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Technical Datasheet

✓ivalytic from Bosch –
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Universal, intuitive, fast.

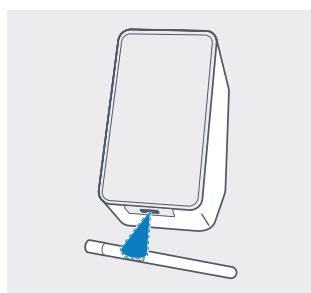


Technical Datasheet

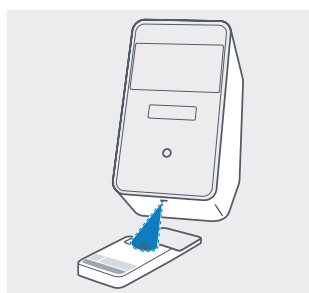
	Description	Value
	Display	7 inch 16:10, 1024 x 600 pixel touchscreen
	Operating air pressure range	850-1,100 hPa, corresponds to pressure range 0-1, 400 m above sea level
	Operating temperature	15-30 °C
	Storage temperature	-20-60 °C
	Data transfer	Ethernet 10/100 MB, WLAN 2.4 GHz (802.11b/g/n); internal: 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

	Description	Value
	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

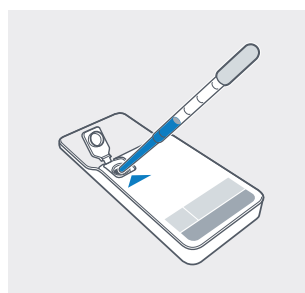
Vivalytic Workflow: Good results can be this easy.



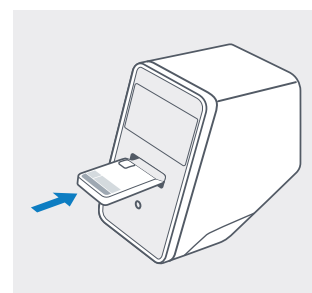
① Scan sample code.



② Scan cartridge code.



③ Insert the sample and close cartridge lid.



④ Insert cartridge. The test starts automatically.

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PCR Test for SARS-CoV-2 DT, Flu A/B and Respiratory Syncytial Virus (RSV)

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✓ivalytic

PCR Test for SARS-CoV-2 DT, Flu A/B and Respiratory Syncytial Virus (RSV)

The high burden caused each year by Covid-19, influenza and RSV infections shows how important it is to identify the different viruses quickly in order to provide the patient with targeted treatment.

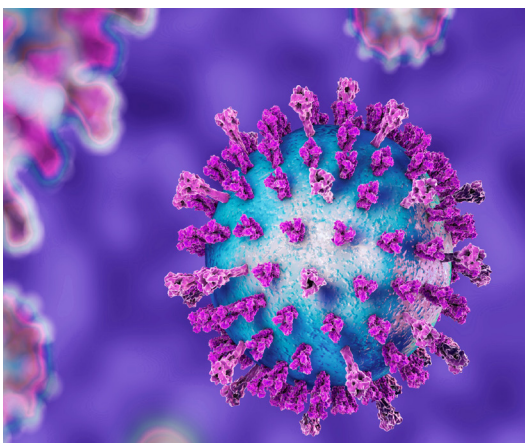
Patients infected with SARS-CoV-2, influenza A (Flu A), influenza B (Flu B) and/or respiratory syncytial virus (RSV) have overlapping symptoms, but the approaches to patient management of infections caused by the viruses are different. The Vivalytic SARS-CoV-2 DT, Flu A/B, RSV test detects and differentiates between these viral nucleic acids, aiding in the diagnosis and thereby enabling pathogen-specific management of patients.

The SARS coronavirus 2 (SARS-CoV-2) is a respiratory pathogen which is responsible for the novel disease COVID-19. With over 10 million cases and 500,000 deaths reported as of end of June 2020, COVID-19 is challenging health care systems and society all over the world. It is important not only to have effective infection-preventing measures in place, but also to trace

and break the chains of infection through extensive testing.

Influenza, also called flu, is a contagious respiratory disease caused by influenza viruses. An influenza infection causes mild to severe illness and can be lethal. In Europe, seasonal influenza causes between 4 and 50 million symptomatic cases each year and the death toll associated with influenza is estimated to be between 15,000 and 70,000 every influenza season, in terms of excess deaths.¹

The respiratory syncytial virus (RSV) is a pathogen for acute diseases of the upper and lower respiratory tract. Especially infants and young children are at risk of developing a severe RSV infection resulting in hospitalization. Since clinical symptoms of RSV are nonspecific and can overlap with other viral respiratory infections such as influenza and SARS-CoV-2, differentiation of pathogens with other viral respiratory infections is needed.



Sample material

Nasal, nasopharyngeal, oropharyngeal, saliva swab samples

Volume

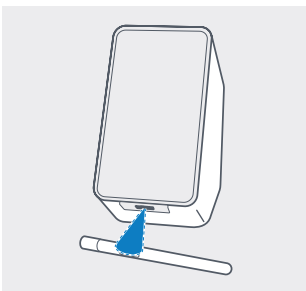
300 µl

Detection method

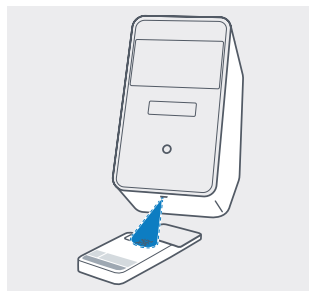
Real-time PCR test

Detectable pathogens

- SARS-CoV-2 virus (dual target detection: E-gene, N-gene)
- Influenza A and Influenza B virus
- Human Respiratory Syncytial Virus (RSV)



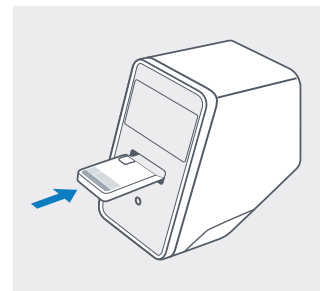
① Scan sample code.



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¹ European Centre for Disease Prevention and Control (ECDC)

The availability of the tests can differ regionally.

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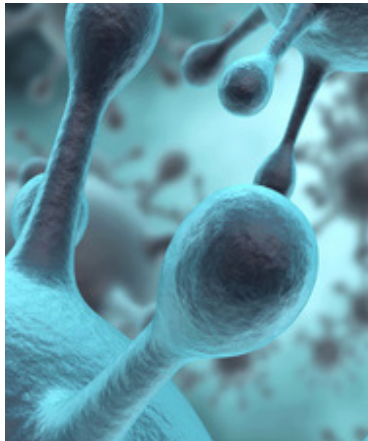
Multiplex Array for Sexually Transmitted Infections

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Multiplex Array for Sexually Transmitted Infections (STI)

Sexually transmitted infections (STIs) present a major public health concern worldwide. However, many STIs are asymptomatic and some display similar or overlapping symptoms, thus co-infections may remain undiagnosed. Use the Vivalytic STI test to diagnose co-infections.



Sample material

Urine, urogenital swabs

Principle

Sample preparation, DNA amplification and detection (μ Array) on a single cartridge.

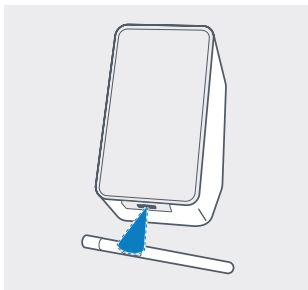
Purpose

Identification of 10 viral, protozoan and bacterial pathogens associated with STIs.

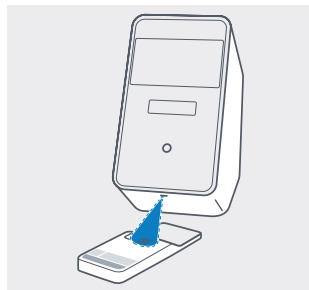
Detectable pathogens

- Herpes simplex virus I
- Herpes simplex virus II
- *Chlamydia trachomatis*
- *Haemophilus ducreyi*
- *Mycoplasma genitalium*
- *Trichomonas vaginalis*
- *Mycoplasma hominis*
- *Neisseria gonorrhoeae*
- *Treponema pallidum*
- *Ureaplasma urealyticum*

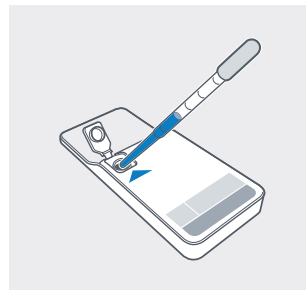
Vivalytic Workflow: Good results can be this easy.



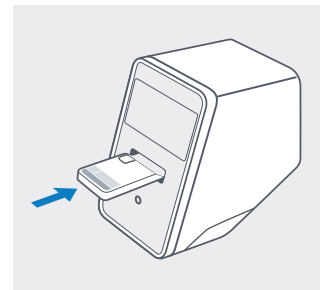
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Vivalytic MG, MH, UP/UU

**Qualitative real-time PCR Test for the Detection of *M. genitalium*,
M. hominis, *U. parvum*/*U. urealyticum* at the Point of Care**

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√ivalytic

Vivalytic MG, MH, UP/UU

Qualitative real-time PCR Test for the Detection of *M. genitalium*, *M. hominis*, *U. parvum*/*U. urealyticum* at the Point of Care

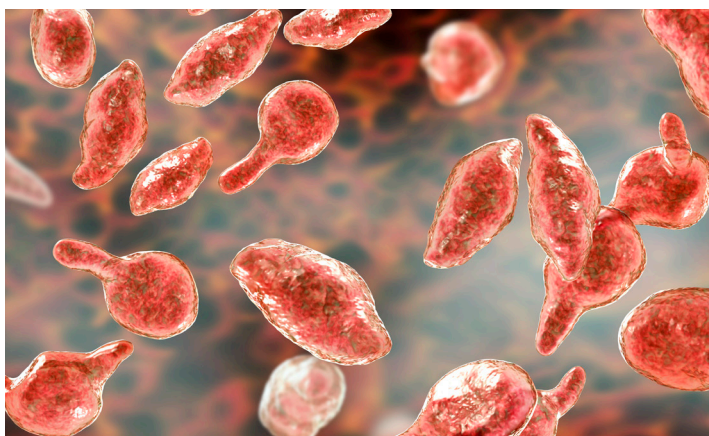
According to the World Health Organization (WHO), over 30 different bacterial species, viruses and parasites have been identified to be involved in the spread of sexually transmitted infections (STIs), with more than one million STIs acquired worldwide every day¹.

M. genitalium, *M. hominis*, *U. parvum*, and *U. urealyticum* belong to the group of human pathogenic bacterial species associated with STIs even though particularly *Ureaplasma* spp. are primarily considered as commensal organisms². All four bacterial species can be detected simultaneously with Vivalytic MG, MH, UP/UU, the new member of the Bosch Healthcare Solutions Vivalytic product portfolio. Since a test result of Vivalytic MG, MH, UP/UU is available

after one hour at the Point of Care no further transport of specimen to a specialized laboratory is necessary. The immediate result is beneficial both for the patient and for the containment of STIs.

Vivalytic MG,MH, UP/UU – Point of Care for STIs

- Time to result in one hour
- Only a few steps from sample to result
- No transport of specimen necessary
- No further laboratory equipment needed
- Simultaneous identification of *Mycoplasma* spp. MG, MH, and *Ureaplasma* spp. UP/UU
- Clinician is offered the possibility to receive a POC result



Sample material

Swab (urethral, vaginal, cervical, rectal), Urine

Volume

300 µl

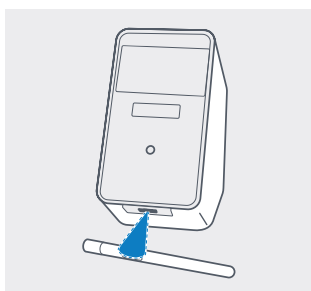
Detection method

real-time PCR

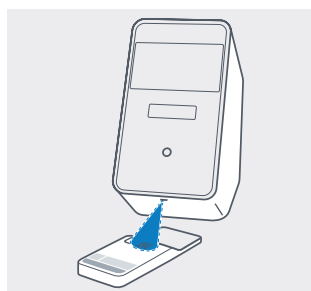
Detectable pathogens

- *Mycoplasma genitalium*
- *Mycoplasma hominis*
- *Ureaplasma parvum* and/or *Ureaplasma urealyticum*

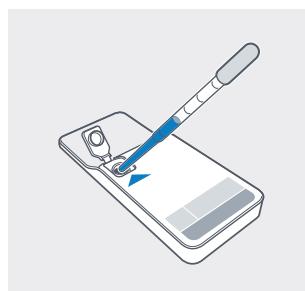
Vivalytic Workflow: Only a few steps from sample to result



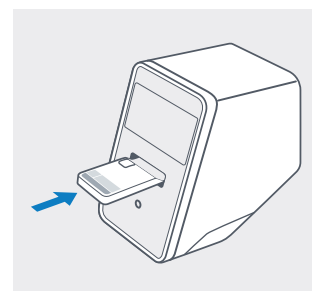
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BioGX
Molecular Made Easy
www.biogx.com

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¹WHO, Sexually transmitted infections (STIs). [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)), Date of query 15.03.2022

²Waites et al., J Mol Diagn. 2012 Sep;14(5):437-50

The Vivalytic MG, MH, UP/UU test is under development. Products with status in development are not available for sale. Future availability cannot be guaranteed.

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Vivalytic Bacterial Meningitis*

Qualitative PCR test for the detection of bacterial pathogens associated with Meningitis

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✓ **vivalytic**

Vivalytic Bacterial Meningitis*

Qualitative PCR test for the detection of bacterial pathogens associated with Meningitis

Bacterial meningitis, an infectious disease characterized by infection and inflammation of the meninges, results in significant morbidity and mortality worldwide. Even when diagnosed early and treated adequately, 8–15 % of the patients die, typically within 24 and 48 hours of symptom onset.¹

Bacterial meningitis as a disease with a high case-fatality rate requires timely and appropriate diagnosis and treatment to avoid death, and can lead to lifelong disability among survivors. A huge reduction in incidence has occurred over the past few decades, largely due to the introduction and widespread use of vaccines decreasing global meningitis deaths by 21 % from 1990 to 2016, from 403 012 to 318 400 with the highest mortality incidence rates in the peri-Saharan countries.^{2,3}

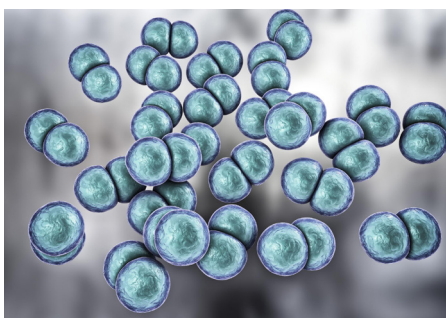
Although meningitis affects all ages, young children are at the highest risk. Newborns are at most risk from Group B

streptococcus, young children are at higher risk from meningococcus, pneumococcus and Haemophilus influenzae. Young adults and adolescents are at particular risk of meningococcal disease whereas the elderly are at particular risk of pneumococcal disease.⁴

Bacterial meningitis poses a medical emergency and appropriate antibiotic treatment should be started immediately. Point of care PCR tests detecting several species at once using cerebrospinal fluid (CSF) are considered promising in accelerating diagnosis.⁵

Vivalytic Bacterial Meningitis - Point of Care where it matters most

- One single test for six bacterial pathogens causing meningitis
- Only a few steps from sample to result
- No further laboratory equipment needed



Sample material
CSF

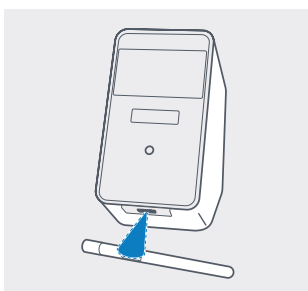
Volume
200 µl

Detection method
Qualitative real-time PCR

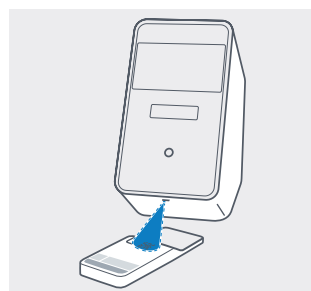
Detectable pathogens

- *Escherichia coli* K1
- *Haemophilus influenzae*
- *Listeria monocytogenes*
- *Neisseria meningitidis*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*

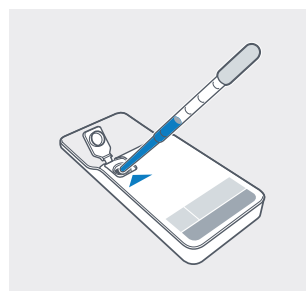
Vivalytic workflow: Only a few steps from sample to result



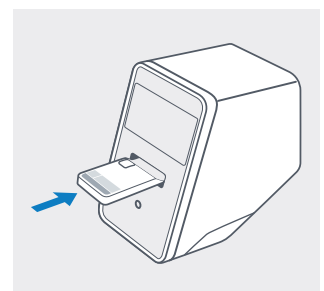
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Our biocontent cooperation partner is:

BioGX
Molecular Made Easy

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¹ Oordt-Speets et al.; PLoS One. 2018 Jun 11;13(6):e0198772.

² GBD 2016 Meningitis Collaborators; Lancet Neurol 2018; 17: 1061–82.

³ McGill et al.; Lancet 2016; 388: 3036–47.

⁴ <https://www.who.int/news-room/fact-sheets/detail/meningitis>

⁵ van de Beek D et al.; Lancet 2021; 398: 1171–83.

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BOSCH

Vivalytic Bordetella*

**Qualitative real-time PCR test for the detection of *B. pertussis*,
B. parapertussis, *B. holmesii***

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vivalytic

Vivalytic Bordetella*

Qualitative real-time PCR test for the detection of *B. pertussis*, *B. parapertussis*, *B. holmesii*

Bordetella pertussis is a gram-negative bacterium that causes an acute respiratory infection called pertussis or whooping cough. In addition, *Bordetella holmesii*, *Bordetella parapertussis*, and *Bordetella bronchiseptica* might also be a cause of whooping cough-like illness with a milder process. Pertussis can cause severe symptoms in people of any age group, which can be life-threatening, especially in infants.¹

It is estimated that approximately 3-35% of *Bordetella* infections are caused by *B. parapertussis*.^{2,3}

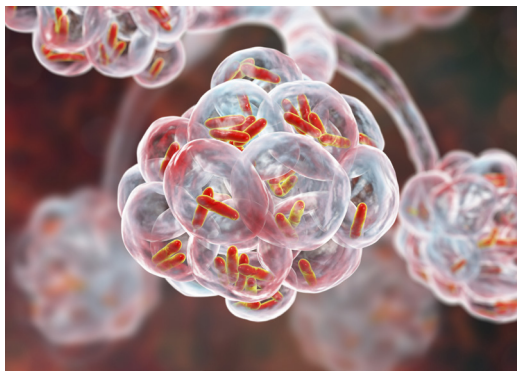
Transmission of *Bordetella* infection is aerogenic via droplet infection.⁴ Various methods are available for laboratory diagnosis of pertussis disease, such as real-time PCR, culture, and serology.

The isolation requires special culture media and takes several days.

The Real-time PCR allows a rapid, sensitive, and specific detection up to 4 weeks after symptom onset. In addition, real-time PCR can be used to differentiate the human pathogenic *Bordetella* species.^{5,6}

Vivalytic Bordetella - Fast laboratory testing for outbreak containment

- Only a few steps from sample to result
- No further laboratory equipment needed
- Reduced risk of infection for the user



Sample medium
eNAT®

Sample material
Nasopharyngeal swab sample
or aspirates

Volume
300 µl

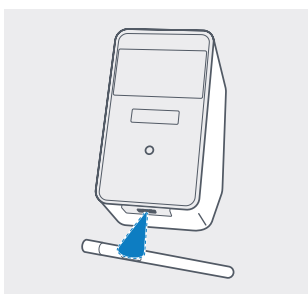
Detectable pathogens

- *B. pertussis*
- *B. parapertussis*
- *B. holmesii*

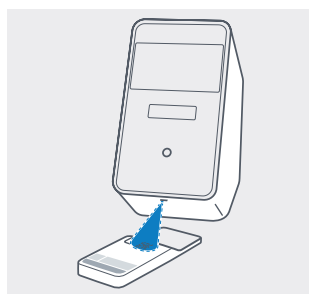
Detection method

Qualitative real-time PCR

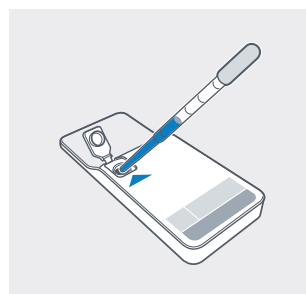
Vivalytic workflow: Only a few steps from sample to result



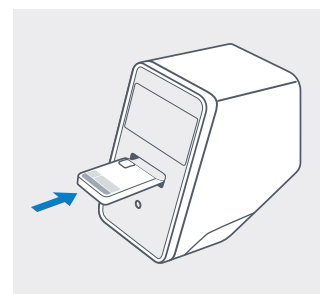
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Our biocontent cooperation partner is:



1 World Health Organization 2011. pertussis. <http://www.who.int/immunization/topics/pertussis/en/index.html>. Accessed on 21.05.2013.
2 Linneman CC und Perry EB. *Bordetella parapertussis*. Recent experience and a review of the literature. Am J Dis Child. 1977, 131 (5): 560-563.
3 Mertsola, J. Mixed outbreak of *Bordetella pertussis* and *Bordetella parapertussis* infection in Finland. Eur J Clin Microbiol. 1985, 4(2): 123-128.

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4 Robert Koch Institute 2013. pertussis (whooping cough). https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Pertussis.html.
5 Centers for Disease Control and Prevention 2012. Pertussis. Epidemiology and Prevention of Vaccine-Preventable Diseases. The Pink Book: Course Textbook -12th Edition Second Printing (May 2012). Accessed on 21.05.2013.
6 Riffelmann M et al. Nucleic Acid amplification tests for diagnosis of *Bordetella* infections. J Clin Microbiol. 2005, 43(10): 4925-4929.
infections. J Clin Microbiol. 2005, 43(10): 4925-4929.

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Vivalytic *C. difficile**

**Qualitative real-time PCR test for the detection of
Clostridioides difficile (*C. difficile*)**

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Vivalytic *C. difficile**

Qualitative real-time PCR test for the detection of *Clostridioides difficile* (*C. difficile*)

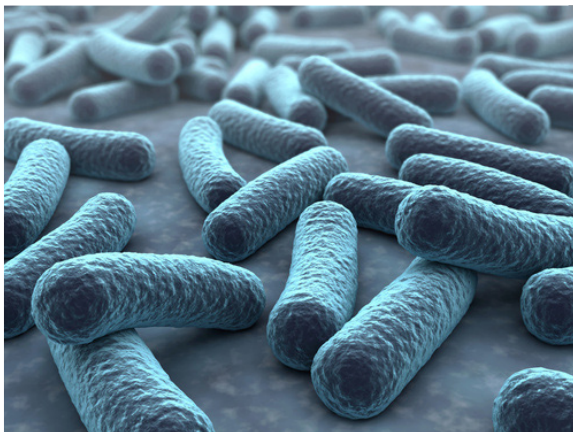
Acute gastrointestinal illness (AGI) has a huge public health impact in terms of disease incidence, prevention issues, and healthcare costs. Gastrointestinal illness (gastroenteritis) is an inflammation of the stomach and small and large intestines. The majority of AGI is caused by infectious agents, mostly by viruses such as Norovirus or Rotavirus but also bacterial pathogens such as *Clostridioides difficile* (*C. difficile*) play an important role, especially in healthcare institutions such as hospitals or nursing homes, or after antibiotic treatment.

C. difficile is an anaerobic 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.¹

Transmission happens frequently in healthcare institutions such as hospitals, via patient-to-patient, contaminated hands of healthcare workers, or by environmental contamination. *C. difficile* is the 8th most frequently detected microorganism among healthcare-associated infections.²

Vivalytic *C. difficile* - Fast laboratory testing for outbreak containment

- Only a few steps from sample to result
- No further laboratory equipment needed
- Reduced risk of infection for the user



Sample medium
eNAT®

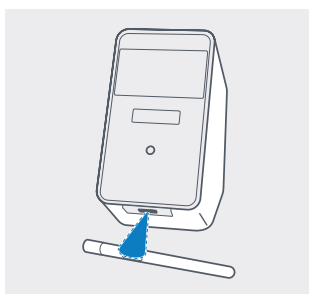
Sample material
Swab samples from liquid or soft human stool specimens

Volume
300 µL

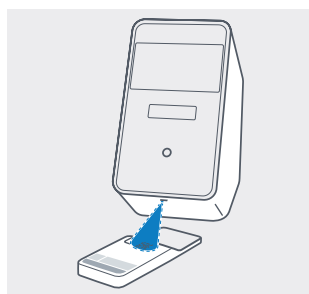
Detectable pathogen
C. difficile
(toxin genes tcdA/tcdB)

Detection method
Qualitative real-time PCR

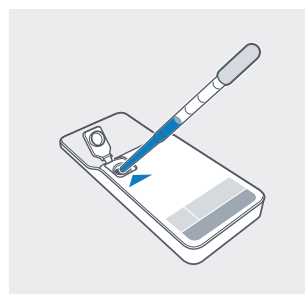
Vivalytic workflow: Only a few steps from sample to result



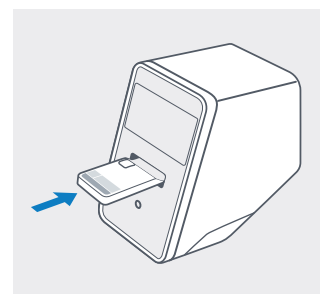
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^{1,2} <https://www.ecdc.europa.eu/en/clostridium-difficile-infections/facts>

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Vivalytic Rota-, Norovirus, *C. diff**

Qualitative real-time PCR test for the detection of Rota-, Norovirus, *C. difficile* (*Clostridioides difficile*)

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Vivalytic Rota-, Norovirus, *C. diff**

Qualitative real-time PCR test for the detection of Rota-, Norovirus, *C. difficile*

Acute gastrointestinal illness (AGI) has a huge public health impact in terms of disease incidence, prevention issues, and healthcare costs. Gastrointestinal illness (gastroenteritis) is an inflammation of the stomach, as well as the small and large intestines. The majority of AGI is caused by infectious agents, mostly by viruses such as Norovirus or Rotavirus but also bacterial pathogens such as *Clostridioides difficile* (*C. difficile*) play an important role, especially in healthcare institutions such as hospitals or nursing homes, or after antibiotic treatment.

C. difficile is an anaerobic 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 happens frequently in healthcare institutions such as hospitals, via patient-to-patient, contaminated hands of healthcare workers, or by environmental contamination.¹

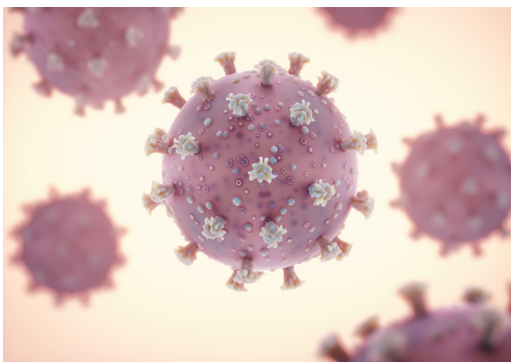
Norovirus causes the majority of all gastrointestinal infections. They are highly contagious and therefore pose a serious issue for healthcare institutions with frail patients such as nursing homes.²

Rotaviruses are the single most important cause of severe diarrhoeal illness in infants and young children worldwide. While infected, many children will be in need of medical attention due to extensive fluid loss.

Besides children, elderly people (60+) are also a risk group.³

Vivalytic Rota-, Norovirus, *C. diff* Fast laboratory testing for outbreak containment

- Only a few steps from sample to result
- No further laboratory equipment needed
- Reduced risk of infection for the user



Sample medium
eNAT®

Sample material
Swab samples from liquid or soft human stool specimens

Volume
300 µL

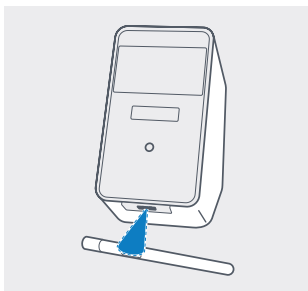
Detectable pathogens

- *Clostridioides difficile* genes (tcdA/tcdB)
- Norovirus (genogroup I/ II)
- Rotavirus type A

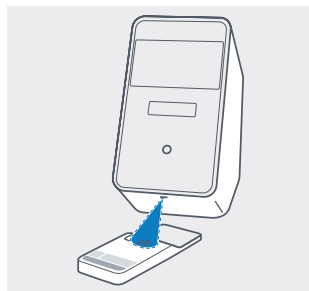
Detection method

Qualitative real-time PCR

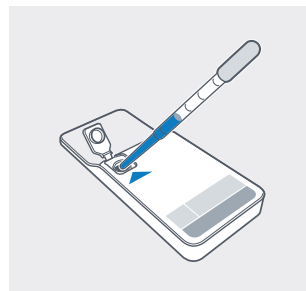
Vivalytic workflow: Only a few steps from sample to result



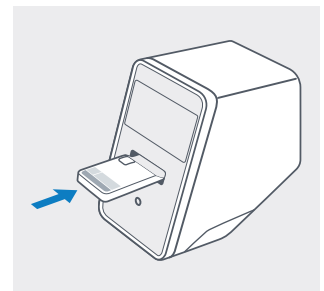
① Scan sample code.



② Scan cartridge code.



③ Insert the sample and close cartridge lid.



④ Insert cartridge.
The test starts automatically.

Our biocontent cooperation partner is:



*Currently under development. Not available for sale.

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Bosch Healthcare Solutions GmbH
Stuttgarter Str. 130, 71332 Waiblingen, Germany

¹ <https://www.ecdc.europa.eu/en/clostridium-difficile-infections/facts>

² <https://www.ecdc.europa.eu/en/norovirus-infection/facts>

³ <https://www.ecdc.europa.eu/en/rotavirus-infection/facts>

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Vivalytic Norovirus*

Qualitative real-time PCR test for the detection of Norovirus

✓ Vivalytic from Bosch –
The universal diagnostic platform.
Universal, intuitive, fast.



✓ **vivalytic**

Vivalytic Norovirus*

Qualitative real-time PCR test for the detection of Norovirus

Acute gastrointestinal illness (AGI) has a huge public health impact in terms of disease incidence, prevention issues, and healthcare costs. It is an inflammation of the stomach, as well as the small and large intestines. The majority of AGI is caused by infectious agents, mostly by viruses such as Norovirus or Rotavirus but also bacterial pathogens such as *Clostridioides difficile* (*C. difficile*) play an important role, especially in healthcare institutions such as hospitals or nursing homes, or after antibiotic treatment.

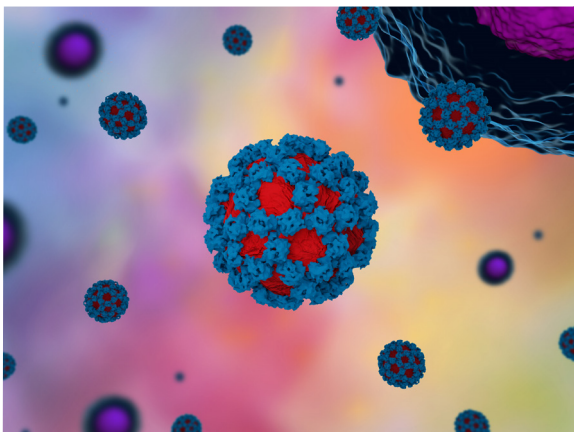
Noroviruses belong to the Caliciviridae family and they are well known as causing “winter-vomiting disease” or “stomach-flu”, referring to their rapid spread in human populations especially during winter months.

Norovirus causes the majority of all gastrointestinal infections and can cause vomiting, diarrhoea, and stomach pain.

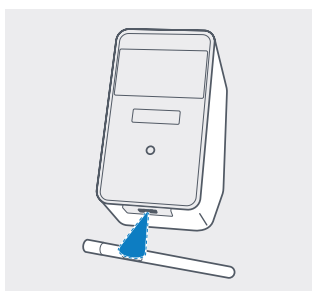
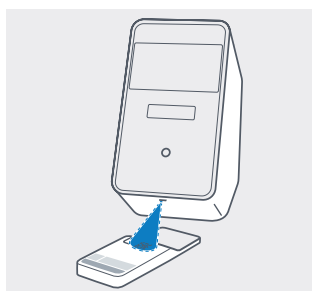
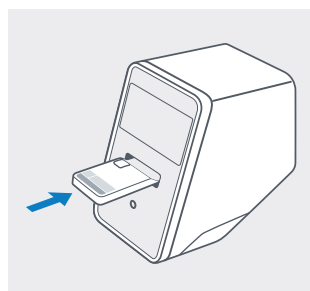
Noroviruses are highly contagious and therefore pose a serious issue for healthcare institutions with frail patients such as nursing homes.¹

Vivalytic Norovirus - Fast laboratory testing for outbreak containment

- Only a few steps from sample to result
- No further laboratory equipment needed
- Reduced risk of infection for the user

	Sample medium eNAT®	Detectable pathogen Norovirus (genogroup I/ II)
	Sample material Swab samples from liquid or soft human stool specimens	Detection method Qualitative real-time PCR
	Volume 300 µL	

Vivalytic workflow: Only a few steps from sample to result

			
1 Scan sample code.	2 Scan cartridge code.	3 Insert the sample and close cartridge lid.	4 Insert cartridge. The test starts automatically.

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¹ <https://www.ecdc.europa.eu/en/norovirus-infection/facts>

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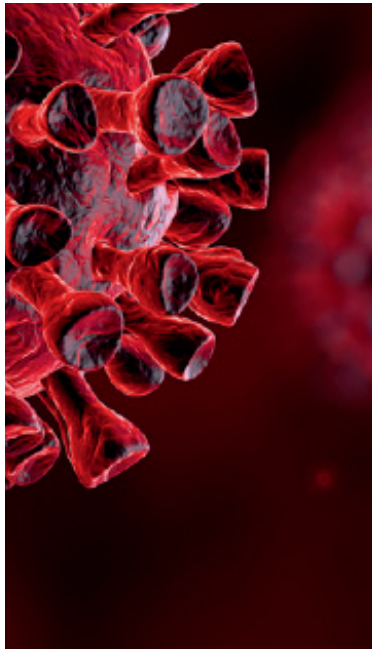
Multiplex Array for Respiratory Infections.

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The universal diagnostic platform.
Universal, intuitive, fast.



Multiplex Array for Respiratory Infections (RTI)

Respiratory pathogens cause acute local and systemic illnesses with distinct severity. Diagnostics are complicated due to the number of viruses and bacteria that can cause such infections. Use the Vivalytic RTI test for direct identification of 14 viral and 8 bacterial pathogens.



Sample material
Swabs (nasal/throat)

Principle
Integration of sample preparation, DNA amplification, detection (μ Array) and analysis on a single cartridge

Purpose
Nucleic acid based testing for direct identification of 14 viral and 8 bacterial pathogens

Detectable pathogens

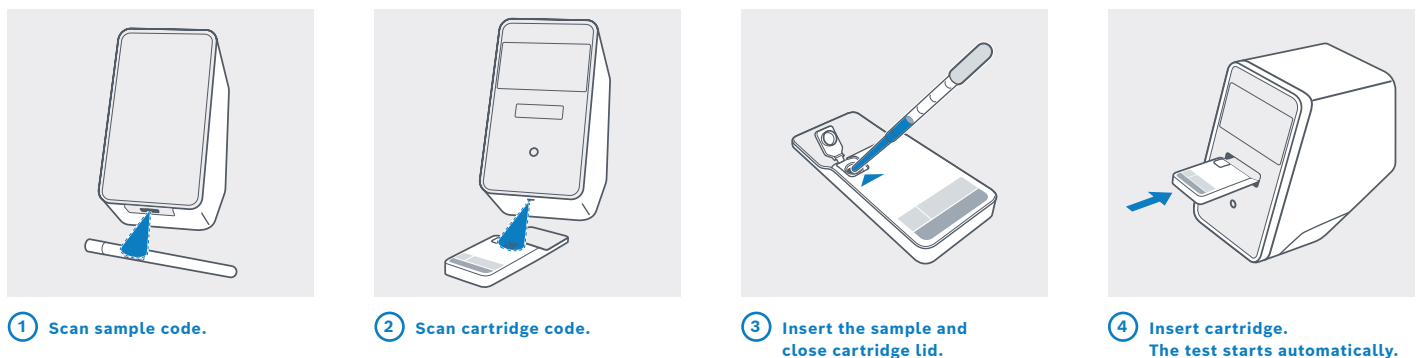
Viral pathogens

- Influenza A virus
- Influenza B virus
- Human adenovirus A/B/C/D/E
- Human bocavirus 1/2/3
- Human coronavirus 229E/NL63

Bacterial pathogens

- Human coronavirus OC43/HKU1
- Human enterovirus A/B/C
- Human metapneumovirus
- Human parainfluenzavirus 1
- Human parainfluenzavirus 2
- Human parainfluenzavirus 3
- Human parainfluenzavirus 4
- Human respiratory syncytial virus A/B
- Human rhinovirus A/B/C
- Bordetella parapertussis
- Bordetella pertussis
- Chlamydomphila pneumoniae
- Haemophilus influenzae
- Legionella pneumophila
- Moraxella catarrhalis
- Mycoplasma pneumoniae
- Streptococcus pneumoniae

Vivalytic Workflow: Good results can be this easy.



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PCR-Test for Methicillin-resistant *Staphylococcus aureus*.

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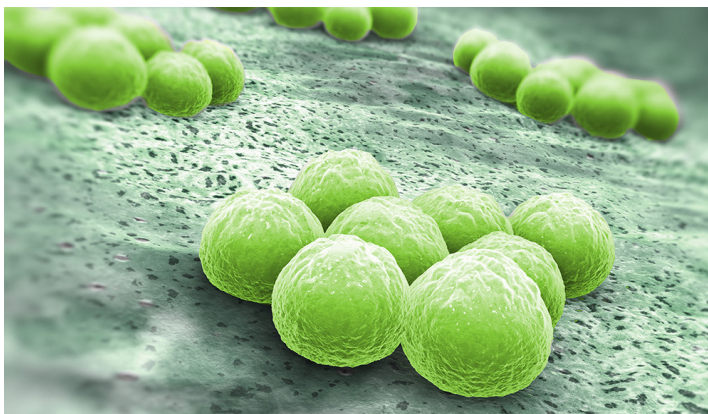
✓ivalytic

PCR-Test for Methicillin-resistant *Staphylococcus aureus* (MRSA/SA).

Methicillin-resistant *Staphylococcus aureus* – commonly known as MRSA – is a major multi-resistant, nosocomial pathogen worldwide. According to the WHO, patients infected with MRSA are about 50% more likely to die than those infected with non-resistant strains.¹ Not only mortality, also length of hospitalization, morbidity, and costs are increased significantly by untreated MRSA.² However, MRSA is not the only pathogen in the genus *Staphylococcus* to cause problems. The majority of *S. aureus* isolates, in Europe 83%³,

belong to the group of methicillin-sensitive *Staphylococcus aureus* (MSSA) bacteria. *Staphylococcus aureus* is the most common pathogen associated with surgical site infections and the second common source of healthcare-associated infections in the United States.⁴

By using one single cartridge, the Vivalytic MRSA/SA test differentiates between MRSA and MSSA in a timely manner so that appropriate antibiotic treatment can be applied.



Sample material

Nasal- or oropharyngeal swab sample

Volume

300 µl

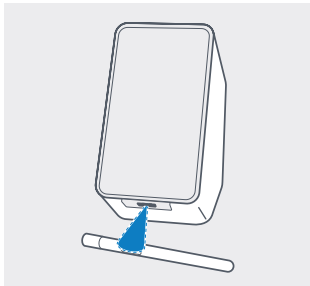
Detection method

Real-time PCR-test.

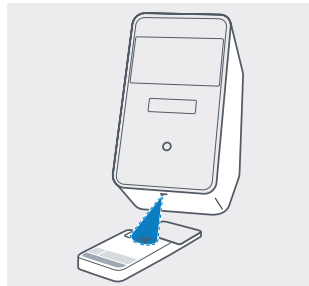
Detectable pathogens

- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Methicillin-sensitive *Staphylococcus aureus* (MSSA)

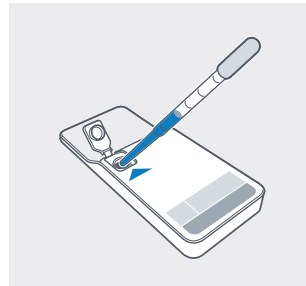
Vivalytic Workflow: Good results can be this easy.



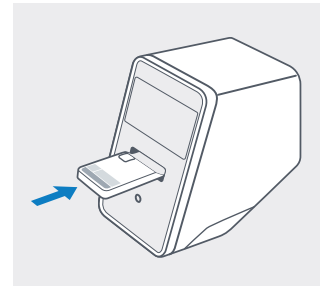
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www.r-biopharm.com

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¹WHO brochure on infection prevention 2016

²GLASS report 2014 p. 20 – 22, 37 – 40, 175 – 176

³ECDC report on AMR in 2018

⁴CDC statistics on HAI 2011-2014

The Vivalytic MRSA/SA test is under development. Products with status in development are not available for sale. Future availability cannot be guaranteed.

www.bosch-vivalytic.com

Art. No.: MDQ-01.733-01-LoC-013_v2