RANDOX

VIVALYTIC

THE ALL IN ONE MOLECULAR SOLUTION



BOSCH Vivalytic

MAKING A POINT TO CARE

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C. auris
RANDOX



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 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 Vivalytic test cartridges and Vivalytic 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 distributes the Vivalytic test cartridges and the Vivalytic analyser.

Vivalytic enables sample to result, cartridge-based Molecular Diagnostic testing. The Vivalytic system is capable of both High-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
- Unique Test Menu
- Fully Automated
- Fast Test Results
- High-Plex & Low-Plex Capabilities
- Wireless Connectivity


BOSCH
Scan sample ID
Sample
Test
Vivalytic

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. High-Plex and Low-Plex tests can be analysed on the Vivalytic system. High-Plex tests utilise Randox patented Biochip Array Technology, enabling end-point qualitative PCR and providing multiple test results simultaneously from one patient sample. Low-Plex tests are based on a variety of detection methods including real-time qualitative PCR.



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

*Actual Size

- All Reagents On-Board
- Room Temperature Storage
- Multiplex Technology
- Multiple Sample Types
- Minimal Contamination Risk

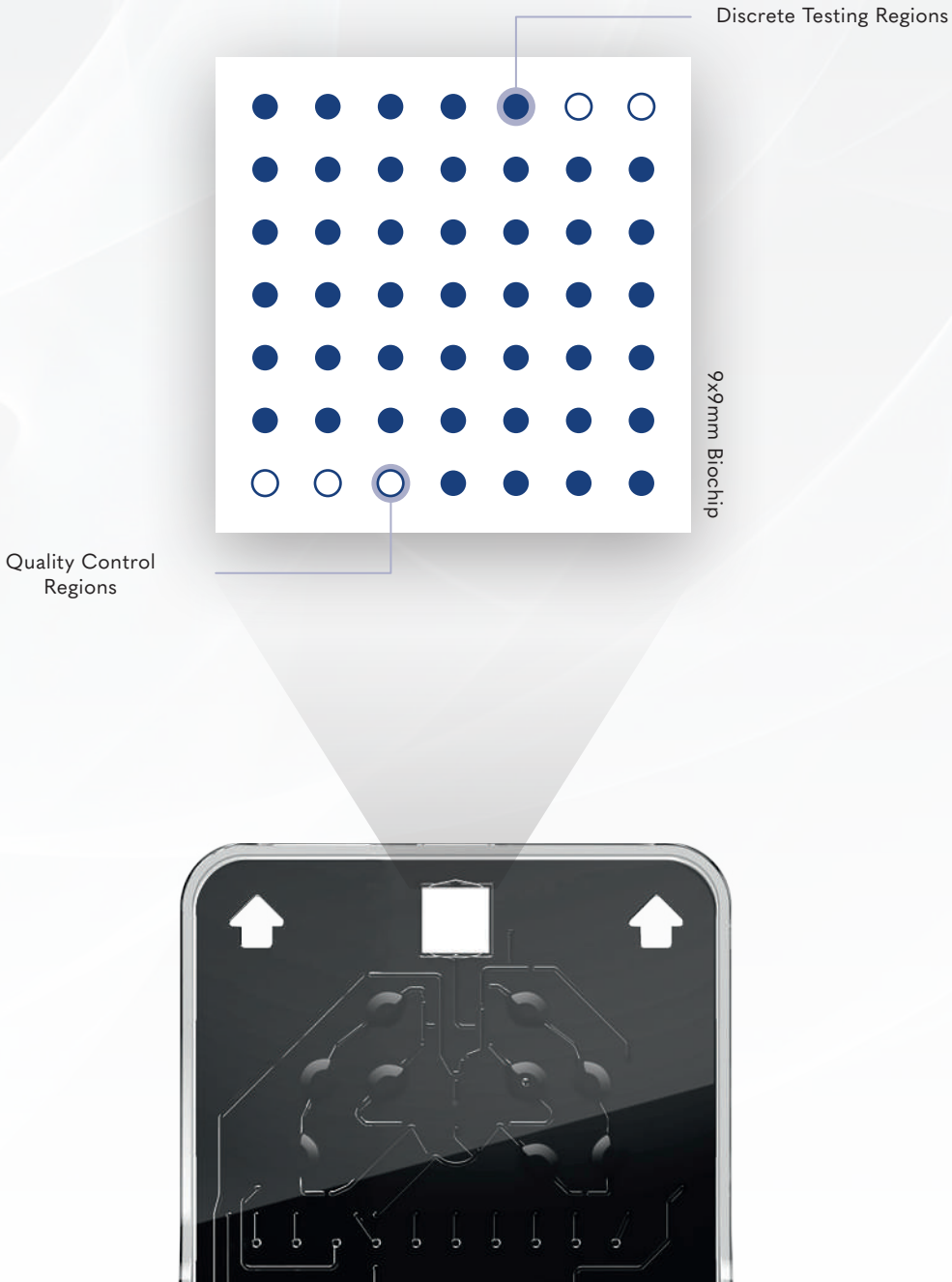
High-Plex Vivalytic Cartridges

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 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 oligonucleotide probes specific to a pathogen or target of interest. The High-Plex capabilities of Biochip Technology eliminates the need to run multiple time consuming and sample intensive assays.

Light emitted from the chemiluminescent reaction that takes place in each DTR is simultaneously detected on the Vivalytic device. 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 and the user then adds sample into the dedicated cartridge slot, closes the cover 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.

AWARD-WINNING DESIGN DELIVERS AN UNCOMPLICATED USER EXPERIENCE















02

Vivalytic Test Menu

Respiratory

SARS-CoV-2 Dual Target

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 (eNAT) or Lolly-Saliva Swab
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Time to Result: 53 minutes

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

SARS-CoV-2-DT, 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-DT, Flu A/B, and RSV is a qualitative test for 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 (eNAT) or Lolly-Saliva Swab
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Time to Result: 53 minutes

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

Vivalytic *Bordetella*

Bordetella pertussis is a gram-negative bacterium that causes an acute respiratory infection called pertussis or whooping cough. Another cause of whooping cough or mild like symptoms can be caused by *Bordetella holmesii* and *Bordetella parapertussis*.

Transmission of *Bordetella* infection is via droplet infection. Various methods are available for laboratory diagnosis- real-time PCR, culture, and serology.

Real-time PCR allows a rapid, sensitive, and specific detections up to 4 weeks after symptoms occur.

Sample Type: Nasopharyngeal swab sample (eNAT)
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: 47 minutes

DETECTABLE PATHOGENS		
B. pertussis	*B. parapertussis*	*B. holmesii*

Vivalytic MPXV*

The Vivalytic MPXV test is a rapid, user-friendly tool to support the global response against MPOX. This zoonotic virus, part of the Orthopoxvirus genus, spreads through animal bites, bodily fluids, and human contact via lesions, respiratory droplets, or contaminated objects. Sexual contact is a key transmission method during outbreaks.

The Vivalytic MPXV Panel detects Monkeypox and non-variola orthopoxviruses, delivering fast and accurate results in just 45 minutes, aiding in outbreak control and prevention.

Sample Type: Swab (eNAT)
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: 45 minutes

DETECTABLE PATHOGENS	
Monkeypox Virus *(Clade I, Clade II)*	Non-variola Orthopoxvirus species (Cowpox Virus, Ectromelia Virus, Monkeypox Virus, Taterapox Virus, Vaccinia Virus)

*Research Use Only

Hospital Acquired Infections

MRSA/SA

MRSA/SA is a qualitative test detecting and differentiating between methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-sensitive Staphylococcus aureus (MSSA). 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: Nasal or Oropharyngeal eSwab(R), Liquid Amies
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

Vivalytic *Candida auris*

Candida auris is an emerging and often multidrug-resistant fungal species that poses a significant threat to public health. This yeast-like fungus can cause severe infections, primarily affecting individuals with compromised immune systems, those in healthcare facilities, or those with underlying medical conditions. *Candida auris* is particularly concerning due to its ability to persist on surfaces, leading to healthcare-associated outbreaks. Diagnosis can be challenging as it is often misidentified with other *Candida* species. Effective management involves prompt identification, strict infection control measures, followed by treatment.

The Vivalytic *Candida auris* test is an automated, qualitative in vitro diagnostic employing real-time PCR to detect *Candida auris* DNA from swabs taken from the human axilla, groin, nasal, and rectal areas. This test serves to screen individuals at risk for colonisation, playing a crucial role in the prevention and control of *Candida auris* outbreaks and infections within healthcare settings.

Sample Type: Nasal Swabs, Bilaterial Axilla, Groin and Nasal Combination Swabs (eSwab(R), Liquid Amies)
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: Less than 1 hour

DETECTABLE PATHOGENS
Candida auris

Vivalytic *C. difficile*

Clostridioides difficile is an anaebrobic bacterium, widely distributed in soil and the intestinal tracts of animals. The clinical spectrum of *C. difficile* infection (CDI) ranges from mild diarrhoea to severe life-threatening pseudomembranous colitis.

Transmission mostly takes place in healthcare institutions such as hospitals, patient to patient, contaminated hands of healthcare workers or by environmental contamination.

Sample Type: Swab samples from liquid or soft human stool specimens
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: Less than 50 minutes

DETECTABLE PATHOGENS
C. difficile (toxin genes tcdA/tcdB)

Vivalytic Norovirus

Noroviruses are known as causing winter-vomiting disease or stomach-flu referring to their rapid spread in human populations especially during the winter period.

Norovirus causes most of all gastrointestinal infections and is highly contagious. Transmission mostly takes place in healthcare institutions such as hospitals, patient to patient, contaminated hands of healthcare workers or by environmental contamination.

Sample Type: Swab samples from liquid or soft human stool specimens
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: Less than 1 hour

DETECTABLE PATHOGENS
Norovirus (genogroup I/II)

Vivalytic Rota-, Norovirus & *C. diff*

Gastroenteritis is an inflammation of the stomach, small and large intestines. Most acute gastrointestinal illnesses (AGI) are caused by viruses such as Norovirus or Rotavirus but also bacterial pathogens such as *Clostridioides difficile (C. difficile)*.

C. difficile is an anaebrobic bacterium, widely distributed in soil and the intestinal tracts of animals. The clinical spectrum of *C. difficile* infection (CDI) ranges from mild diarrhoea to severe life-threatening pseudomembranous colitis.

Norovirus causes most of all gastrointestinal infections and are highly contagious. Rotaviruses are the very cause of severe diarrhoeal illness in infants and young children.

Transmission mostly takes place in healthcare institutions such as hospitals, patient to patient, contaminated hands of healthcare workers or by environmental contamination.

Sample Type: Swab samples from liquid or soft human stool specimens
Sample Volume: 300 µL
Detection Method: Real-Time PCR
Result Time: Less than 1 hour

DETECTABLE PATHOGENS		
Clostridioides difficile genes (tcdA/tcdB)	Norovirus (genogroup I/ II)	Rotavirus type A

Genitourinary

Sexually Transmitted Infections (STI)

The Sexually Transmitted Infections (STI) assay 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 (eNAT, Roche COBAS medium, or PBS*)
Sample Volume: 300 µL
Detection Method: Randox Biochip Technology (end-point PCR)
Time to Result: 2 hours 20 minutes

*Phosphate-buffered saline (PBS) is only permitted for swab specimens and is not approved for urine samples.

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)

Multiplex STI Controls Designed for Vivalytic Testing

Qnostics have introduced two multiplex solutions specifically designed to support assay verification and routine performance monitoring of STI testing on the Vivalytic platform.

Sexually Transmitted Infections Multiplex (STIVX) Evaluation Panel

Dedicated evaluation panel to help laboratories develop their molecular assay procedures for the identification of pathogens associated with sexually transmitted infections including *Trichomonas vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Chlamydia trachomatis* and *Neisseria gonorrhoeae.*

Matrix: Transport Medium
Panel Members: 5
Shelf Life: Up to 2 years

CATALOGUE CODE	PRODUCT DESCRIPTION	PACK SIZE
STIVXEP	STI Multiplex Evaluation Panel	5 x 0.2 ml

Sexually Transmitted Infections Multiplex (STIVX) Q Control

Qnostic's Sexually Transmitted Infections Multiplex Q Control is a panel containing 5 positive controls. Combining common STI pathogens: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Treponema pallidum, Herpes simplex virus, Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma urealyticum* and *Haemophilus ducreyi* in a single vial.

Matrix: Transport Medium
Panel Members: 5
Shelf Life: Up to 2 years

CATALOGUE CODE	PRODUCT DESCRIPTION	PACK SIZE
STIVXQC	STI Multiplex Q Control	5 x 0.2 ml

MG, MH, UP/UU

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 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
Detection Method: Real-Time PCR
Time to Result: 53 minutes

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

Vivalytic UTI *

Urinary tract infections are one of the most common infections to experience, affecting people worldwide. UTI's are classified as uncomplicated and complicated depending on underlying conditions.

One single native urine sample is used to screen for 16 uropathogens and 7 antibiotic resistance gene markers simultaneously

Sample Type: Native Urine
Sample Volume: 300 µL
Detection Method: Randox Biochip Technology (end-point PCR)
Result Time: 2 hours 30 minutes

DETECTABLE PATHOGENS		
GRAM-NEGATIVE BACTERIAL SPECIES	**GRAM-POSITIVE BACTERIA SPECIES**	**ANTIMICROBIAL RESISTANCE GENES**
Acinetobacter baumannii	*Enterococcus faecalis*	**TRIMETHOPRIM RESISTANCE**
Enterobacter cloacae	*Enterococcus faecium*	*dfrA1*
Escherichia coli	*Staphylococcus aureus*	*dfrA5*
Klebsiella aerogenes	*Staphylococcus epidermidis*	*dfrA17*
Klebsiella oxytoca	*Staphylococcus saprophyticus*	*dfrA12*
Klebsiella pneumoniae	*Streptococcus agalactiae*	**METHICILLIN RESISTANCE**
Morganella morganii		*mecA*
Proteus spp.		**VANCOMYCIN RESISTANCE**
Providencia stuartii		*vanA*
Pseudomonas aeruginosa		*vanB*

*Research Use Only


BOSCH
Scan sample ID
vivalytic





03

Vivalytic Specifications

Specifications



TECHNICAL DATA	
Display	7 inch 16:10, 1024 x 600 pixel touchscreen
Operating Air Pressure Range	Serial number: 00001 to 13198: 850 – 1.100 hPa, corresponds to 0 – 1.400 m above sea level; Serial number starting from 13199: 795 – 1.100 hPa, corresponds to 0 – 2.000 m 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

Vivasuite is a user-friendly digital ecosystem which allows users to reduce service costs and ensure the availability of their system. All Vivalytic analysers can be connected to Vivasuite, which is powered by the Bosch managed 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 device performance
- Monitoring of usage in remote settings



*Vivalytic analyser ready for third party plugins via HL7-Interface


1000



04

Vivalytic
Ordering Information

Ordering Information

PRODUCT	QUANTITY	CATALOGUE NUMBER
Analyser		
Vivalytic One	x1	F09G300115
Test Cartridges		
Vivalytic STI	1 Kit (15 Cartridges)	F09G300078
Vivalytic MG, MH, UP/UU	1 Kit (15 Cartridges)	F09G300705
Vivalytic SARS-CoV-2-DT, Flu A/B & RSV	1 Kit (15 Cartridges)	F09G300747
Vivalytic MPXV *	1 Kit (15 Cartridges)	F09G300868
Vivalytic SARS-CoV-2 DT	1 Kit (15 Cartridges)	F09G300711
Vivalytic MRSA/SA	1 Kit (15 Cartridges)	F09G300622
Vivalytic UTI *	1 Kit (15 Cartridges)	F09G300385
Vivalytic Bordetella	1 Kit (15 Cartridges)	F09G300976
Vivalytic C. auris	1 Kit (15 Cartridges)	F09G301032
Vivalytic C. difficile	1 Kit (15 Cartridges)	F09G300885
Vivalytic Norovirus	1 Kit (15 Cartridges)	F09G300879
Vivalytic Rota-, Norovirus, C. diff	1 Kit (15 Cartridges)	F09G300891

*** Available in Research Use Only**

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

reddot design award






BOSCH
Scan cartridge (2/4)
Sample
3553-FF95-AB1B-9412345-128429
Test
BOSCH
C. auris
RANDOX

RANDOX

www.randox.com

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