

### **VIVALYTIC**

# THE ALL IN ONE MOLECULAR SOLUTION





# RANDOX BIOSCIENCES

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## Vivalytic

Vivalytic brings innovation to the Molecular Diagnostic testing market. It is the result of a collaboration involving Bosch, the German technology giant, and Randox Laboratories, a global IVD company. With over 35 years experience in assay development, Randox is dedicated to improving global healthcare.

Vivalytic enables sample to answer, cartridge-based Molecular Diagnostic testing. The Vivalytic platform is capable of both Hi-Plex and Lo-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.









Unique Test Menu



Fully Automated



Fast Test Results



Hi-Plex & Lo-Plex Capabilities



Wireless Connectivity

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### 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 Lo-Plex tests can be analysed on the Vivalytic. Hi-Plex tests utilise Randox patented Biochip Array Technology, enabling end-point qualitative PCR and providing multiple test results from each sample. Lo-Plex tests are based on a variety of detection methods including real-time qualitative PCR and melting curve analysis.





All Reagents On-Board



Room Temperature Storage



Multiplex Technology



Multiple Sample Types



Minimal Contamination Risk

\*Actual Size

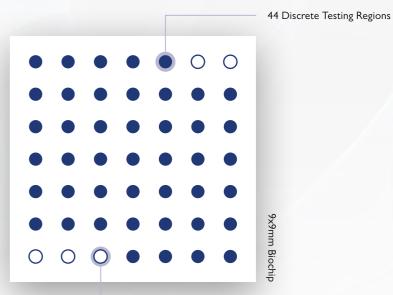
### Hi-Plex Vivalytic Cartridges

### Powered by Randox Biochip Array Technology

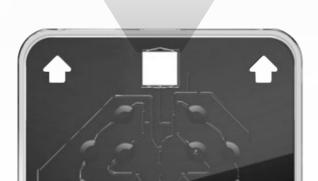
Biochip Array Technology enables sample to answer multiplex Molecular Diagnostic testing. Every biochip-powered cartridge produces multiple test results from each patient sample. The intelligent, chemically activated 9x9mm ceramic biochip acts as a solid phase reaction surface.

The biochips are pre-fabricated with spatially discrete tests regions (DTRs). Each DTR represents an individual test and each biochip can contain up to 44 DTRs. Each DTR can be occupied with oligonucleotides specific to a pathogen of interest. The Hi-Plex capabilities of Biochip Array Technology eliminate the need to run multiple time consuming and sample intensive PCR assays.

The biochip detection system is based on a chemiluminescent signal. This is the emission of light, without heat, due to an enzymatic chemical reaction. 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 discrete test sites on each biochip. The Vivlaytic automatically generates a result report for all targets.



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













II Vivalytic Tests



### Respiratory Tract Infections (RTI)

The Respiratory Tract Infections 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. The test can be carried out with nasopharyngeal swabs, sputum or broncheoalveolar lavage (BAL).

Sample Type: Nasopharyngeal Swab, Sputum, BAL

Sample Volume: 200 μL

**Detection Method:** Biochip Array Technology

VIRUSES		
Influenza A	Coronavirus OC43/HKUI	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 I	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	

### O Flu A/B & RSV

The Flu A/B & RSV assay utilises a one-step real-time PCR format where the automated reverse transcription of influenza RNA and/or RSV RNA is followed by the detection of pathogen specific genes in the same cartridge. The test can be carried out with nasopharyngeal swabs, sputum or broncheoalveolar lavage (BAL).

Sample Type: Nasopharyngeal Swab, Sputum, BAL

Sample Volume: 200 µL

**Detection Method:** Real-Time PCR

	VIRUSES	
Influenza A	Influenza B	Respiratory Syncytial Virus (RSV)



The Chronic Lung Disease cartridge is a world leading multiplex test, detecting 132 species associated with long term lung disease e.g. Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD). The 132 species are simultaneously detected across this 32-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.

Sample Type: Sputum Sample Volume: 200 µL

**Detection Method:** Biochip Array Technology

	VIF	RUSES	
Adenovirus	Respiratory	syncytial virus B	Influenza virus B
Metapneumovirus	Rhinovi	rus A/B/C	
Respiratory syncytial virus A	Influen	nza virus A	
	BAC	CTERIA	
Achromobacter xylosoxidans	Moraxell	la catarrhalis	Pseudomonas aeruginosa
Bordetella pertussis	Mycoplasm	na pneumoniae	Staphylococcus aureus
Burkholderia cepacia complex (2 l spp	Non-tuberculous m	ycobacterium (15 spp)	Stenotrophomonas maltophilia
Burkholderia cenocepacia	Mycobacterium abscessus subgroup (4 spp)  Streptococcus pneumoniae (2		Streptococcus pneumoniae (21 spp)
Burkholderia multivorans Mycobacterium avium complex (4 spp) Streptococcus species (19 s		Streptococcus species (19 spp)	
Chlamydia pneumoniae	Pandoraea	Pandoraea species (5 spp) Veillonel	
Haemophilus influenza	Prevotella s	pecies (16 spp)	
	FL	JNGI	
Aspergillus fumigatus	Candida albicans	Exophialia dermatitid	is Scedosporium species (7 spp,
	ANTIBIOTIC RES	ISTANCE MARKERS	

# Genitourinary QÔ



### Sexually Transmitted Infections (STI)

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

Sample Type: Swab or Urine Sample Volume: 200 μL

**Detection Method:** Biochip Array Technology

INFECTIONS	
Chlamydia trachomatis (CT)	Herpes simplex virus I (HSV-I)
Neisseria gonorrhoea (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)



### Urinary Tract Infections (UTI)

The Urinary Tract Infections is a market leading test detecting bacterial, fungal with associated resistance markers from a single urine sample. Identification of a multi-plex 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.

Sample Type: Urine Sample Volume: 200 μL

**Detection Method:** Biochip Array Technology

	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 I	Trimethoprim Resistance 5
Trimethoprim Resistance 2	Van A (Vancomycin Resistance A)
Trimethoprim Resistance 3	Van B (Vancomycin Resistance B)

# Hospital Acquired Infections





### Methicillin-Resistant Staphylococcus Aureus (MRSA)

MRSA 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). A variety of swabs can be used including human nasal or nasal/throat swabs, cultures, wounds, axilla, groin and perineum swabs.

Sample Type: Swab Sample Volume: 200 μL

Detection Method: Real-Time PCR

BACTERIA		
Methicillin-resistant Staphylococcus aureus (MRSA)	Methicillin-sensitive Staphylococcus aureus (MSSA)	Methicillin-resistant coagulase-negative Staphylococci (MRCoNS)



VIVALYTIC FASCINATES WITH A MARKEDLY MINIMALIST DESIGN WHOSE STRENGTH LIES IN ITS HIGH USER-FRIENDLINESS AND **FUNCTIONALITY** 











# **Vivalytic Specifications**



PERFORMANCE CHARACTERISTICS		
Analyser Type Fully Automated		
Sample Volume	200µl	
Relative Humidity Range	Operating humidity 30-80% (not condensing)	
Peripherals	None Required	
Weight	15KG	
Storage Humidity	20-95% (not condensing)	
Sample Types	Sputum, swab, urine, blood and BAL	
Storage Capacity	16G	
Noise Output	65 dB	

POWER & CONNECTIVITY		
Display  7" high resolution LCD (RGB)(1024x600)  Touch-sensitive screen (responsive to lab gloves)		
Electrical Data 100-240 V~, 50/60Hz, 160VA		
SYSTEM CONNECTIONS		

STSTEM CONNECTIONS	
Data Transfer / Connectivity	Supports: HL7, GDT & POCT-1A Ethernet 10/100MN WiFi 2.4GHz (802.11b/g/n) Internal: Bluetooth v4.1 2.4 GHz (low energy), USB 2.0, 3 USB Ports GSM
Memory Capacity	16GB

## Vivalytic Up

Vivalytic is a versatile analyser suitable as a stand-alone platform. Alternatively, it can be transformed into a modular and expandable system. Stacking of the analysers provides the user with a scalable, flexible and space saving Molecular Diagnostic testing solution. Vivalytic Up offers a multi-slot, random access testing platform allowing the user the ability to use one analyser as the master user-interface that communicates with the other analysers. Integrated cable management is available allowing just one main power cable to power up to 8 analysers at one time.



### **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

- Extended warranty options for connected products
- Automatic software updates, including product releases
- Real-time monitoring of internal machine performance
- Monitoring of usage in remote settings





23 Vivalytic Test Menu

TEST	TARGETS	
RESPIRATORY		
Respiratory Tract Infection Array	I 4 viral targets 8 bacterial targets	
Flu A/Flu B/RSV	3 viral targets	
Chronic Lung Infection Array	20 bacterial targets 7 viral targets 4 fungal targets I antibiotic resistance marker	
GENITOURINARY		
Sexually Transmitted Infection Array	10 targets	
Urinary Tract Infection Array	20 bacterial targets I fungal targets 8 antibiotic resistance markers	
hospital acquired infections		
MRSA	3 bacterial targets	

## Molecular Quality Solutions

Randox has a strategic partnership with both Qnostics and QCMD, internationally renowned providers of IQC and EQA products for infectious diseases. Qnostics are a provider of complete QC solutions and their products can be used in the daily monitoring of assay performance. Linearity assessment, assay evaluation, validation/verification of new assays and staff training can also be facilitated using these products.

QCMD also play an essential role in assuring laboratory quality by providing EQA samples across a wide range of infectious disease areas.

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