RANDOX

VIVALYTIC

THE ALL IN ONE MOLECULAR SOLUTION









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Vivalytic

Molecular Diagnostics at the Point of Care

Vivalytic brings innovation to the Molecular Diagnostic testing market. It is the result of a successful collaboration between German technology expert, Bosch Healthcare Solutions and Randox Laboratories, a global IVD company and one of Bosch's first bio-content partners.

Bosch Healthcare Solutions has developed the Vivalytic system, which includes the test cartridge and analyser. Randox as the first partner on the Vivalytic platform, supplies Bosch with biological components needed inside the test cartridges to detect different pathogens in the samples. Furthermore, Randox distribute the Vivalytics analyser and test cartridges.

Vivalytic enables sample to answer, cartridge-based Molecular Diagnostic testing. The Vivalytic platform is capable of both Hi-Plex and Low-Plex testing. Nucleic acid extraction, PCR amplification followed by a suite of detection methods are combined in a truly revolutionary, fully automated platform. Manual preparation, cold chain reagents and the use of multiple devices are no longer required.

No further peripherals such as a laptop, keyboard, barcode scanner or filling station are required, making Vivalytic a unique space-saving, hygienic solution for Molecular Diagnostic testing.



4-Step Workflow



Test Results



Unique Test Menu



Hi-Plex & Low-Plex Capabilities



Fully **Automated**



Wireless Connectivity



Vivalytic Cartridges

Vivalytic cartridges are compact, technologically advanced Molecular Diagnostic tests utilising micro-fluidics to enable simple and accurate diagnostic testing. Vivalytic cartridges are powered by a variety of technologies, dependent upon the test application. Hi-Plex and Low-Plex tests can be analysed on the Vivalytic system. Hi-Plex tests utilise Randox patented Biochip Array Technology, enabling endpoint qualitative PCR and providing multiple test results from each sample. Low-Plex tests are based on a variety of detection methods including real-time qualitative PCR and melting curve analysis.



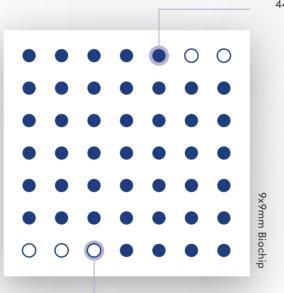
Hi-Plex Vivalytic Cartridges

Powered by Randox Biochip Technology

Randox patented Biochip Technology allows simultaneous detection of multiple targets from a single patient sample. The biochip detection system is based on a chemiluminescent signal, this is the emission of light, without heat, as a result of a chemical reaction.

Each biochip is prefabricated with spatially discrete testing regions (DTR's). Each DTR represents an individual test. Each DTR can be occupied with oligonucleotides specific to a pathogen or target of interest. The Hi-Plex capabilities of Biochip Technology eliminates the need to run multiple time consuming and sample intensive assays.

An enzyme is used to catalyse the chemical reaction of the biochip which generates the chemiluminescent signal. The light emitted from the chemiluminescent reaction that takes place in each DTR is simultaneously detected and quantified using a Charge - Coupled Device (CCD) Camera. This CCD Camera simultaneously records the light emission from all the DTRs on each biochip. The Vivalytic automatically generates a result report for all targets.



44 Discrete Testing Regions

5 Quality Control Regions



Vivalytic Workflow

4 Easy Steps for Optimised Workflow

Intuitive engineering of Vivalytic ensures the analyser is user friendly. The process of patient sample to result comprises a very simple 4 step workflow. To begin the test, the user scans or enters sample information. The cartridge code is then scanned into the embedded Vivalytic software. The user then adds sample into the dedicated cartridge slot, closes the lid and inserts the cartridge into the Vivalytic. The touchscreen display will countdown the time remaining to test completion. Results will be displayed on the screen. Multiple Vivalytics can be wirelessly connected allowing the user to control multiple tests at one time all reporting to a master Vivalytic platform.



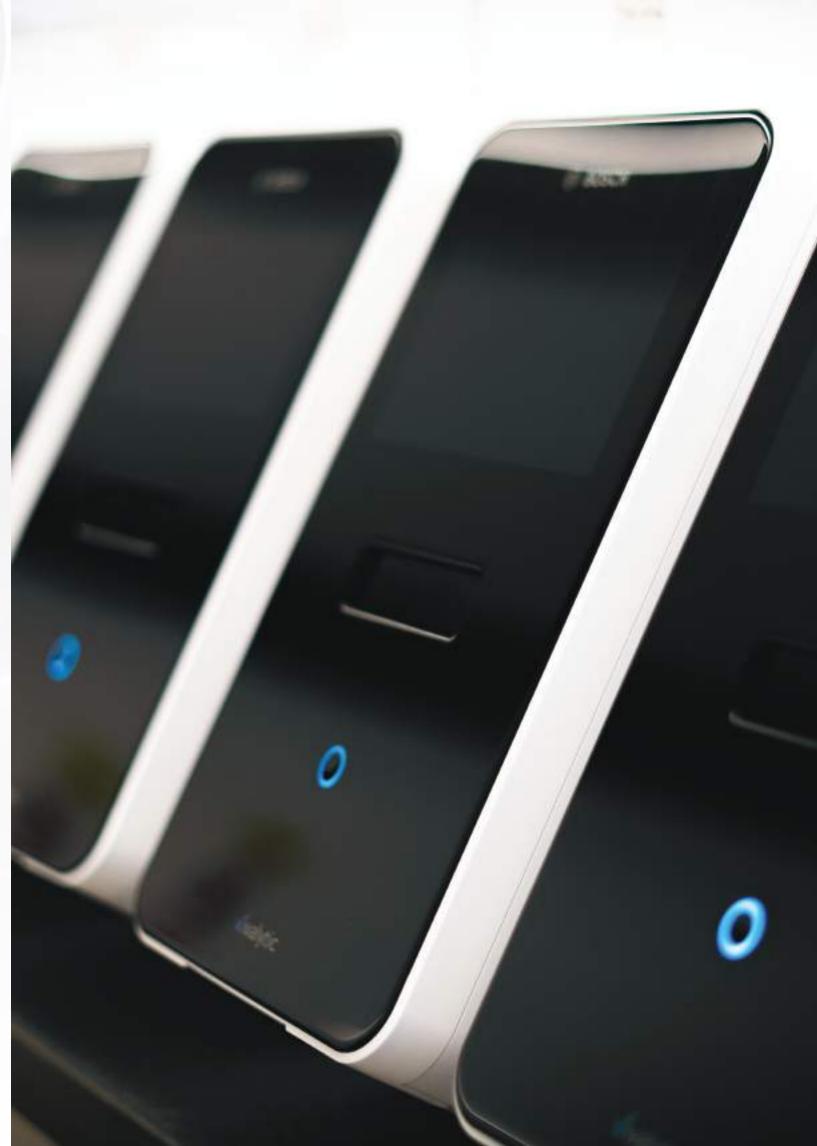
AWARD-WINNING DESIGN DELIVERS AN UNCOMPLICATED USER EXPERIENCE















Respiratory (1)



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 (MEF		
Coronavirus 229E/NL63 Respiratory Syncytial Virus A/B (RSV)		



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)



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 re-

maining 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 (€

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 Exophialia 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 coagulasenegative 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 PATH	HOGENS
Methicillin-resistant Staphylococcus aureus (MRSA)	Methicillin-sensitive Staphylococcus aureus (MSSA)

SPECIFIC GENE TARGETS

SCCmec/orfX junction, mecA/ mecC, SA422

Genitourinary QO





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

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)	





VIVALYTIC FASCINATES WITH A MARKEDLY MINIMALIST DESIGN WHOSE STRENGTH LIES IN ITS HIGH USERFRIENDLINESS AND FUNCTIONALITY









Vivalytic Specifications



TECHNICAL DATA		
Display	7 inch 16:10, 1024 x 600 pixel touchscreen	
Operating Air Pressure Range	850-1,100 hPa, corresponds to pressure range 0-1, 400m above sea level	
Operating Temperature	15-30 °C	
Storage Temperature	-20-60 °C	
Data Transfer	Ethernet 10/100, MB, WLAN 2.4 GHz, (802.11b/g/n); internal: Bluetooth v4.1, 2.4 GHz (low energy), USB 2.0	
Electromagnetic Compatibility	IEC/EN 61326-2-6, RED 2014/53/EC, FCC47 CFR 15	
Dimensions	Length 400 mm, Width 204 mm, Height 388 mm	
Distance/Space to the wall	~20 cm	
Weight	15 kg	
Storage Humidity	20-95 % (not condensing)	
Operating Humidity	30-80 % (not condensing)	
Electrical Data	100-240 V~, 50/60 Hz, 160 VA	
Instrumental Safety	IEC/EN 61010-1, IEC/EN 61010-2-010 IEC/EN 61010-2-101, Regulation 2017/746	
Memory Capacity	16 GB	
Mean Loudness	≤ 55 dB(A) in operating mode. Short term loudness can exceed mean loudness	
Socket	Use multiple sockets for EU countries and UK	



Vivasuite

All Vivalytic analysers can be connected to Vivasuite, a valuable device management system. Vivasuite is the digital Vivalytic ecosystem allowing you to reduce service cost and ensures clarity of your systems. Vivasuite runs on the Bosch IoT Cloud and applies the highest standards regarding IT security and data privacy. Functionality of the Vivasuite includes registration, device management and automatic software updates, giving the device administrators an informed perspective on the usage of the devices.

Benefits

- Automatic software updates, including product releases
- Real-time monitoring of internal machine performance
- Monitoring of usage in remote settings **>>**





Ordering Information

PRODUCT	QUANTITY	CATALOGUE NUMBER		
Analyser				
Vivalytic One	x1	F09G300115		
Test Cartridges				
Vivalytic STI Test	1 Kit (15 Cartridges)	F09G300078		
Vivalytic MG, MH, UP/UU Test	1 Kit (15 Cartridges)	F09G300705		
Vivalytic SARS-CoV-2, Flu A/B & RSV Test	1 Kit (15 Cartridges)	F09G300747		
Vivalytic SARS-CoV-2 Test	1 Kit (15 Cartridges)	F09G300411		
Vivalytic SARS-CoV-2 Pooling Test	1 Kit (15 Cartridges)	F09G300587		
Vivalytic SARS-CoV-2 DT Test	1 Kit (15 Cartridges)	F09G300711		
Vivalytic MRSA/SA Test	1 Kit (15 Cartridges)	F09G300622		
Future Planned Panels				
Vivalytic VRI Test	1 Kit (15 Cartridges)	F09G300636		
Vivalytic UTI Test	1 Kit (15 Cartridges)	F09G300333		
Chronic Lung (CLD)	1 Kit (15 Cartridges)	*Planned		
Respiratory Tract Infections (RTI)	1 Kit (15 Cartridges)	*Planned		

MAKING A POINT TO CARE

55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY



www.randox.com