

**Molecular
Clinical Diagnostics
qPCR Portfolio**



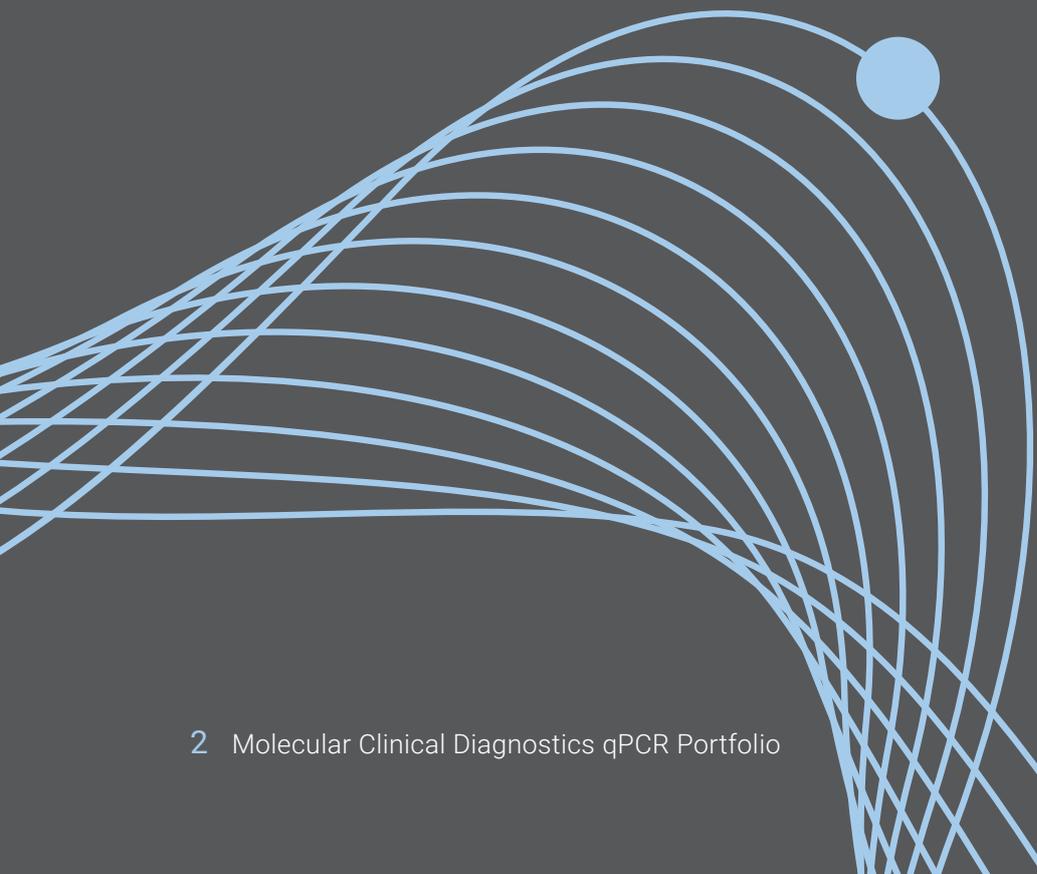
NOVACYT

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Novacyt strives to tackle high unmet needs in diagnostics with customer focused solutions. Our broad product portfolio and continual innovation enable us to remain prepared and ready to react quickly to new and changing customer needs and priorities.

As an innovator in global diagnostics we protect people and society in the fight against infectious diseases by offering tests that accurately detect infections, and this support public health. We pride ourselves on our ability to offer solutions that target high unmet needs in infectious diseases and our agility in responding to significant outbreaks around the world with diagnostic products and solutions.

Novacyt is proud to partner with Clonit srl as a preferred partner and distributor, with significant global reach. The collaboration adds Clonit's strengths in innovative research, development and manufacturing of qPCR assays for rapid and reliable diagnostics, to Novacyt's expanding qPCR assay portfolio, with the added synergy of Novacyt qPCR instrumentation experience and associated product range.



Our Product Brands:

PRIMER
DESIGN





Clonit srl: history, passion and innovation for Molecular Diagnostics.

Since 1987, Clonit has been focused in developing, manufacturing and distributing of innovative and reliable in Vitro Diagnostic Equipment and Reagents for Molecular Diagnostics.

A deep expertise in Molecular Biology mixed to our strong culture of business ethics make our company a valued partner for laboratories and hospitals around the world.

With our high standard and high performance IVDs portfolio, we aim to improve healthcare by enhancing and supporting the decision-making process, in line with scientific and technological evolution.

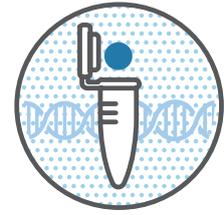
Our clinical diagnostic products are used to detect a broad range of diseases in several key areas such as viral, bacterial and fungal infections (including sexually transmitted diseases, transplantation/immunocompromised related infections, tropical diseases, healthcare associated infections), thrombophilia, oncohematology and several genetic disorders.

The company is registered and authorized by the Italian Ministry of the Health for the development, manufacturing and commercialization of Medical Diagnostic devices.

The standardization of internal quality control system and cross-checks in external reference labs, allow Clonit to ensure application of the highest standards of care and quality (ISO 9001 and ISO 13485 Certified). Moreover in May 2022 we obtained the certification of our products according to EU 2017/746 Regulation on In Vitro Diagnostic Medical Devices (IVDR). Certification for Class C products was issued by TÜV SÜD Product Service after a successful two-stage Audit.

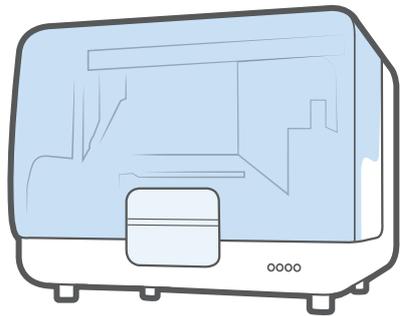
We listen carefully to our customers' needs and work closely with health care professionals to transform them into solutions that provide people a better quality of life.

Assays validated for use on multiple instruments, including Primer Design instruments



Set-up

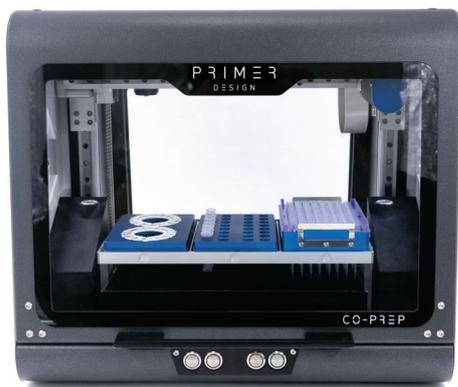
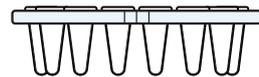
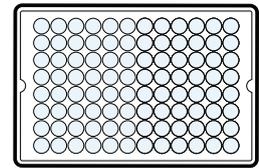
Analysis



**Pipetting/
Liquid handling**



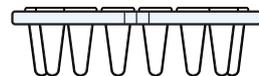
Other qPCR instruments



**Primer Design™
CO-Prep™ Automated
Liquid Handling System**

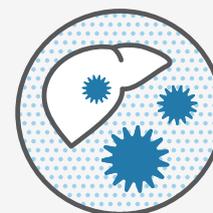


**Primer Design™
genesig™ q32 Real Time
PCR Instrument**



Not all products are CE marked or have 510(k) clearance. Availability of products in each country depends on local regulatory marketing authorization status.

Realtime PCR Hepatitis Virus



Hepatitis is an inflammation of the liver. It can be developed as a result of alcoholism or medications but is most commonly caused by viral infection. Five distinct hepatitis viruses have been identified: A, B, C, D and E. Together they affect about 400 million people worldwide. Viral hepatitis A and E are food- and water-borne infections that can result in acute outbreaks in communities with unsafe water and poor sanitation. HDV infection is linked to HBV infection.

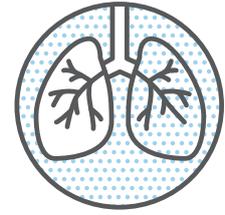
Hepatitis E is a liver disease caused by the Hepatitis E virus (HEV). HEV infection usually results in a self-limited, acute illness. Although rare in developed countries, locally acquired HEV infection can result in acute hepatitis with tendency to progress to chronic hepatitis mainly among solid organ transplant recipients. The unique characteristics of HEV is that it displays different clinical and epidemiologic

profile depending on where the infection is acquired which is mainly due to the viral genotype. There are four genotypes of HEV, each displaying different epidemiological and clinical characteristics between developing and developed countries. Hepatitis E virus is usually spread by the fecal-oral route. The most common source of HEV infection is fecally contaminated drinking water. In developing countries, HEV genotypes 1 and 2 are spread by fecally contaminated drinking water. In developed countries sporadic cases of HEV genotype 3 have occurred following consumption of uncooked/undercooked pork or deer meat.

Consumption of shellfish was a risk factor in a recently described outbreak in a cruise ship. HEV genotype 4, detected in China, Taiwan, and Japan, has also been associated with foodborne transmission.

Product Description	Code	CE Mark	Description
quanty HEV	RT-41	CE IVD	24 Tests

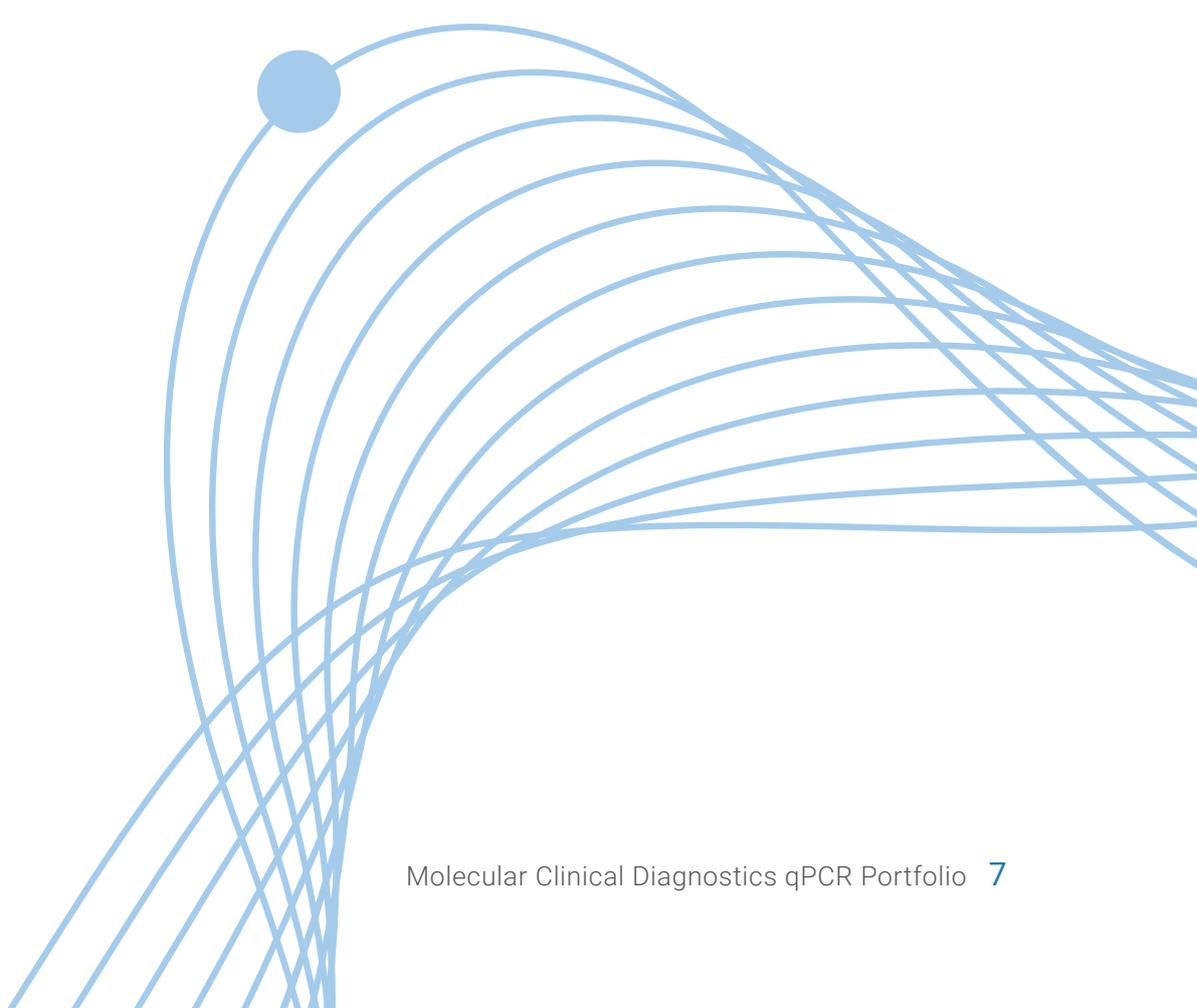
Realtime PCR Respiratory Infections



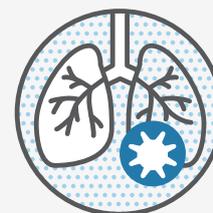
Respiratory infections are among the top ten causes of death worldwide and represent a main cause of pediatric outpatient consultations in the industrialized world. A quick and sensitive

diagnostic test is critical for immediate diagnosis and treatment of the patient and for preventing further spreading of the infections.

Product Description	Code	CE Mark	Description
M. tuberculosis Complex	EBR019032	CE IVD	32 Tests
Mycoplasma pneumoniae	EBR012032	CE IVD	32 Tests
Legionella pneumophila	EBR007032	CE IVD	32 Tests
Mycobacterium avium Complex	EBR010032	CE IVD	32 Tests



Realtime PCR Respiratory Infections: Influenza-like Illnesses (COVID, Influenza, RSV)



Patients infected (or potentially co-infected) with Influenza, COVID or RSV show similar symptoms, such as fever (in over 90% of cases), dry cough (over 80% of cases), fatigue, shortness of breath (about 20% of cases) and difficulty of breathing (about 15% of cases).

Tests made available by Novacyt include our flagship multiplex winter viruses RT-PCR assay (genesig Winterplex™ Kit), targeting Influenza A/Influenza B/RSV/COVID (ORF1ab)/COVID (S gene)/COVID (M gene).

Direct-to-PCR COVID testing assays (PROmate™ kits) and Variant of Concern kits (SNPsig™ EscapePLEX™ kits).

Novacyt took a leading position in the development and supply of COVID-19 diagnostic tests, and was the first European Medical Device manufacturer to have launched a detection test for the novel Coronavirus (2019-nCoV), eventually going on to supply supplying over 60 countries (including UK, US and China) with one of the first CE-marked tests also approved by the US Food and Drug Administration (FDA) for Emergency Use Approval.

Product Description	Code	CE Mark	Description
genesig™ SARS-CoV-2 FluA/B RSV Winterplex*	D00020	CE IVD	96 Tests
PROmate™ COVID-19 (q32) 1G*	D00070 (previously D00051)	CE IVD	96 Tests
PROmate™ COVID-19 (q16) 1G*	D00068 (previously D00050)	CE IVD	96 Tests
PROmate™ COVID-19 q32 2G*	D00074	CE IVD	96 Tests
SNPsig™ SARS-CoV-2 EscapePLEX™ CE*	D00152	CE IVD	96 Tests
genesig™ Real-Time PCR COVID-19 Assay*	Z-Path-COVID-19-CE	CE IVD	96 Tests

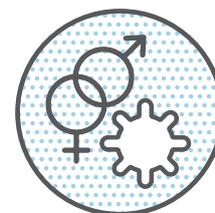
*Compatible with q series instruments

Reference:

<https://novacyt.com/wp-content/uploads/2020/02/Novacyt-CE-mark-approval-coronavirus-test-ENG.pdf>

<https://novacyt.com/wp-content/uploads/2020/03/Novacyt-Covid-19-test-update-ENGLISH-16.03.20.pdf>

Realtime PCR Sexually Transmitted Diseases



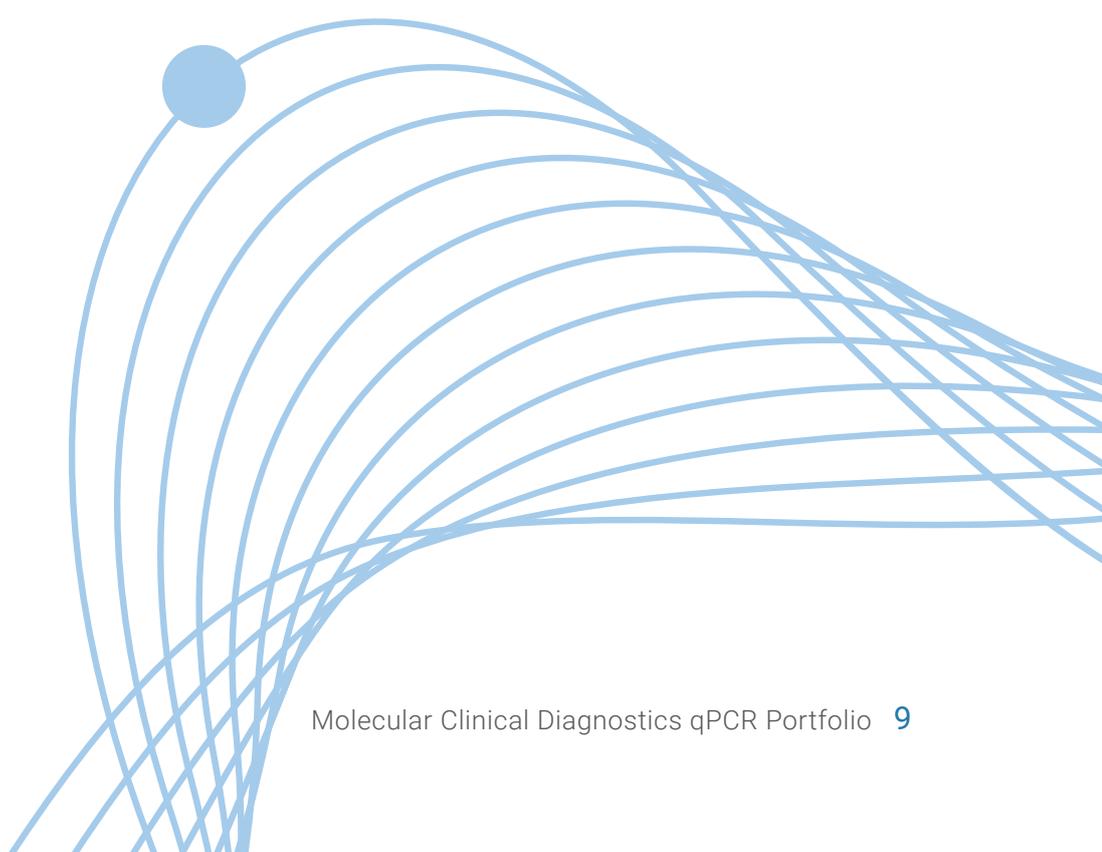
Sexually transmitted diseases (STDs) are the most widespread diseases in the world. The most frequently reported STDs are caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and Mycoplasmas.

Diagnosis of STDs is problematic as they often cause no specific symptoms. Due to its rapidity and sensitivity, molecular diagnostics is becoming a worldwide standard in this field.

Product Description	Code	CE Mark	Description
Trichomonas vaginalis*	EBR038032	CE IVD	32 Tests
Ureaplasma urealyticum	EBR016032	CE IVD	32 Tests
Neisseria gonorrhoeae*	EBR018032	CE IVD	32 Tests
Mycoplasma genitalium*	EBR027032	CE IVD	32 Tests
Multiplex CT/NG*	RT-44	CE IVD**	48 Tests
Chlamydia trachomatis*	RT-22	CE IVD**	48 Tests

*Compatible with q series instruments

**NB. 0318



Realtime PCR Nosocomial Infections



Clostridium difficile has been recognized as an increasingly important cause of nosocomial diseases. The *C. difficile* infections or CDI are the leading cause of infectious diarrhea in hospitals

worldwide. The major virulence factors of *C. difficile* are thought to be toxin A and toxin B produced by the pathogen.

Product Description	Code	CE Mark	Description
Clostridium difficile Toxin A- Toxin B*	EBR026032	CE IVD	32 Tests

*Compatible with q series instruments





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