RANDOX

# VIVALYTIC

## THE ALL IN ONE MOLECULAR SOLUTION


BOSCH vivalytic

# CONTENTS

# 01

Vivalytic
& Cartridges

# Vivalytic

## Molecular Diagnostics at the Point of Care

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.

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.


- 4-Step Workflow
- 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



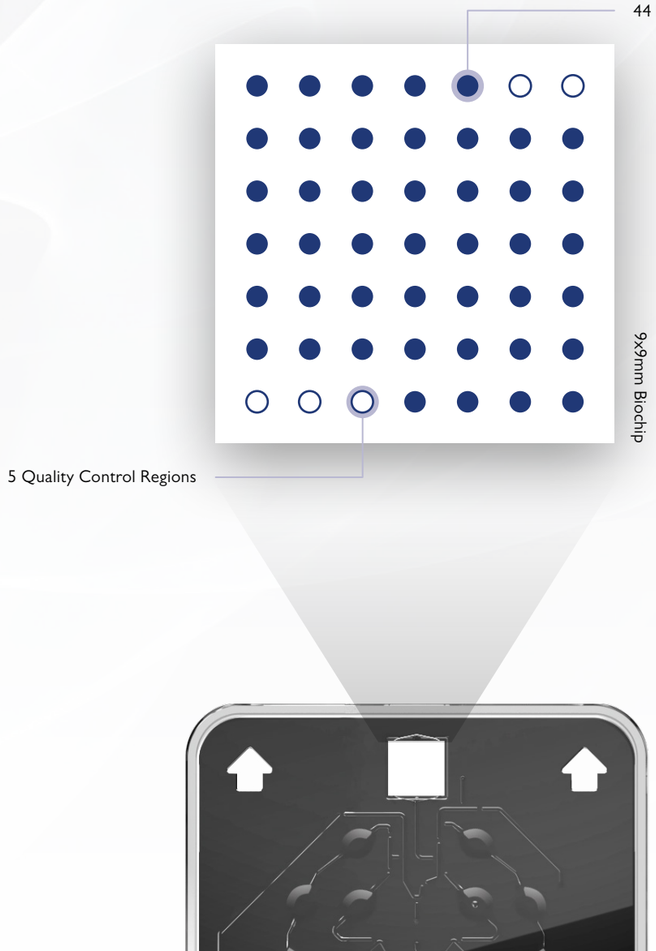
# Hi-Plex Vivalytic Cartridges

## Powered by Randox Biochip 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.



# 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

1 Scan/Input Sample Code

2 Scan/Input Cartridge Code

3 Insert Sample into Test Cartridge and Close Cover

4 Insert Cartridge: Extraction - PCR - Detection


# 02

Vivalytic
Test Cartridges

# Respiratory

## Viral Respiratory Tract Infections (VRI)

The Viral Respiratory Tract Infections (VRI) test cartridge detects 10 viral respiratory infections including COVID-19 (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 (COVID-19) | Adenovirus A/B/C/D/E |
| Sarbecovirus (SARS, SARS like, SARS-CoV-2) | Enterovirus A/B/C |
| Coronavirus 229E/NL63 | Influenza A |
| Coronavirus OC43/HKUI | Influenza B |
| Middle East Respiratory Syndrome Coronavirus (MERS-CoV) | Rhinovirus A/B |

## SARS-CoV-2 (COVID-19) CE

SARS-CoV-2 (COVID-19) 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 (COVID-19) |

## SARS-CoV-2 (COVID-19 Pooling Test) CE

The test provides a reliable SARS-CoV-2 (COVID-19) result in 39 minutes and is currently one of the fastest polymerase chain reaction (PCR) tests in the world. Pooling Cartridge can test upto 5 patient samples at one time, 150 µL per-patient sample (if less than 5 patient samples, supplement the remaining volume with eNAT solution).

**Sample Type:** Nasopharyngeal or Oropharyngeal Swab
**Sample Volume:** 750 µL
**Detection Method:** Real-Time PCR
**Time to Result:** 39 minutes

| VIRUS |
|---|
| SARS-CoV-2 (COVID-19) |



## CoV (COVID-19 2-plex) CE

CoV is a rapid test for the detection of SARS-CoV-2 providing a clear and concise result in a timely manner direct at the point of care. Available on the Vivalytic, the CoV test cartridge detects both ORF1ab gene specific for SARS-CoV-2 and E gene specific for Sarbecovirus (confirmatory target), to report COVID-19 positive patient samples. This enables the patient to take the recommended safety precautions without delay.

**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

| VIRUS | |
|---|---|
| SARS-CoV-2 (COVID-19) | Sarbecovirus (SARS, SARS like, SARS-CoV-2) |

## Flu A/B & RSV **In Development*

The Flu A/B & RSV test cartridge 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.

**Sample Type:** Nasopharyngeal Swab
**Sample Volume:** 300 µL
**Detection Method:** Real-Time PCR
**Time to Result:** TBC

| VIRUSES | | |
|---|---|---|
| Influenza A | Influenza B | Respiratory Syncytial Virus (RSV) |

## Respiratory Tract Infections (RTI) **In Development*

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.

**Sample Type:** Nasopharyngeal Swab
**Sample Volume:** 300 µL
**Detection Method:** Randox Biochip Technology (end-point PCR)
**Time to Result:** TBC

| 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) **In Development*

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.

**Sample Type:** Sputum
**Sample Volume:** 300 µL
**Detection Method:** Randox Biochip Technology (end-point PCR)
**Time to Result:** TBC

| 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

## Methicillin-Resistant Staphylococcus Aureus (MRSA) **In Development*

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:** 300 µL
**Detection Method:** Real-Time PCR
**Time to Result:** TBC

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



# 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 30 minutes

| 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) |

## 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.

**Sample Type:** Urine
**Sample Volume:** 300 µL
**Detection Method:** Randox Biochip Technology (end-point PCR)
**Time to Result:** TBC

| 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) |

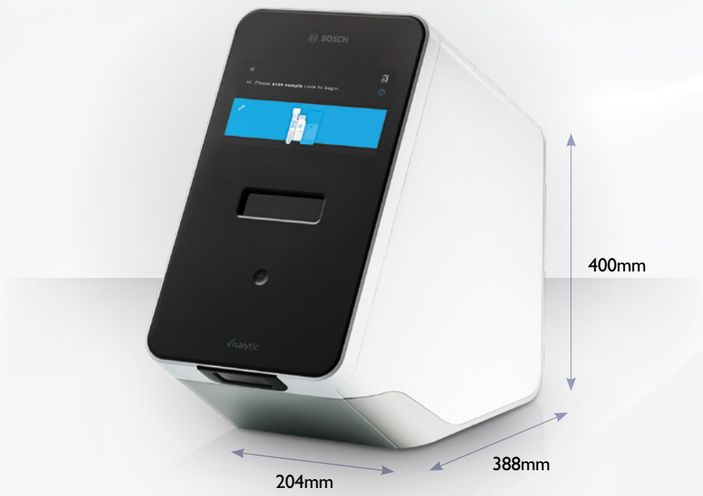
reddot design award

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

# 03

Vivalytic
Specifications

# Vivalytic Specifications




| TECHNICAL DATA | |
|---|---|
| Model | Vivalytic One |
| Display | 7 inch 16:10,<br>1024 x 600 pixel touchscreen |
| Dimensions | 400mm x 204mm x 388mm |
| Weight | 15kg |
| Storage Humidity | 20-95% (not condensing) |
| Operating Humidity | 20-80% (not condensing) |
| Electrical Data | 100-240 V~, 50/60Hz, 160 VA |
| Instrumental Safety | IEC/EN 61010-1<br>IEC/EN 61010-2-010<br>IEC/EN 61010-2-101<br>Directive 98/79/EC |
| Memory Capacity | 16 GB |
| Mean Loudness | ≤ 55 dB(A) in operating mode.<br>Short term loudness can exceed<br>mean loudness. |
| Operating Air Pressure Range | 850 – 1,100 hPa, corresponds<br>to 0 – 1,400 m above sea level |
| Operating Temperature | 15 – 30 °C |
| Storage Temperature | -20 – 60 °C |
| Data Transfer | Ethernet 10/100MB,<br>WLAN 2.4 GHz (802.11b/g/n);<br>internal: Bluetooth v4.1, 2.4 GHz<br>(low energy), USB 2.0 |
| Electromagnetic Compatibility | IEC/EN 61326-2-6<br>RED 2014/53/EC<br>FCC47 CFR 15 |



# 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**

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

# 04

Vivalytic
Ordering Information

# Ordering Information

| PRODUCT | QUANTITY | CATALOGUE NUMBER |
|---|---|---|
| **Analyser** | | |
| Vivalytic System | x1 | F09G300115 |
| Vivalytic Up Starter Set | x1 | F09G300269 |
| Vivalytic Up Extension Set | x1 | F09G300270 |
| | | |
| **Test Cartridges** | | |
| Viral Respiratory Tract Infections (VRI) | 1 Kit (15 Cartridges) | F09G300382 |
| SARS-CoV-2 (COVID-19) | 1 Kit (15 Cartridges) | F09G300411 |
| SARS-CoV-2 (COVID-19 Pooling Test) | 1 Kit (15 Cartridges) | F09G300587 |
| CoV (COVID-19 2-plex) | 1 Kit (15 Cartridges) | F09G300599 |
| Sexually Transmitted Infections (STI) | 1 Kit (15 Cartridges) | F09G300078 |
| | | |
| **Test Cartridges In Development** | | |
| Flu A/Flu B/RSV | 1 Kit (15 Cartridges) | *In Development |
| Chronic Lung Infection Array (CLI) | 1 Kit (15 Cartridges) | *In Development |
| Respiratory Tract Infections (RTI) | 1 Kit (15 Cartridges) | *In Development |
| Urinary Tract Infections (UTI) | 1 Kit (15 Cartridges) | *In Development |
| MRSA | 1 Kit (15 Cartridges) | *In Development |

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

**Email.** marketing@randox.com

**Tel.** +44 (0) 28 9442 2413

RANDOX

www.randox.com

BOSCH vivalytic



LT735OCT20