

**ANALITICA**  
A Gold Standard Diagnostics Company

# *Product catalogue*



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## AB ANALITICA: 30 Years of Excellence in Molecular Diagnostics

For over 30 years, AB ANALITICA has been at the forefront of molecular diagnostics. Our long history has witnessed unwavering dedication to the design, development, production, and marketing of *in vitro* diagnostics, a constantly evolving field. What guides us on this journey is our commitment to our customers and our core values:

### SECURITY



### CERTIFIED QUALITY



### INNOVATION



### SUPPORT



## Design, Development and Innovation

We take pride in being one of the few Italian entities with our own Research and Development sector. Our multidisciplinary team includes experts in medical biotechnology, engineering, computer science, and pharmacogenetics. The synergy between our researchers and product specialists enables us to provide comprehensive answers and effective solutions to our customers. We consistently work closely with our clients, focusing on innovation to continuously update our portfolio with automation products and solutions that best meet user needs.

## Production Excellence

Our *in vitro* diagnostics (IVD) are manufactured at our headquarters in Padua, where extensive laboratories are dedicated to the Production and Research Departments.

The entire production cycle undergoes rigorous quality controls, ensuring the utmost reliability of our products.

AB ANALITICA is synonymous with excellence and constant commitment. Our history is characterized by progress and dedication to providing services and products of the highest quality in the field of molecular diagnostics. We are grateful for the trust of our customers and look forward to the future with enthusiasm, aware of the importance of continuing to drive innovation in this crucial sector for human health.



## Corporate Transparency: Our Commitment to Open and Honest Communication

At AB ANALITICA, transparency is the key to our innovation mission. We believe that only through open and honest communication can lasting relationships of trust be built with our partners, customers, and industry colleagues. Here's how we implement transparency in our company:

### Research and Innovation: Sharing and Collaboration

Research and Development are the heart of our business. We understand the importance of sharing meaningful results and innovations with the scientific community. We publish our studies, actively collaborate with universities and research institutions, and participate in conferences and workshops to share our discoveries and learn from others.

### Involvement of Our Researchers

Our researchers are our most valuable resource. We support open dialogue and collaboration within our team. Every voice matters, and we encourage feedback and innovative ideas for continuous progress in human diagnostics.

### Reliability and Reproducibility

Our products must be reliable and reproducible. We provide comprehensive details on product specifications so that customers can have confidence in the results of their tests.

### Social and Ethical Responsibility

The company is committed to maintaining high ethical standards in the research and development of biotechnological products. We consistently strive to adhere strictly to laws and regulations, in addition to closely monitoring and publicly disclosing our progress towards sustainability and social responsibility goals.

## Commitment to Eco-Sustainability: Our Contribution to Reducing Greenhouse Gas Emissions

Since 2018, AB ANALITICA took significant steps towards environmental excellence by investing in initiatives aimed at energy conservation and the reduction of climate-influencing gas emissions.

### HVAC (Heating, Ventilation, and Air Conditioning) Automation

We have implemented an HVAC system for air conditioning, optimizing energy use and reducing waste. The external solar shades help prevent overheating in summer.

### 49.5 kWp Photovoltaic System

We have installed a 49.5 kWp photovoltaic system, enabling the production of clean and sustainable energy directly from solar resources.

### Installation of Eco-Freon Refrigeration Cells

Our implementation of refrigeration cells utilizing Eco-Freon technology has not only enabled us to maintain our products at precisely controlled temperatures but has also played a pivotal role in minimizing our environmental footprint.

### Impressive Energy Savings

Thanks to these initiatives, we are able to declare significant savings:

- 34% savings in terms of kWh.
- Savings equivalent to 35.8 metric tons of oil equivalent (TOE).
- Savings of 35.6 kilograms of equivalent CO<sub>2</sub> (kg of CO<sub>2</sub> eq).

At AB ANALITICA, we believe it is our duty to protect our planet for future generations. These results are the outcome of our commitment to building an environmentally sustainable company, and they consistently drive us to explore new ways to enhance our environmental impact.

## Excellence and Quality in Medical Diagnostic Devices: Our Certified Commitment

At AB ANALITICA, the quality of our services and products is an absolute priority. Our dedication to excellence is affirmed by the following certifications and collaborations:

UNI CEI EN ISO 13485: *In vitro* Diagnostic Medical Devices (IVD)  
 Our certification to UNI CEI EN ISO 13485 confirms our expertise in the design, development, production, and marketing of *in vitro* diagnostic medical devices (IVD). This specific standard is crucial to ensuring the safety and performance of our devices used in diagnostic settings.

Certification in Compliance with Article 10(8) of Regulation (EU) 2017/746  
 Since 2022, our Quality Management System has been certified in accordance with Article 10(8) of Regulation (EU) 2017/746, related to *in vitro* diagnostic medical devices, certifying our company's regulatory compliance with European laws in the sector and our commitment to keeping diagnostic devices available in the market for patients.

UNI EN ISO 9001: Quality Management System  
 We are certified according to the UNI EN ISO 9001 standard, attesting to the adoption of rigorous quality management standards in all aspects of our business. This allows us to ensure effective processes, reliable services, and high-quality products.

Collaboration with TÜV SÜD, Notified Body (0123)  
 For the verification of our Quality Management System and our diagnostic devices, we rely on TÜV SÜD, an internationally renowned Notified Body with notification number 0123. This collaboration ensures adherence to the highest standards in the industry.

At AB ANALITICA, we are constantly committed to surpassing quality standards to provide products and services that contribute to the well-being of individuals and the advancement of medicine. Our dedication to quality is evidenced by these prestigious certifications and our close collaboration with a trusted partner such as TÜV SÜD. We take pride in contributing to the health and well-being of individuals through our *in vitro* diagnostic medical devices.

## AB ANALITICA Becomes Part of Gold Standard Diagnostics: A New Chapter in Diagnostic Innovation

In January 2026, AB ANALITICA became part of Gold Standard Diagnostics (GSD), a leading network of companies providing diagnostic solutions for the clinical, industrial and animal health segments.

GSD has an extensive experience in the clinical market, including manufacturing and commercializing automated platforms and a broad menu of tests in the fields of virology, bacteriology, parasitology, mycology, hormones, autoimmune diseases, and in oncology. AB ANALITICA's deep scientific expertise and strong innovation pipeline align perfectly with GSD's long-term vision to offer efficient, integrated and cutting-edge solutions that enhance clinical decision-making and improve patient outcome.

<https://clinical.goldstandarddiagnostics.com/>

AB ANALITICA:

*"We produce valuable solutions, serving better diagnostics. Every day, we innovate, envision alternatives, and grow alongside our customers."*



REALQUALITY  
Real Time PCR



For most kits:

Kit for automation on the GENEQUALITY® X120 (GQ X120), GENEQUALITY® Max (GQ Max) and GENEQUALITY® 2050 (GQ 2050) platforms or for manual applications.

Qualitative and quantitative assays.

PKG: 50/100.

Stability of kits up to 18 months.

Most assays require 5 µL of extracted nucleic acid.

dUTP/UNG system for contamination prevention.

Endogenous or Exogenous internal control (IC) in multiplex with the pathogen target.

Internal control to be included in the extraction step for acellular matrices.



## Transplant monitoring



Rejection and infection are the main causes of transplant failure and are two intimately associated and interdependent processes. Immunosuppressive therapies create a favorable condition for the onset of infectious processes and it is therefore extremely important to monitor the patient periodically before and after the transplant to prevent the occurrence of rejection.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-CMV	Identification of <b>Cytomegalovirus</b>	RQ-09-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Cytomegalovirus</i>	RQ-10-SM	12 runs	Manual
REALQUALITY RQ-EBV	Identification of <b>Epstein-Barr virus</b>	RQ-11-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Epstein-Barr virus</i>	RQ-122-SM	12 runs	Manual
REALQUALITY RS-HSV 1	Identification of <b>Herpes simplex virus type 1</b>	RQ-05-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Herpes simplex virus type 1</i>	RQ-06-SM	12 runs	Manual
REALQUALITY RS-HSV 2	Identification of <b>Herpes simplex virus type 2</b>	RQ-07-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Herpes simplex virus type 2</i>	RQ-108-SM	12 runs	Manual
REALQUALITY RS-HHV 6	Identification of <b>Human herpes virus type 6</b>	RQ-15-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Human herpes virus type 6</i>	RQ-16-SM	12 runs	Manual
REALQUALITY RQ-HHV 7	Identification of <b>Human herpes virus type 7</b>	RQ-19-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Human herpes virus type 7</i>	RQ-20-SM	12 runs	Manual
REALQUALITY RQ-HHV 8	Identification of <b>Human herpes virus type 8</b>	RQ-17-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Human herpes virus type 8</i>	RQ-18-SM	12 runs	Manual
REALQUALITY RS-VZV	Identification of <b>Varicella-zoster virus</b>	RQ-35-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Varicella-zoster virus</i>	RQ-36-SM	12 runs	Manual
REALQUALITY RQ-PARVO B19	Identification of <b>Parvovirus B19</b>	RQ-37-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Parvovirus B19</i>	RQ-38-SM	12 runs	Manual
REALQUALITY RQ-BKV v2.0	Identification of <b>BK virus</b>	RQ-49-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>BK virus</i>	RQ-50-SM	12 runs	Manual

## Transplant monitoring

Product	Description	Code	Pkg	Application
REALQUALITY RQ-ENTERO	Identification of <b>Enterovirus</b>	RQ-89-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Enterovirus</i>	RQ-90-SM	12 runs	Manual
REALQUALITY RQ-ADENO	Identification of <b>Adenovirus</b>	RQ-93-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Adenovirus</i>	RQ-94-SM	12 runs	Manual
REALQUALITY RQ-MBT Complex	Identification of <b>Mycobacterium tuberculosis complex</b>	RQ-85-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Mycobacterium tuberculosis complex</i>	RQ-86-SM	12 runs	Manual
REALQUALITY RQ-TOXO	Identification of <b>Toxoplasma gondii</b>	RQ-117-6M	100 tests	Manual

## Meningitis/Encephalitis



Meningitis and encephalitis are acute inflammatory diseases affecting the central nervous system. They are often very serious and can be due to various etiological agents of viral, bacterial, fungal or parasitic origin. The rapidity in the diagnosis of meningitis/encephalitis and the patient's prognosis are closely related and the Real-Time PCR technology enables rapid and efficient diagnosis.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-CMV	Identification of <b>Cytomegalovirus</b>	RQ-09-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Cytomegalovirus</i>	RQ-10-SM	12 runs	Manual
REALQUALITY RQ-EBV	Identification of <b>Epstein-Barr virus</b>	RQ-11-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Epstein-Barr virus</i>	RQ-122-SM	12 runs	Manual
REALQUALITY RS-HSV 1	Identification of <b>Herpes simplex virus type 1</b>	RQ-05-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Herpes simplex virus type 1</i>	RQ-06-SM	12 runs	Manual
REALQUALITY RS-HSV 2	Identification of <b>Herpes simplex virus type 2</b>	RQ-07-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Herpes simplex virus type 2</i>	RQ-108-SM	12 runs	Manual
REALQUALITY RS-HHV 6	Identification of <b>Human herpes virus type 6</b>	RQ-15-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Human herpes virus type 6</i>	RQ-16-SM	12 runs	Manual
REALQUALITY RQ-HHV 7	Identification of <b>Human herpes virus type 7</b>	RQ-19-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Human herpes virus type 7</i>	RQ-20-SM	12 runs	Manual

Product	Description	Code	Pkg	Application
REALQUALITY RS-VZV	Identification of <b>Varicella-zoster virus</b>	RQ-35-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Varicella-zoster virus</i>	RQ-36-SM	12 runs	Manual
REALQUALITY RQ-ADENO	Identification of <b>Adenovirus</b>	RQ-93-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Adenovirus</i>	RQ-94-SM	12 runs	Manual
REALQUALITY RQ-ENTERO	Identification of <b>Enterovirus</b>	RQ-89-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Enterovirus</i>	RQ-90-SM	12 runs	Manual
REALQUALITY RQ-PARVO B19	Identification of <b>Parvovirus B19</b>	RQ-37-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Parvovirus B19</i>	RQ-38-SM	12 runs	Manual

## Respiratory infections



The respiratory system, due to its enormous surface area of contact with the external environment, is particularly exposed to infections and the consequent diseases are by far the most frequent pathologies.

Identification of the possible etiological agent is essential for the resolution of the pathology and the setting of the most appropriate therapy.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-ADENO	Identification of <b>Adenovirus</b>	RQ-93-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Adenovirus</i>	RQ-94-SM	12 runs	Manual
REALQUALITY RQ-MBT Complex	Identification of <b>Mycobacterium tuberculosis complex</b>	RQ-85-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Mycobacterium tuberculosis complex</i>	RQ-86-SM	12 runs	Manual
REALQUALITY RQ-ENTERO	Identification of <b>Enterovirus</b>	RQ-89-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>Enterovirus</i>	RQ-90-SM	12 runs	Manual
REALQUALITY ResP-Aria	Identification of respiratory viruses <b>Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B</b> and <b>Respiratory Syncytial Virus (RSV)</b>	RQ-133-6M	100 tests	Manual
REALQUALITY ResP-REM	Identification of <b>Respiratory Syncytial Virus (RSV), metapneumovirus (MPV)</b> and <b>enterovirus (EV)</b>	RQ-134-6M	100 tests	Manual
REALQUALITY SARS-CoV-2 5G	Identification of the ORF1ab, N and S genes of <b>Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2)</b>	RQ-140-6M	100 tests	Manual

## HPV and other Sexually Transmitted Infections (STIs)



Sexually Transmitted Infections (STIs) are a group of infectious diseases that are widespread worldwide and can cause acute symptoms, chronic infections and serious long-term complications for millions of people each year. Today, several pathogens, including bacteria, viruses, fungi and parasites, are known to be responsible for STIs. Rapid diagnosis is important, both to define the right therapy for the patient and to prevent possible complications and to avoid transmission to others.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-HPV HR Multiplex	<b>14 GENOTYPES</b> Identification of <b>14 HPV genotypes with high oncogenic risk:</b> 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. <b>Genotyping of HPV 16 and HPV 18.</b>	RQ-97-6M	100 tests	Manual
		RQ-97R-6M	100 tests	Manual LC 480 II
REALQUALITY RQ-HPV Screen	<b>14 GENOTYPES</b> Identification of <b>14 HPV genotypes with high oncogenic risk:</b> 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. <b>Genotyping of HPV 16 and HPV 18.</b> Validated according to Meijer guidelines (Iacobellis et al., 2018; Meijer C. et al., 2009)	RQ-123-6M	100 tests	Manual
REALQUALITY RQ-HPV HR/LR Multiplex	<b>22 GENOTYPES</b> Identification of <b>14 genotypes at high oncogenic risk, 6 at possible high oncogenic risk and 2 at low oncogenic risk</b> of Human Papilloma Virus. <b>Genotyping of HPV 6, HPV 11, HPV 16 and HPV 18.</b>	RQ-99-6M	100 tests	Manual
		RQ-99R-6M	100 tests	Manual LC 480 II
REALQUALITY RQ-Multi HPV Detection	<b>28 GENOTYPES</b> Identification of <b>14 genotypes at high oncogenic risk, 6 at possible high oncogenic risk and 8 at low oncogenic risk</b> of the Human Papilloma Virus. <b>Genotyping of HPV 16 and HPV 18.</b>	RQ-103-6M	100 tests	Manual
		RQ-103R-6M	100 tests	Manual LC 480 II
REALQUALITY RQ-SevenSTI	Identification of <b>Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium, Mycoplasma hominis, Trichomonas vaginalis, Ureaplasma urealyticum and Ureaplasma parvum</b>	RQ-127-6M	100 tests	Manual
REALQUALITY RQ-STI CT/NG/MG	Identification of <b>Chlamydia trachomatis, Neisseria gonorrhoeae and Mycoplasma genitalium</b>	RQ-107-6M	100 tests	Manual

## Gastrointestinal infections



Gastrointestinal infections of viral, bacterial, or parasitic origin cause diseases resulting in inflammation of the gastrointestinal tract (stomach, small intestine, and colon), typically manifested by diarrhea, vomiting, and abdominal pain. Prompt diagnosis is a crucial measure to provide the correct therapy in a timely manner and to control the infection.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-ADENO	Identification of <b>Adenovirus</b> <b>Quantification standards</b> for Adenovirus	RQ-93-6M	100 tests	Manual
		RQ-94-SM	12 runs	Manual

## Antibiotic resistance



Antimicrobial resistance (AMR) represents a global threat to health and development, requiring urgent action to achieve the Sustainable Development Goals (SDGs). The World Health Organization (WHO) considers it one of the top ten global public health challenges. Poor management and misuse of antimicrobials contribute to the development of resistant pathogens. AMR also has significant economic costs: in addition to causing deaths and disability, resistant infections lead to longer hospital stays, more expensive treatments, and financial burdens for patients.  
<https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

Product	Description	Code	Pkg	Application
REALQUALITY <b>Carba-Screen</b>	Identification of <b>Carbapenem Resistance Classes</b> (Carbapenemases Class B, Class A+D, Acinetobacter OXA) -Screening-	RQ-170-6M Var C1	100 tests	Manual
	Identification of genes encoding resistance to <b>carbapenems</b> and <b>colistin</b> (IMP, VIM, NDM, KPC, OXA-48, MCR1,2,4) -Identification-	RQ-170-4M Var C3	50 tests	Manual

## Fungal infections



*Candida* is a genus of yeasts naturally present in the human body, which can cause infections ranging from mild conditions, such as oral or vaginal candidiasis, to severe systemic infections, especially in immunocompromised patients. *Aspergillus* is a common filamentous fungus found in the environment, responsible for aspergillosis, a respiratory infection that can spread to other organs and pose a serious health risk, particularly in immunocompromised individuals.

Product	Description	Code	Pkg	Application
REALQUALITY <b>Candida Plus</b>	Identification of <b>Candida albicans, Candida auris,</b> <b>Candida glabrata, Candida krusei,</b> <b>Candida parapsilosis, Candida tropicalis,</b> <b>Candida spp.</b>	RQ-174-6M	100 tests	Manual
REALQUALITY <b>Aspergillus</b>	Identification of <b>Aspergillus fumigatus,</b> <b>Aspergillus terreus,</b> <b>Aspergillus spp.</b>	RQ-171-6M	100 tests	Manual

## “Vector Borne” Infections



Vector-borne infections are diseases resulting from the transmission of an infectious agent from an infected animal to humans or another animal. The vectors are often arthropods such as mosquitoes, ticks, flies, fleas and lice, but also mammals such as mice and cats (e.g. *Toxoplasma gondii*), and they can transmit infectious diseases either actively or passively.

Product	Description	Code	Pkg	Application
REALQUALITY <b>RQ-TOXO</b>	Identification of <b>Toxoplasma gondii</b>	RQ-117-6M	100 tests	Manual

## Monitoring Antiviral Therapy (ART)



The total amount of HIV DNA in blood or peripheral blood mononuclear cells (PBMCs) provides information on both the pathogenesis and the course of the infection. In untreated patients, total HIV DNA is indicative of progression to the established stage of the disease. The amount of total HIV DNA at baseline is predictive of response to ART. It can be useful for treatment personalization and as a marker of long-term efficacy in patients on antiretroviral treatment (Sarmati et al., 2007; Parisi et al., 2012).

Product	Description	Code	Pkg	Application
REALQUALITY RQ-HIV DNA	Identification of <b>HIV-1 DNA</b>	RQ-125-6M	100 tests	Manual
	<b>Quantification standards</b> for HIV-1 DNA	RQ-126-SM	10 runs	
	<b>Beta Globin Standard</b>	RQ-128-SM	10 runs	

## Coagulation



Clotting disorders are dysfunctions in the body's ability to control the formation of blood clots. They occur when the body is unable to produce enough proteins, called clotting factors, necessary to start clotting and stop bleeding. In cases where there is a genetic abnormality of these factors, hereditary thrombophilia can arise. Molecular testing represents the gold standard for screening for genetic defects that predispose to hereditary thrombophilia.

Product	Description	Code	Pkg	Application
REALQUALITY <b>THROMBO FII-FVL</b>	Identification and genotyping of the <b>Factor II G20210A</b> and <b>Factor V Leiden</b> mutations	RQ-177-6M	100 tests	Manual
REALQUALITY <b>THROMBO MTHFR</b>	Identification and genotyping of the <b>MTHFR C677T</b> and <b>MTHFR A1298C</b> mutations	RQ-178-6M	100 tests	Manual
REALQUALITY <b>RS-FACTOR V LEIDEN</b>	Identification and genotyping of the <b>G1691A mutation (Leiden)</b> in the gene coding for Coagulation Factor V	RQ-25-6M	100 tests	Manual
REALQUALITY <b>RS-FACTOR V H1299R</b>	Identification and genotyping of the <b>H1299R</b> mutation (HR2 haplotype) in the gene coding for Coagulation Factor V	RQ-111-6M	100 tests	Manual
REALQUALITY <b>RQ-FACTOR V Y1702C</b>	Identification and genotyping of the <b>Y1702C</b> mutation in the gene coding for Coagulation Factor V	RQ-69-6M	100 tests	Manual
REALQUALITY <b>RS-FACTOR II G20210A</b>	Identification and genotyping of the <b>G20210A</b> mutation in the gene coding for Coagulation Factor II	RQ-27-6M	100 tests	Manual
REALQUALITY <b>RS-MTHFR A1298C</b>	Identification and genotyping of the <b>A1298C</b> mutation in the gene coding for MTHFR	RQ-31-6M	100 tests	Manual
REALQUALITY <b>RS-MTHFR C677T</b>	Identification and genotyping of the <b>C677T</b> mutation in the gene coding for MTHFR	RQ-29-6M	100 tests	Manual

## Coagulation

Product	Description	Code	Pkg	Application
REALQUALITY RQ-PAI-1 4G/5G	Identification and genotyping of the <b>-675 4G/5G</b> polymorphism in the gene coding for the plasminogen activator type 1 inhibitor	RQ-119-6M	100 tests	Manual
REALQUALITY RQ-ACE (I/D)	Identification and genotyping of the <b>insertion/deletion (I/D)</b> polymorphism in the <b>intron 16</b> of the gene coding for the angiotensin converting enzyme (ACE)	RQ-75-6M	100 tests	Manual

## Hemochromatosis



Hemochromatosis is an autosomal recessive genetic disease due to a defect in iron metabolism.

The disease is characterized by excessive accumulation of iron in the body due to increased absorption of dietary iron at the level of the intestinal mucosa.

The most obvious damage is to the liver with enlargement of the organ, leading to irreversible damages such as liver cirrhosis. Other damaged organs are the heart, pancreas, endocrine organs and finally the joints.

Product	Description	Code	Pkg	Application
REALQUALITY RS-HEMO C282Y	Identification and genotyping of the <b>C282Y</b> mutation in the HFE gene	RQ-39-6M	100 tests	Manual
REALQUALITY RS-HEMO H63D	Identification and genotyping of the <b>H63D</b> mutation in the HFE gene	RQ-41-6M	100 tests	Manual
REALQUALITY RQ-HEMO S65C	Identification and genotyping of the <b>S65C</b> mutation in the HFE gene	RQ-43-6M	100 tests	Manual

## Oncohematology



Molecular analysis in the oncohematological field allows to study the molecular alterations that characterize blood cancers. These alterations can be completely specific and allow for a certain diagnosis, or the presence of a certain molecular rearrangement can make the diagnosis more precise, allow the prognosis to be better defined and a more targeted therapeutic intervention to be implemented.

The application of more sensitive Molecular Biology techniques also makes it possible to monitor the disease, to better evaluate the efficacy of a given therapy, the persistence or absence of minimal residual disease or any initial signs of relapse.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-BCR-ABL p210 One-Step	Identification of translocation <b>t(9;22) (q34;q11), variant p210 – BCR-ABL p210 (M-bcr)</b> Reverse transcription and PCR in <b>one step</b>	RQ-105-6M	100 tests	Manual
	Single-plasmid <b>quantification standards</b> for BCR-ABL p210 (M-bcr), ABL and GUSB transcripts	RQ-54-SM	6 runs	

Product	Description	Code	Pkg	Application
REALQUALITY RQ-BCR-ABL p190 One-Step	Identification of translocation <b>t(9;22) (q34;q11), variant p190 – BCR-ABL p190(m-bcr)</b> Reverse transcription and PCR in <b>one step</b>	RQ-115-6M	100 tests	Manual
	Single-plasmid <b>quantification standards</b> for <i>BCR-ABL p190 (m-bcr)</i> , <i>ABL</i> transcripts	RQ-116-SM	6 runs	
REALQUALITY RS-WT-1	Identification of the expression of <b>Wilms Tumor (WT 1) gene</b>	RQ-S57-96	96 tests	Manual
	<b>Quantification standards</b> for WT 1 and the <i>ABL</i> gene transcripts	RQ-58-ST	10 runs	
REALQUALITY RS-AML1-ETO	Identification of the <b>t(8;21) (q22;q22) translocation</b>	RQ-S59-96	96 tests	Manual
	<b>Quantification standards</b> for <i>AML1-ETO</i> and <i>ABL</i> transcripts	RQ-60-ST	10 runs	
REALQUALITY RS-INV 16	Identification of the <b>inv(16)(p13;q22) inversion</b>	RQ-S61-96	96 tests	Manual
	<b>Quantification standards</b> for <i>INV-16</i> and <i>ABL</i> transcripts	RQ-62-ST	10 runs	
REALQUALITY RQ-PML-RARa bcr1 One-Step	Identification of translocation <b>t(15;17) (q22;q21), variant bcr1 – PML-RARA bcr1</b>	RQ-179-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>PML-RARA bcr1</i> and <i>ABL</i> transcripts	RQ-180-SM	6 runs	
REALQUALITY RQ-PML-RARa bcr2 One-Step	Identification of translocation <b>t(15;17) (q22;q21), variant bcr2 – PML-RARA bcr2</b>	RQ-181-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>PML-RARA bcr2</i> and <i>ABL</i> transcripts	RQ-182-SM	6 runs	
REALQUALITY RQ-PML-RARa bcr3 One-Step	Identification of translocation <b>t(15;17) (q22;q21), variant bcr3 – PML-RARA bcr3</b>	RQ-183-6M	100 tests	Manual
	<b>Quantification standards</b> for <i>PML-RARA bcr3</i> and <i>ABL</i> transcripts	RQ-184-SM	6 runs	
<b>p210 RNA Reference</b>	<b>Reference RNA</b> for molecular identification and/or quantification of the <b>BCR-ABL p210 transcript</b>	RQ-185-SM	10 runs	Manual

## Other reagents

Product	Description	Code	Pkg	Application
<b>Rev-T Kit RQ variant</b>	RNA reverse transcription kit for Real-Time PCR applications	06-R1-25	25 tests	Manual
		06-R1-50	50 tests	

The Roche instruments Lightcycler 2.0 (LC 2.0) and Lightcycler 480 II (LC 480 II) require an instrument-specific color compensation file/object for correct reading of the fluorescence signals. The color compensation file/object has to be created once before using the Real-Time PCR assays and used for all subsequent analysis runs.

<b>REALQUALITY LC 2.0 Color compensation kit</b>	Kit for creating an instrument-specific color compensation file for Roche Lightcycler 2.0 Real-Time PCR system	RQ-SCLC2	For 1 color compensation file	Manual
<b>REALQUALITY LC 480 Color compensation kit</b>	Kit for creating an instrument-specific color compensation file for Roche Lightcycler 480 Real-Time PCR system version II	RQ-SCLC48	For 1 color compensation object	Manual



# REVERSE LINE BLOT

## Genetics

## Coagulation



Clotting disorders are dysfunctions in the body's ability to control the formation of blood clots. They occur when the body is unable to produce enough of the proteins, called clotting factors, necessary to start clotting and stop bleeding. In cases where there is a genetic abnormality of these factors, hereditary thrombophilia can arise. Molecular testing represents the gold standard for screening for genetic defects that predispose to hereditary thrombophilia.

Product	Description	Code	Pkg	Application
GENEQUALITY <b>AB- THROMBO TYPE PLUS</b>	Simultaneous identification of mutations in the genes coding for <b>Factor V Leiden G1691A (Arg506Gln), Factor II G20210A, MTHFR C677T, MTHFR A1298C, PAI 1 4G/5G, Factor V (HR2) H1299R</b> by Multiplex PCR and Reverse Line Blot	04-71A-20 M	20 tests	Manual
		04-71A-20 A	20 tests	Dynablot Heat, Autoblot 3000H, ProfiBlot™ T48

## Genetic disorders



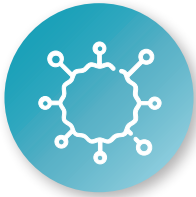
Some genetic disorders can predispose to the onset of celiac disease, microdeletions of the Y chromosome can instead lead to infertility. Molecular analysis of these genetic alterations makes it possible to accurately diagnose the predisposition to these pathologies.

Product	Description	Code	Pkg	Application
GENEQUALITY <b>AZF Y-TYPE</b>	Identification of <b>deletions at the AZF locus</b> by Multiplex PCR and Reverse Line Blot	04-18A-20 M	20 tests	Manual
		04-18A-20 A	20 tests	Dynablot Heat, Autoblot 3000H, ProfiBlot™ T48
GENEQUALITY <b>CD-TYPE v2.0</b>	Identification of genetic susceptibility to <b>celiac disease</b> by Multiplex PCR and Reverse Line Blot. Interpretive software included.	02-14A-20 M	20 tests	Manual
		02-14A-20 A	20 tests	Dynablot Heat, Autoblot 3000H, ProfiBlot™ T48



# REVERSE LINE BLOT

## Virology



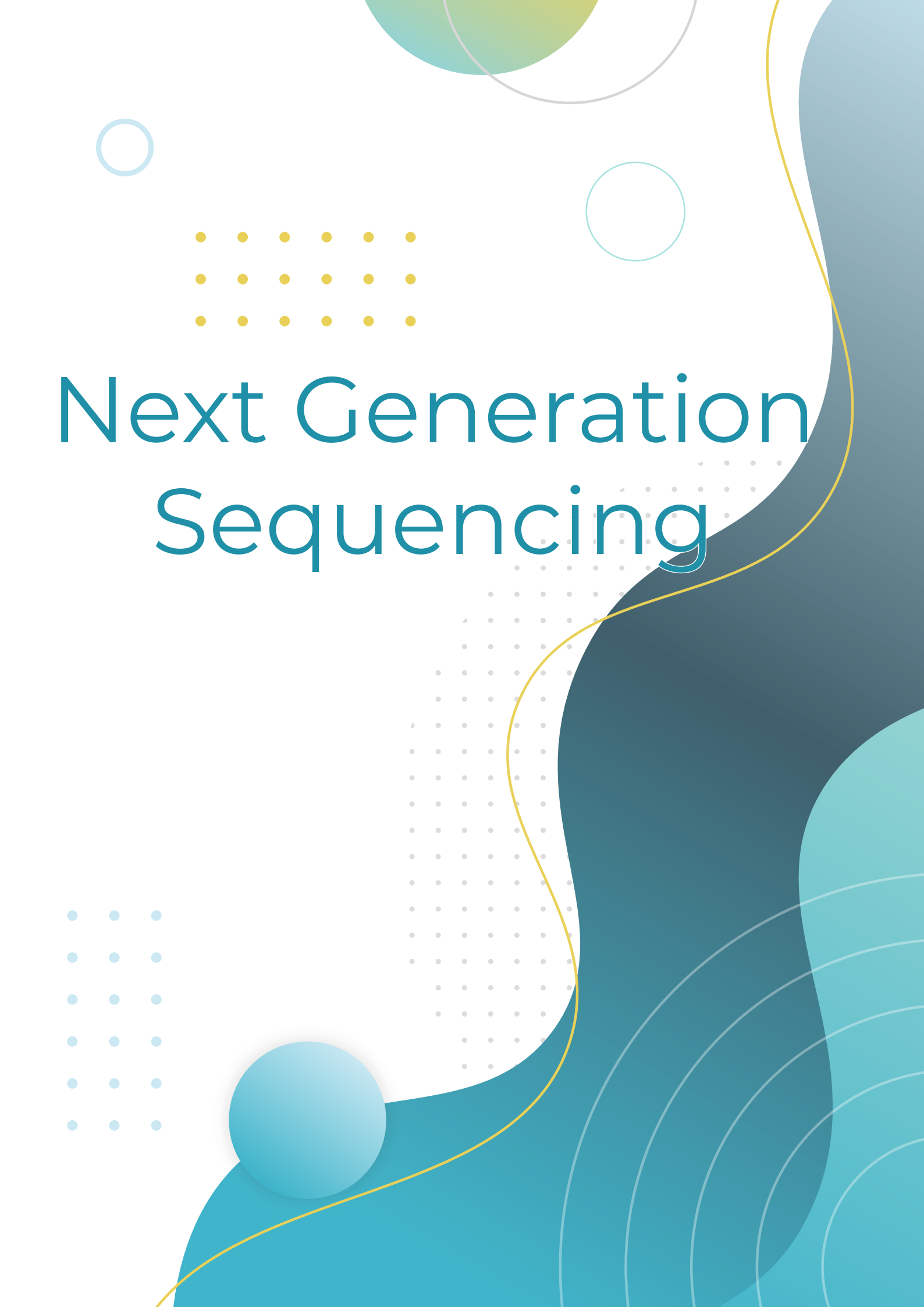
Hepatitis C virus (HCV) has a genome characterized by a high degree of variability. Seven major HCV genotypes have been identified (Smith et al, 2013; Murphy DG et al. 2015). Each genotype in turn includes several subtypes identified by lowercase letters of the alphabet (Simmonds et al, 2005). In turn, each subtype includes numerous variants. The HCV genome consists of single-stranded RNA. The coding regions consist of the CORE domains. The coding region is flanked by highly conserved untranslated regions (UTRs). The 5'UTR region can provide useful information for the identification of genotypes 1-5, 6a-b and 7 (Pickett et al., 2011; Chevaliez et al., 2009). Simultaneous investigation of the 5'UTR and CORE regions allows for a more accurate assignment of the viral genotype and subtypes (Chevaliez et al., 2009).

Product	Description	Code	Pkg	Application
AMPLIQUALITY HCV TYPE PLUS	Identification of <b>genotypes 1-7</b> of the Hepatitis C virus (HCV) and <b>subtypes a and b of genotype 1</b> , by Reverse transcription, PCR and Reverse Line Blot of the 5'UTR and CORE regions. Interpretive software included	03-05-20 M	20 tests	Manual
		03-05-20 A	20 tests	Dynablot Heat, Autoblot 3000H, ProfiBlot™ T48



Human Papillomavirus (HPV) infection is caused by a DNA virus of the Papillomaviridae family. Many HPV infections cause no symptoms and 90% resolve spontaneously. In some cases, an HPV infection persists and causes warts or precancerous lesions. These lesions, depending on the affected site, increase the risk of cancer of the cervix, vulva, vagina, penis, anus, mouth, tonsils, or throat. The strains most involved in cervical cancer are HPV16 and HPV18. HPV6 and HPV11 are considered low-risk cancer and cause genital warts and laryngeal papillomatosis.

Product	Description	Code	Pkg	Application
AMPLIQUALITY HPV TYPE EXPRESS v3.0	Identification and typing of Human Papilloma Virus by single step PCR and Reverse Line Blot. The system is able to identify the following 40 HPV genotypes: <b>6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 42, 43, 44, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 64, 66, 67, 68 (a and b), 69, 70, 71, 72, 73, 81, 82, 83, 84, 87, 89, 90</b>	03-35A-20 M	20 tests	Manual
		03-35A-20 A	20 tests	Dynablot Heat, Autoblot 3000H, ProfiBlot™ T48
HPV-TYPE EXPRESS Strip Reader	Software for interpretation and report generation for the AMPLIQUALITY HPV-TYPE EXPRESS kit	08-RLB-32	1 CD	



# Next Generation Sequencing

# Next Generation Sequencing

## GENEQUALITY® Whole Exome Sequencing



GENEQUALITY Library Prep, GENEQUALITY Purification Kit, and GENEQUALITY Unique Dual Indexes are *in vitro* diagnostic medical devices intended to be used together by qualified personnel for the preparation of libraries for subsequent diagnostic applications based on Next-Generation Sequencing (NGS) techniques. The libraries are prepared from high-quality genomic DNA isolated from human cells. The devices include, respectively, reagents for enzymatic fragmentation and library preparation, reagents for library purification, and universal adapters.

GENEQUALITY Whole Exome Sequencing is an *in vitro* diagnostic medical device intended for use by qualified personnel for the production of libraries enriched with the exome and mitochondrial genome for subsequent *in vitro* diagnostic tests involving Next-Generation Sequencing (NGS) applications.

Product	Code	Pkg
<b>GENEQUALITY® Library Prep</b>	04-N01-6M	96 tests
<b>GENEQUALITY® Purification kit</b>	04-N02-6M	96 tests
<b>GENEQUALITY® Unique Dual Indexes</b>	04-N03-6M	96 tests
<b>GENEQUALITY® Whole Exome Sequencing</b>	04-NWE-6M	8x12 rxns

## GENEQUALITY® CFTR



The CFTR gene encodes a membrane protein that plays a fundamental role in regulating chloride and bicarbonate transport across epithelial surfaces. Mutations in this gene lead to the production of thick, viscous secretions that can obstruct airways and ducts, promoting chronic infections.

GENEQUALITY® CFTR is an easy-to-use NGS library preparation kit specifically designed for the targeted analysis of the CFTR gene through target amplification.

GENEQUALITY® CFTR is an *in vitro* diagnostic medical device (IVD) intended for the preparation of amplification-based libraries for the qualitative detection of mutations, insertions/deletions (indels), and CNVs in the exons, flanking regions, and clinically relevant intronic regions of the CFTR gene, for NGS-based *in vitro* diagnostic assays.

Product	Code	Pkg
<b>GENEQUALITY® CFTR</b>	04-NFC-24	24 tests



# Instruments

## Automated extraction and PCR setup



## GENEQUALITY® X120

Completely automated walk-away system to perform routine molecular diagnostics, optimizing efficiency and versatility.

DNA and RNA purification from different types of matrices in the same run, starting from the primary tube.

Up to 96 biological samples processed simultaneously from primary tubes.

Up to 24 different Real-Time PCR reactions per plate.

Full traceability of the entire workflow.

Touch screen interface software.

Extraction protocol is based on magnetic beads with preloaded cartridges.

Decontamination control with the integrated UV lamp.

Direct exportation of PCR configuration files.

Bidirectional interface to the laboratory management system.

Product	Description	Code	Pkg
<b>GENEQUALITY® X120</b>	Platform for 96 simultaneous extractions	08-20-96	1 instrument

## GENEQUALITY® Max SAMPLE TO RESULT

## "SAMPLE-TO-RESULT" System

Sample-To-Results platform, versatile and efficient in routine molecular diagnostics.

Purification of DNA and RNA from different matrices in the same analytical run, starting from the primary tube.

Simultaneous management of up to 48 biological samples, from loading to PCR reaction setup up to Real-Time PCR amplification (up to 24 assays simultaneously).

Complete traceability of the entire workflow.

Software with touch screen interface.

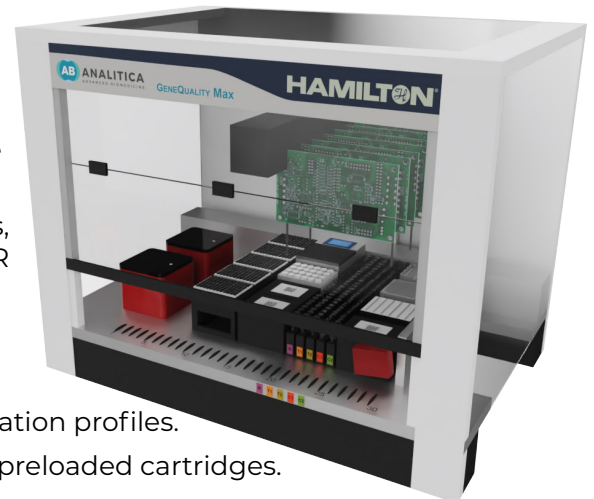
Simultaneous management of two distinct thermal amplification profiles.

Extraction system based on the use of magnetic beads with preloaded cartridges.

Decontamination control by integrated UV lamp.

Bidirectional interfacing to the laboratory management system.

Two integrated Real-Time PCR thermal cyclers with capacity of 48 samples each.



Product	Description	Code	Pkg
<b>GENEQUALITY® Max</b>	"Sample-to-result" platform for 48 simultaneous extractions including 2 on-board thermal cyclers for Real-Time PCR analysis	08-22-48	1 instrument

## GENEQUALITY® X120 / GENEQUALITY® Max reagents

Product	Description	Code	Pkg
<b>GENEQUALITY® X120 Pathogen kit</b>	Kit for the purification of viral DNA/ RNA, bacterial DNA and genomic DNA with magnetic particle technology, from different types of biological samples.	05-X12-6A	100 tests
<b>IC RNA (4,2 ml)</b>	RNA internal control	05-76-04	100 tests
<b>IC DNA (4,2 ml)</b>	DNA internal control	05-78-04	100 tests
<b>AMR Extraction Control</b>	Internal control associated with the REALQUALITY Carba-Screen kit.	05-80-04	100 tests
<b>GENEQUALITY® X120 LB-P</b>	Sample pretreatment solution (in combination with GENEQUALITY® X120 Pathogen kit).	05-X13-25	1.250 tests

## GENEQUALITY® X120 / GENEQUALITY® Max accessories

Product	Description	Code	Pkg
<b>Work Plate</b>	Work Plate, 2 mL, sterile for GENEQUALITY® X120	20-43001-0200	10 pcs
<b>Elution Plate</b>	Elution Plate, 1 mL, sterile for GENEQUALITY® X120	20-43001-1016	10 pcs
<b>Filter tips, 300 µL</b>	Filter tips, 300 µL for GENEQUALITY® X120	20-49008-0104	5760 pcs
<b>Filter tips, 1000 µL</b>	Filter tips, 1000 µL for GENEQUALITY® X120	20-49009-0104	3840 pcs
<b>Filter tips, 50 µL</b>	Filter tips, 50 µL for GENEQUALITY® X120	20-49010-0104	5760 pcs
<b>“96-well PCR plate Aria Dx”</b>	96-well PCR plate, with low border profile (for Real-Time Aria Dx Thermal Cycler)	AB-E1403-5200	10 pcs
<b>Strips of 8 flat optical caps Aria Dx</b>	Strips of 8 flat optical caps (for Real-Time Aria Dx Thermal Cycler)	AB-I1400-0900	125 pcs
<b>96-well PCR plate, with low border profile</b>	96-well PCR plate, with low border profile	AB-401491	25 pcs
<b>Mx3000P Optical Strip Caps</b>	Mx3000P Optical Strip Caps	AB-401425	120 pcs
<b>96 well 0.1 mL white plates with barcode Bio-Rad CFX 96™</b>	96 well 0.1 mL white plates (for Real-Time Bio-Rad CFX 96™ thermal cycler)	BP-B17489	25 pcs
<b>Optical cap strip for Bio-Rad CFX 96™</b>	Optical cap strips for PCR Real-Time PCR (for Bio-Rad CFX 96 Real-Time Thermal Cycler)	BP-B57801B	300 pcs
<b>Waste bags</b>	Waste bags for GENEQUALITY® X120	20-199202	25 pcs
<b>2 mL microtube</b>	2 mL microtube, Flat, no-grad, Sterile	20-72664	500 pcs
<b>Screw cap for 2mL microtube</b>	Screw cap for 2mL microtube	20-65716	500 pcs
<b>Aluminium cover film</b>	Aluminium cover film, -80°C to +120°C	20-94001-0216	100 pcs
<b>Hamilton MIC Tubes &amp; V-Caps</b>	Hamilton MIC Tubes & V-Caps (GENEQUALITY® Max)	20-10110770	960 pcs

## Automated systems

### GENEQUALITY 2050 TwentyFifty

**Fully Integrated System  
Sample To Result**



GENEQUALITY® 2050 (GQ 2050) is a fully integrated Real-Time PCR system able to performing all steps from primary sample collection, extraction, Real-Time PCR amplification, to result analysis without the need for operator intervention.

Up to 32 samples of different matrices and sizes can be processed.

Sample tubes ranging in diameter from 11 to 16 mm and height from 65 to 105 mm.

Extremely rapid extraction using magnetic beads with a rod magnetic system.

Results in less than two hours with a hands-on-time of 5 minutes.

Up to 48 positions for both qualitative and quantitative assays in amplification.

Refrigerated rack for PCR master mix.

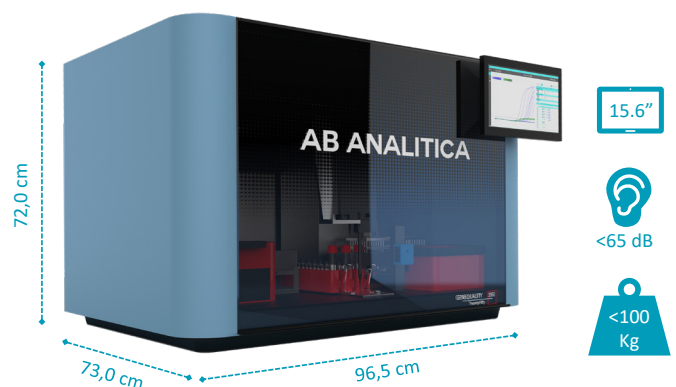
Complete process traceability (samples, extraction and amplification reagents) ensured through automatic barcode reading.

Integrated Real-Time PCR amplification system, RBC MIC, with 4 fluorescence channels.

Equipped with a Hepa filter for environmental safety, UV lamp and tips with filters to manage and limit potential contaminations.

The system features various control and safety mechanisms, including:

- Error management system for sample withdrawal errors caused by foam, clots, and/or aspirated air for level errors.
- Temperature control.
- Control of heating and cooling block temperatures.
- Control of tip combs positioning, extraction cartridge, and racks.



Product	Description	Code	Pkg
<b>GENEQUALITY® 2050</b>	Fully integrated Sample-To-Result Real-Time PCR system.	08-GQ2050-01	1 instrument
<b>GENEQUALITY® 2050 Extraction</b>	Kit for the purification of viral DNA/ RNA, bacterial DNA and genomic DNA with magnetic particle technology, from different types of biological samples.	05-25P-3A	32 tests



# FERTILITY

## Seminal fluid analysis

Ready-to-use solutions and kits for analysis or staining of sperm cells on microscope or spectrophotometer.

Product	Description	Code	Pkg
<b>LIFE TEST</b>	Test for differentiation of viable from non-viable spermatozoa, regardless of their motility.	00-01R-50	50 tests
<b>SWELLING TEST</b>	Test for assessment of the membrane integrity of sperm cells.	00-02R-50	50 tests
<b>HISTON COLOR TEST</b>	Test for assessment of the maturation state of sperm cells by staining of histones in the cell nucleus.	00-03R-50	50 tests
<b>DECON TEST</b>	Test for assessment of the maturation state of sperm cells by analysis of the chromosome-decondensation process in the cell nucleus.	00-04R-50	50 tests
<b>ROUND CELL TEST</b>	Test for assessment of nemaspermic chromatin.	00-05R-50	50 tests
<b>FRUCTOSE</b>	Test for assessment of the D-Fructose content in seminal fluid (UV absorption spectrophotometry).	20-FK00100	100 tests
<b>ZINC</b>	Test for assessment of the Zinc content in serum, plasma, urine and seminal fluid without deproteinization (colorimetric test).	20-FK00200	50 tests
<b>CITRIC ACID (for seminal fluid)</b>	Test for assessment of the Citric Acid content in seminal fluid by UV absorption spectrophotometry.	20-FK00250	100 tests
<b>SET of CONTROLS for Fructose, Zinc, Citric Acid</b>	Controls for analysis of biochemical parameters of seminal fluid.	20-FK00400	3 vials of 1mL



# BREATH TEST

## BREATHQUALITY UBT

### <sup>13</sup>C-UREA Breath test for diagnosis of gastroduodenal infection by *Helicobacter pylori*.

Oral solution, single dose (75 mg <sup>13</sup>C urea/10 mL), for breath testing for in vivo diagnosis of gastroduodenal *Helicobacter pylori* infection in adults and children

Liquid.

Ready to use.

Complete.

Authorized for pediatric use.

Free of preservatives, colorants and flavors.

Tested for allergic reactions.



Product	Description	Code	Pkg
<b>BREATHQUALITY - UBT</b>	Breath test for in vivo diagnosis of gastroduodenal infection by <i>Helicobacter pylori</i> . Oral solution, single dose (75 mg <sup>13</sup> C urea/10 mL)	11-75-00	1 test

## Accessories for breath testing

### TEST TUBES FOR BREATH TEST:

2 glass vials (12 mL) with blue cap, labeled (BASE-).

2 glass vials (12 mL) with red cap, labeled (POST-).

The vials have a flat base, a silicon coating baked onto the inside wall of the vial, giving a clearer visible breath sample without interfering with the analysis and a screw-cap with pierceable rubber septum.

Suitable for analysis with Mass Spectrometer and Infrared Analyzer.

### STRAWS:

2 straws in Polypropylene (PP).



Product	Description	Code
<b>AB 13C-AMINOPIRINA</b>	<sup>13</sup> C <b>Aminopyrine</b> : Substrate for study of liver function	13-01A-75
<b>AB 13C-METACETINA</b>	<sup>13</sup> C <b>Methacetin</b> : Substrate for study of liver function	13-02A-75
<b>AB 13C-TRIGLICERIDI MISTI</b>	<b>Mixed <sup>13</sup>C Triglycerides</b> : Substrate for study of pancreatic lipase activity in the duodenum	13-07A-250
<b>AB 13C-ACIDO OTTANOICO</b>	<sup>13</sup> C <b>Octanoic Acid</b> : Substrate for evaluation of gastric emptying	13-09A-100





**AB ANALITICA srl**  
Via Svizzera, 16  
35127 Padova - ITALY  
VAT number 02375470289  
Tel. + 39 049 761698  
Fax. +39 049 8709510  
[www.abanalitica.com](http://www.abanalitica.com)  
[customersupport@abanalitica.it](mailto:customersupport@abanalitica.it)

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