkholderia cepacia complex (21 spp)	*Non-tuberculous Mycobacterium (17 spp)*	*Stenotrophomonas maltophilia*
Burkholderia cenocepacia	*Mycobacterium abscessus subgroup (4 spp)*	*Streptococcus pneumoniae (21 spp)*
Burkholderia multivorans	*Mycobacterium avium complex (4 spp)*	*Streptococcus species (19 spp)*
Chlamydophila pneumoniae	*Pandoraea species (5 spp)*	*Veillonella species (3 spp)*
Haemophilus influenzae	*Prevotella species (16 spp)*	

FUNGI			
Aspergillus fumigatus	*Candida albicans*	*Exophiala dermatitidis*	*Scedosporium species (7 spp)*

ANTIBIOTIC RESISTANCE MARKERS
mecA (incl MRSA)

Hospital Acquired Infections

MRSA/SA CE

MRSA/SA is a qualitative test detecting and differentiating between methicillin-resistant Staphylococcus aureus (MRSA), methicillin-sensitive Staphylococcus aureus (MSSA) and methicillin-resistant coagulase-negative Staphylococci (MRCoNS). By using one single cartridge, the Vivalytic MRSA/SA test aids in the diagnosis of MRSA infection in a speedy manner so that appropriate antibiotic treatment can be applied, and complications prevented.

Sample Type: Swab
Sample Volume: 600 µL
Detection Method: Real-Time PCR
Time to Result: 53 minutes

DETECTABLE PATHOGENS	
Methicillin-resistant Staphylococcus aureus (MRSA)	*Methicillin-sensitive Staphylococcus aureus (MSSA)*

SPECIFIC GENE TARGETS
SCCmec/orfX junction, mecA/ mecC, SA422

Genitourinary

Sexually Transmitted Infections (STI) CE

The Sexually Transmitted Infections (STI) is the broadest cartridge-based STI panel on the market. The test simultaneously detects 10 bacterial, viral and protozoan infections for a comprehensive sexual health profile.

Sample Type: Swab or Urine
Sample Volume: 300 µL
Detection Method: Randox Biochip Technology (end-point PCR)
Time to Result: 2 hours

INFECTIONS	
Chlamydia trachomatis (CT)	Herpes simplex virus 1 (HSV-1)
Neisseria gonorrhoeae (NG)	Herpes simplex virus 2 (HSV-2)
Trichomonas vaginalis (TV)	Haemophilus ducreyi (HD)
Mycoplasma genitalium (MG)	Mycoplasma hominis (MH)
Treponema pallidum (Syphilis) (TP)	Ureaplasma urealyticum (UU)

Mycoplasma genitalium, Mycoplasma hominis & Ureaplasma parvum/urealyticum CE

Aiding in the diagnosis and containment of sexually transmitted infections (STIs) of symptomatic and asymptomatic individuals, the MG, MH, UP/UU test guides appropriate treatment decisions at the earliest opportunity for improved patient management, prevention of transmission and supporting emerging macrolide resistance. MG, MH, UP/UU belong to the group of human pathogenic bacterial species associated with STIs even though particularly Ureaplasma ssp. are primarily considered as commensal organisms.

Sample Type: Swab (Urethral, Vaginal, Cervical, Rectal), Urine
Sample Volume: 300 µL Clinical Sample
Detection Method: Real-Time PCR
Time to Result: 1 hour

BACTERIA		
Mycoplasma genitalium	*Mycoplasma hominis*	*Ureaplasma parvum/urealyticum*

Urinary Tract Infections (UTI) *In Development

The Urinary Tract Infections is a market leading test detecting bacterial, fungal with associated resistance markers from a single urine sample. Identification of a multiplex UTI can prevent further damage to the renal system including the kidneys and bladder. The various antibiotic resistance markers are included to assist antibiotic stewardship.

BACTERIA		
Acinetobacter baumannii	*Escherichia coli*	*Providencia stuartii*
Citrobacter freundii	*Klebsiella oxytoca*	*Serratia marcescens*
Citrobacter koseri	*Klebsiella pneumoniae*	*Staphylococcus aureus*
Klebsiella aerogenes	*Morganella morganii*	*Staphylococcus epidermidis*
Enterobacter cloacae	*Proteus spp.*	*Staphylococcus saprophyticus*
Enterococcus faecalis	*Pseudomonas aeruginosa*	*Streptococcus agalactiae (GBS)*
Enterococcus faecium	*Providencia rettgeri*	
FUNGUS		
Candida albicans		

ANTIBIOTIC RESISTANCE MARKERS	
mecA (incl MRSA)	Trimethoprim Resistance 4
Trimethoprim Resistance 1	Trimethoprim Resistance 5
Trimethoprim Resistance 2	Van A (Vancomycin Resistance A)
Trimethoprim Resistance 3	Van B (Vancomycin Resistance B)