

RANDOX
BIOSCIENCES



VIVALYTIC

THE ALL IN ONE
MOLECULAR SOLUTION



 **BOSCH** |  vivalytic

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Vivalytic

01

Vivalytic
& Cartridges

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.



Ease of Use



Unique Test Menu



Fully Automated



Fast Test Results



Hi-Plex & Lo-Plex Capabilities



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 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.



185mm (L) 75mm (W) 17mm (D)

*Actual Size



All Reagents On-Board



Room Temperature Storage



Multiplex Technology



Multiple Sample Types



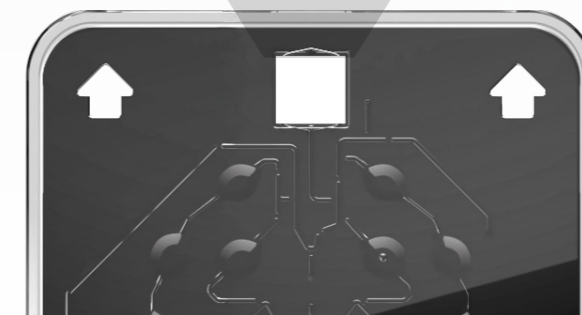
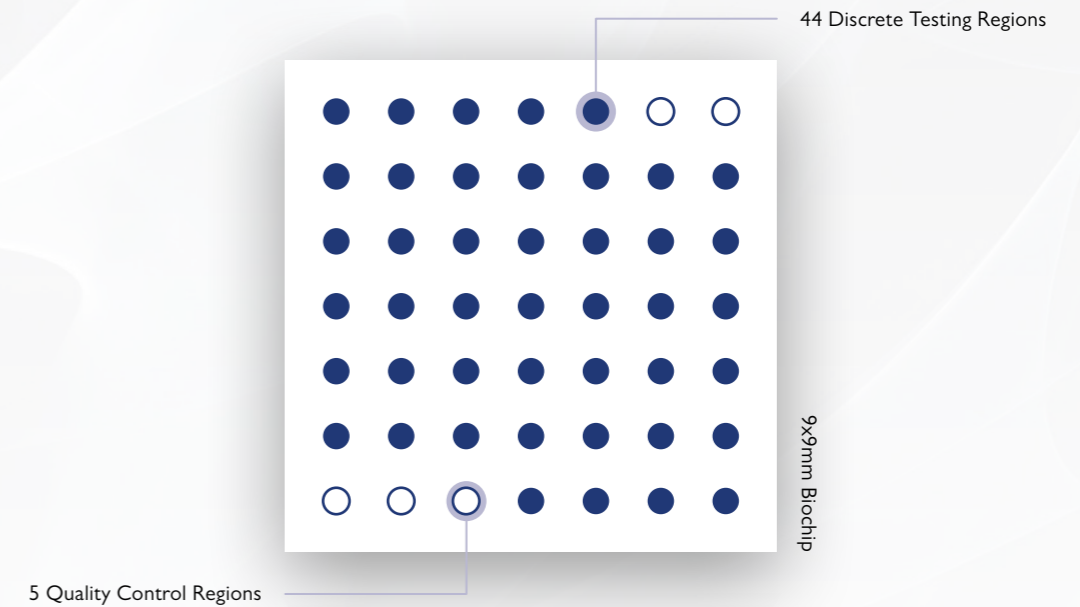
Minimal Contamination Risk

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 Vivalytic automatically generates a result report for all targets.

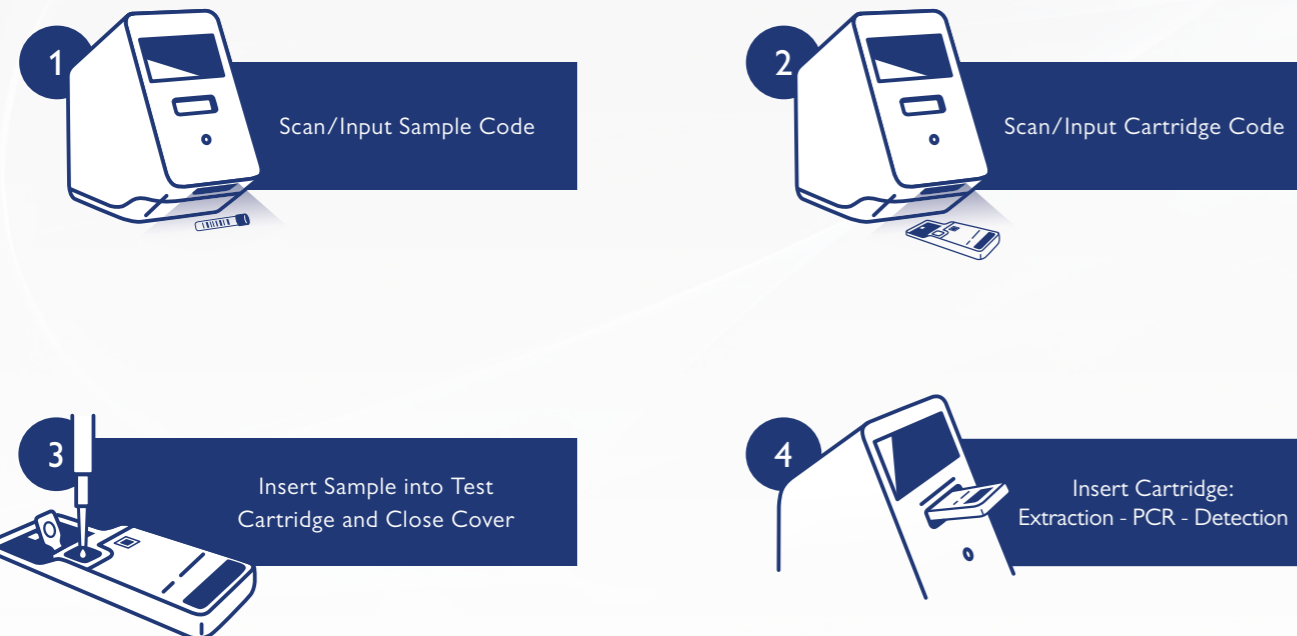


Vivalytic Workflow

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”





Vivalytic

02

Vivalytic
Tests

Respiratory

⦿ 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 bronchoalveolar lavage (BAL).

Sample Type: Nasopharyngeal Swab, Sputum, BAL

Sample Volume: 200 µL

Detection Method: Biochip Array Technology

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		
<i>Bordetella parapertussis</i>	<i>Haemophilus influenzae</i>	<i>Mycoplasma pneumoniae</i>
<i>Bordetella pertussis</i>	<i>Legionella pneumophila</i>	<i>Streptococcus pneumoniae</i>
<i>Chlamydomphila pneumoniae</i>	<i>Moraxella catarrhalis</i>	

⦿ 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 bronchoalveolar 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)

⦿ Chronic Lung Disease (CLD)

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

VIRUSES		
Adenovirus	Respiratory syncytial virus B	Influenza virus B
Metapneumovirus	Rhinovirus A/B/C	
Respiratory syncytial virus A	Influenza virus A	
BACTERIA		
<i>Achromobacter xylosoxidans</i>	<i>Moraxella catarrhalis</i>	<i>Pseudomonas aeruginosa</i>
<i>Bordetella pertussis</i>	<i>Mycoplasma pneumoniae</i>	<i>Staphylococcus aureus</i>
<i>Burkholderia cepacia complex (21 spp)</i>	<i>Non-tuberculous mycobacterium (15 spp)</i>	<i>Stenotrophomonas maltophilia</i>
<i>Burkholderia cenocepacia</i>	<i>Mycobacterium abscessus subgroup (4 spp)</i>	<i>Streptococcus pneumoniae (21 spp)</i>
<i>Burkholderia multivorans</i>	<i>Mycobacterium avium complex (4 spp)</i>	<i>Streptococcus species (19 spp)</i>
<i>Chlamydia pneumoniae</i>	<i>Pandora species (5 spp)</i>	<i>Veillonella species (3 spp)</i>
<i>Haemophilus influenza</i>	<i>Prevotella species (16 spp)</i>	
FUNGI		
<i>Aspergillus fumigatus</i>	<i>Candida albicans</i>	<i>Exophiala dermatitidis</i>
		<i>Scedosporium species (7 spp)</i>
ANTIBIOTIC RESISTANCE MARKERS		
mecA (incl MRSA)		

Genitourinary

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 1 (HSV-1)
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		
<i>Acinetobacter baumannii</i>	<i>Escherichia coli</i>	<i>Providencia stuartii</i>
<i>Citrobacter freundii</i>	<i>Klebsiella oxytoca</i>	<i>Serratia marcescens</i>
<i>Citrobacter koseri</i>	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus aureus</i>
<i>Klebsiella aerogenes</i>	<i>Morganella morganii</i>	<i>Staphylococcus epidermidis</i>
<i>Enterobacter cloacae</i>	<i>Proteus spp.</i>	<i>Staphylococcus saprophyticus</i>
<i>Enterococcus faecalis</i>	<i>Pseudomonas aeruginosa</i>	<i>Streptococcus agalactiae (GBS)</i>
<i>Enterococcus faecium</i>	<i>Providencia rettgeri</i>	

FUNGUS
<i>Candida albicans</i>

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)

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)



reddot design award

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



RTI PANEL
by Infections
2019-12-10

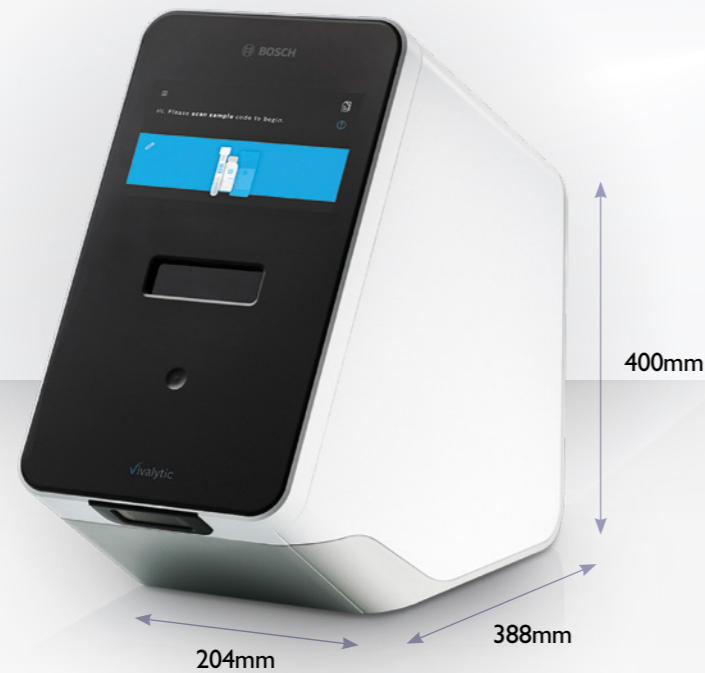
vivalytic



03

Vivalytic
Specifications

Vivalytic Specifications



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.



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	
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

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



Insert cartridge and insert into slot.

46-23
Williams
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RTI PANEL
Respiratory Infections
2019-12-10

04

Vivalytic
Test Menu

Test Menu

TEST	TARGETS
RESPIRATORY	
Respiratory Tract Infection Array	14 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 1 antibiotic resistance marker
GENITOURINARY	
Sexually Transmitted Infection Array	10 targets
Urinary Tract Infection Array	20 bacterial targets 1 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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