AB ANALITICA
ADVANCED BIOMEDICINE

Product catalogue

Valid from October 1st, 2024

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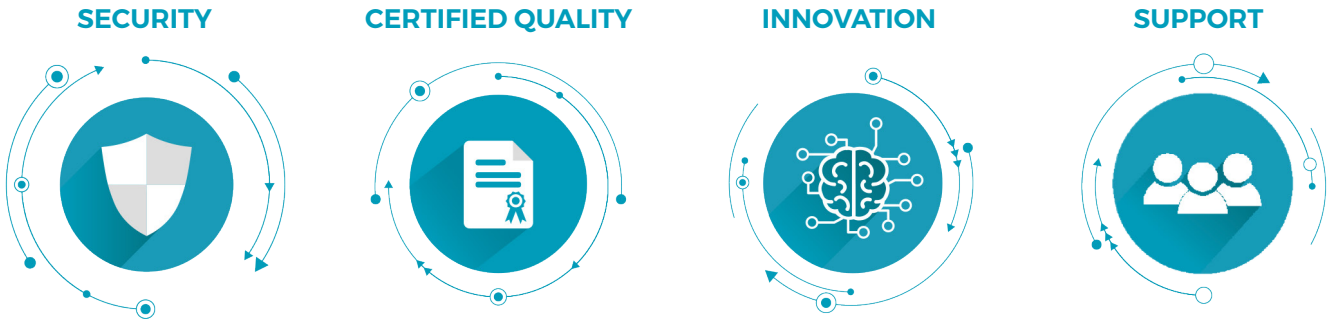
AB ANALITICA: 30 Years of Excellence in Molecular Diagnostics

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:



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. Additionally, we have two locations dedicated to research and design: one at the AREA SCIENCE PARK in Padriciano - Trieste (TS) and the other within the H-Bio Puglia scrl district.

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.

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.

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.

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.

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.

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.

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_2 (kg of CO_2 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:
"We produce valuable solutions, serving better diagnostics. Every day, we innovate, envision alternatives, and grow alongside our customers."

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 058438 0015 Rev. 01

Manufacturer: AB ANALITICA Srl
Via Svizzera, 16
35127 Padova
ITALY

SRN Manufacturer - IT-MF-000032625

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 058438 0015 Rev. 01

Report No.: ITA200220001280
Preceding Certificate No.: V12 058438 0015 Rev. 00
Valid from: 2024-03-22
Valid until: 2027-09-27
Date of Initial Issuance: 2022-09-28

Issue date: 2024-03-22
Marta Carnielli
Head of Certification IVD

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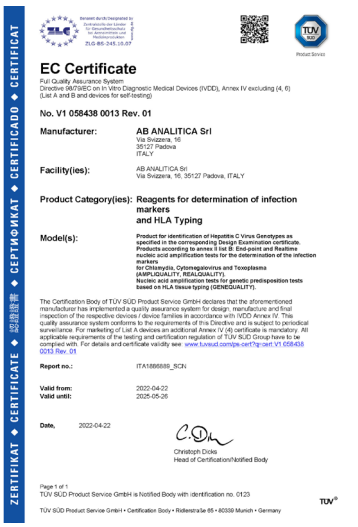
CERTIFICATO
Nr. 50 100 5732/B Rev.010
AB ANALITICA S.r.l.
SEDE LEGALE E OPERATIVA:
VIA SVIZZERA 16 IT - 35127 PADOVA (PD)
UNI CEI EN ISO 13485:2021
Progettazione, sviluppo, produzione e immissione in commercio di dispositivi medico diagnostici in vitro (reagenti, calibratori e controlli per indagini infettivologiche, genetiche, oncologiche, citologiche e chimico clinicihe).
Progettazione, sviluppo, gestione della produzione, immissione in commercio ed assistenza tecnica di strumenti per diagnostica in vitro e software per il trattamento di dati relativi alla diagnostica in vitro. Commercializzazione di dispositivi medico diagnostici in vitro (reagenti, calibratori e controlli) e commercializzazione ed assistenza tecnica di strumenti per diagnostica in vitro in ambito infettivologico, genetico, oncologico, citologico e chimico clinico
Design, development, production and placing on the market of in vitro diagnostic medical devices (reagents, calibrators and controls for Infectivology, Genetics, Oncology, Cytology and Clinical Chemistry). Design, development, management of production, placing on the market and servicing of instruments for in vitro diagnostics and software for the management of in vitro diagnostics data. Trade of in vitro diagnostic medical devices (reagents, calibrators and controls) and trade and servicing of instruments for in vitro diagnostics in Infectivology, Genetics, Oncology, Cytology and Clinical Chemistry
Per l'Organismo di Certificazione / For the Certification Body: TÜV Italia S.r.l.
Validità / Validity: Dal / From: 2024-03-31 Al / To: 2027-03-30
SGQ N° 049A
Data emissione / Issuing Date: 2024-03-25
PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2006-04-13
DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE / EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2024-03-30

CERTIFICATO
Nr. 50 100 5732/A Rev.008
AB ANALITICA S.r.l.
SEDE LEGALE E OPERATIVA:
VIA SVIZZERA 16 IT - 35127 PADOVA (PD)
UNI EN ISO 9001:2015
Progettazione, sviluppo, produzione e immissione in commercio di dispositivi medico diagnostici in vitro (reagenti, calibratori e controlli per indagini infettivologiche, genetiche, oncologiche, citologiche e chimico clinicihe).
Progettazione, sviluppo, gestione della produzione, immissione in commercio ed assistenza tecnica di strumenti per diagnostica in vitro e software per il trattamento di dati relativi alla diagnostica in vitro. Commercializzazione di dispositivi medico diagnostici in vitro (reagenti, calibratori e controlli) e commercializzazione ed assistenza tecnica di strumenti per diagnostica in vitro in ambito infettivologico, genetico, oncologico, citologico e chimico clinico. Progettazione, sviluppo, gestione della produzione e commercializzazione di breath test. Erogazione di servizi di laboratorio per analisi chimico cliniche
Design, development, production and placing on the market of in vitro diagnostic medical devices (reagents, calibrators and controls for Infectivology, Genetics, Oncology, Cytology and Clinical Chemistry). Design, development, management of production, placing on the market and servicing of instruments for in vitro diagnostics and software for the management of in vitro diagnostics data. Trade of in vitro diagnostic medical devices (reagents, calibrators and controls) and trade and servicing of instruments for in vitro diagnostics in Infectivology, Genetics, Oncology, Cytology and Clinical Chemistry. Design, development, management of production and trade of breath test. Provision of laboratory services for clinical chemistry analysis
Per l'Organismo di Certificazione / For the Certification Body: TÜV Italia S.r.l.
Validità / Validity: Dal / From: 2024-03-31 Al / To: 2027-03-30
SGQ N° 049A
Data emissione / Issuing Date: 2024-03-25
PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2006-04-13
DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2024-03-30
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2024-03-30



EC Certificate
Full Quality Assurance System
Directive 98/79/EC on in Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)
No. V1 058438 0013 Rev. 01
Manufacturer: AB ANALITICA Srl
Via Svizzera, 16
35127 Padova
ITALY
Facility(ies): AB ANALITICA Srl
Via Svizzera, 16, 35127 Padova, ITALY
Product Category(ies): Reagents for determination of infection markers and HLA Typing
Model(s): Product for identification of Hepatitis C Virus Genotypes as specified in the corresponding Design Examination certificate.
Products according to annex II list B: End-point and Realtime nucleic acid amplification tests for the determination of the infection markers
for Chlamydia, Cytomegalovirus and Toxoplasma (AMPLIQUALITY, REALQUALITY).
Nucleic acid amplification tests for genetic predisposition tests based on HLA tissue typing (GENEQUALITY).
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 058438 0013 Rev. 01
Report no.: ITA1866888_SCN
Valid from: 2022-04-22
Valid until: 2025-05-26
Date, 2022-04-22
Christoph Dicks
Head of Certification/Notified Body
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EC Certificate
EC Design-Examination Certificate
Directive 98/79/EC on in Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)
No. V7 058438 0014 Rev. 01
Manufacturer: AB ANALITICA Srl
Via Svizzera, 16
35127 Padova
ITALY
Product: NAT-Test for Hepatitis C marker
The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 058438 0014 Rev. 01
Report No.: ITA1986980_SCN_V7
Valid from: 2022-04-22
Valid until: 2025-05-26
Date, 2022-04-22
Christoph Dicks
Head of Certification/Notified Body
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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 - 48/96 tests.
- 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 mutiplex 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 occurence of rejection.

Product	Description	Code	Pkg	Application
REALQUALITY RQ-**CMV**	Identification of ***Cytomegalovirus***	RQ-09-4M	50 tests	Manual
		RQ-09-6M	100 tests	
		RQ-09-4A	50 tests	GQ X120/Max/2050
		RQ-09-6A	100 tests	
	Quantification standards for *Cytomegalovirus*	RQ-10-SM	12 runs	Manual
		RQ-10-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**EBV**	Identification of ***Epstein-Barr virus***	RQ-11-4M	50 tests	Manual
		RQ-11-6M	100 tests	
		RQ-11-4A	50 tests	GQ X120/Max/2050
		RQ-11-6A	100 tests	
	Quantification standards for *Epstein-Barr virus*	RQ-122-SM	12 runs	Manual
		RQ-122-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HSV 1**	Identification of ***Herpes simplex virus* type 1**	RQ-05-4M	50 tests	Manual
		RQ-05-6M	100 tests	
		RQ-05-4A	50 tests	GQ X120/Max/2050
		RQ-05-6A	100 tests	
	Quantification standards for *Herpes simplex virus* type 1	RQ-06-SM	12 runs	Manual
		RQ-06-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HSV 2**	Identification of ***Herpes simplex virus* type 2**	RQ-07-4M	50 tests	Manual
		RQ-07-6M	100 tests	
		RQ-07-4A	50 tests	GQ X120/Max/2050
		RQ-07-6A	100 tests	
	Quantification standards for *Herpes simplex virus* type 2	RQ-108-SM	12 runs	Manual
		RQ-108-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HHV 6**	Identification of ***Human herpes virus* type 6**	RQ-15-4M	50 tests	Manual
		RQ-15-6M	100 tests	
		RQ-15-4A	50 tests	GQ X120/Max/2050
		RQ-15-6A	100 tests	
	Quantification standards for *Human herpes virus* type 6	RQ-16-SM	12 runs	Manual
		RQ-16-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**HHV 7**	Identification of ***Human herpes virus* type 7**	RQ-19-4M	50 tests	Manual
		RQ-19-6M	100 tests	
		RQ-19-4A	50 tests	GQ X120/Max/2050
		RQ-19-6A	100 tests	
	Quantification standards for *Human herpes virus* type 7	RQ-20-SM	12 runs	Manual
		RQ-20-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**HHV 8**	Identification of ***Human herpes virus* type 8**	RQ-17-4M	50 tests	Manual
		RQ-17-6M	100 tests	
		RQ-17-4A	50 tests	GQ X120/Max/2050
		RQ-17-6A	100 tests	
	Quantification standards for *Human herpes virus* type 8	RQ-18-SM	12 runs	Manual
		RQ-18-SA	9 runs	GQ X120/Max/2050

Transplant monitoring

Product	Description	Code	Pkg	Application
REALQUALITY RS-**VZV**	Identification of ***Varicella-zoster virus***	RQ-35-4M	50 tests	Manual
		RQ-35-6M	100 tests	
		RQ-35-4A	50 tests	GQ X120/Max/2050
		RQ-35-6A	100 tests	
	Quantification standards for *Varicella-zoster virus*	RQ-36-SM	12 runs	Manual
		RQ-36-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**PARVO B19**	Identification of ***Parvovirus B19***	RQ-37-4M	50 tests	Manual
		RQ-37-6M	100 tests	
		RQ-37-4A	50 tests	GQ X120/Max/2050
		RQ-37-6A	100 tests	
	Quantification standards for *Parvovirus B19*	RQ-38-SM	12 runs	Manual
		RQ-38-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**BKV** v2.0	Identification of ***BK virus***	RQ-49-4M	50 tests	Manual
		RQ-49-6M	100 tests	
		RQ-49-4A	50 tests	GQ X120/Max/2050
		RQ-49-6A	100 tests	
	Quantification standards for *BK virus*	RQ-50-SM	12 runs	Manual
		RQ-50-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**JCV**	Identification of ***JC virus***	RQ-83-4M	50 tests	Manual
		RQ-83-6M	100 tests	
		RQ-83-4A	50 tests	GQ X120/Max/2050
		RQ-83-6A	100 tests	
	Quantification standards for *JC virus*	RQ-84-SM	12 runs	Manual
		RQ-84-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**ENTERO**	Identification of ***Enterovirus***	RQ-89-4M	50 tests	Manual
		RQ-89-6M	100 tests	
		RQ-89-4A	50 tests	GQ X120/Max/2050
		RQ-89-6A	100 tests	
	Quantification standards for *Enterovirus*	RQ-90-SM	12 runs	Manual
		RQ-90-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**ADENO**	Identification of ***Adenovirus***	RQ-93-4M	50 tests	Manual
		RQ-93-6M	100 tests	
		RQ-93-4A	50 tests	GQ X120/Max/2050
		RQ-93-6A	100 tests	
	Quantification standards for *Adenovirus*	RQ-94-SM	12 runs	Manual
		RQ-94-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**MBT Complex**	Identification of ***Mycobacterium tuberculosis complex***	RQ-85-4M	50 tests	Manual
		RQ-85-6M	100 tests	
	Quantification standards for *Mycobacterium tuberculosis complex*	RQ-86-SM	12 runs	Manual
REALQUALITY RQ-**TOXO**	Identification of ***Toxoplasma gondii***	RQ-117-4M	50 tests	Manual
		RQ-117-6M	100 tests	
		RQ-117-4A	50 tests	GQ X120/Max/2050
		RQ-117-6A	100 tests	
REALQUALITY **ResP-PnJ** *	Identification and quantification (**standards** included) of ***Pneumocystis jirovecii***	RQ-150-6A	96 tests	Manual and GQ X120/Max/2050

* ***Lyophilized format***

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 ***Cytomegalovirus***	RQ-09-4M	50 tests	Manual
		RQ-09-6M	100 tests	
		RQ-09-4A	50 tests	GQ X120/Max/2050
		RQ-09-6A	100 tests	
	Quantification standards for *Cytomegalovirus*	RQ-10-SM	12 runs	Manual
		RQ-10-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**EBV**	Identification of ***Epstein-Barr virus***	RQ-11-4M	50 tests	Manual
		RQ-11-6M	100 tests	
		RQ-11-4A	50 tests	GQ X120/Max/2050
		RQ-11-6A	100 tests	
	Quantification standards for *Epstein-Barr virus*	RQ-122-SM	12 runs	Manual
		RQ-122-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HSV 1**	Identification of ***Herpes simplex virus* type 1**	RQ-05-4M	50 tests	Manual
		RQ-05-6M	100 tests	
		RQ-05-4A	50 tests	GQ X120/Max/2050
		RQ-05-6A	100 tests	
	Quantification standards for *Herpes simplex virus* type 1	RQ-06-SM	12 runs	Manual
		RQ-06-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HSV 2**	Identification of ***Herpes simplex virus* type 2**	RQ-07-4M	50 tests	Manual
		RQ-07-6M	100 tests	
		RQ-07-4A	50 tests	GQ X120/Max/2050
		RQ-07-6A	100 tests	
	Quantification standards for *Herpes simplex virus* type 2	RQ-108-SM	12 runs	Manual
		RQ-108-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**HHV 6**	Identification of ***Human herpes virus* type 6**	RQ-15-4M	50 tests	Manual
		RQ-15-6M	100 tests	
		RQ-15-4A	50 tests	GQ X120/Max/2050
		RQ-15-6A	100 tests	
	Quantification standards for *Human herpes virus* type 6	RQ-16-SM	12 runs	Manual
		RQ-16-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**HHV 7**	Identification of ***Human herpes virus* type 7**	RQ-19-4M	50 tests	Manual
		RQ-19-6M	100 tests	
		RQ-19-4A	50 tests	GQ X120/Max/2050
		RQ-19-6A	100 tests	
	Quantification standards for *Human herpes virus* type 7	RQ-20-SM	12 runs	Manual
		RQ-20-SA	9 runs	GQ X120/Max/2050
REALQUALITY RS-**VZV**	Identification of ***Varicella-zoster virus***	RQ-35-4M	50 tests	Manual
		RQ-35-6M	100 tests	
		RQ-35-4A	50 tests	GQ X120/Max/2050
		RQ-35-6A	100 tests	
	Quantification standards for *Varicella-zoster virus*	RQ-36-SM	12 runs	Manual
		RQ-36-SA	9 runs	GQ X120/Max/2050

Meningitis/Encephalitis

Product	Description	Code	Pkg	Application
REALQUALITY RQ-**ADENO**	Identification of ***Adenovirus***	RQ-93-4M	50 tests	Manual
		RQ-93-6M	100 tests	
		RQ-93-4A	50 tests	GQ X120/Max/2050
		RQ-93-6A	100 tests	
	Quantification standards for *Adenovirus*	RQ-94-SM	12 runs	Manual
		RQ-94-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**ENTERO**	Identification of ***Enterovirus***	RQ-89-4M	50 tests	Manual
		RQ-89-6M	100 tests	
		RQ-89-4A	50 tests	GQ X120/Max/2050
		RQ-89-6A	100 tests	
	Quantification standards for *Enterovirus*	RQ-90-SM	12 runs	Manual
		RQ-90-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**PARVO B19**	Identification of ***Parvovirus B19***	RQ-37-4M	50 tests	Manual
		RQ-37-6M	100 tests	
		RQ-37-4A	50 tests	GQ X120/Max/2050
		RQ-37-6A	100 tests	
	Quantification standards for *Parvovirus B19*	RQ-38-SM	12 runs	Manual
		RQ-38-SA	9 runs	GQ X120/Max/2050
REALQUALITY **ResP-HNS** *	Identification of ***Haemophilus influenzae***, ***Neisseria meningitidis*** and ***Streptococcus pneumoniae***	RQ-151-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **Meningo Bact** *	Identification of ***Streptococcus agalactiae***, ***Listeria monocytogenes*** and ***Escherichia coli***	RQ-152-6A	96 tests	Manual and GQ X120/Max/2050

** Lyophilized format*

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 ***Adenovirus***	RQ-93-4M	50 tests	Manual
		RQ-93-6M	100 tests	
		RQ-93-4A	50 tests	GQ X120/Max/2050
		RQ-93-6A	100 tests	
	Quantification standards for *Adenovirus*	RQ-94-SM	12 runs	Manual
		RQ-94-SA	9 runs	GQ X120/Max/2050
REALQUALITY RQ-**MBT Complex**	Identification of ***Mycobacterium tuberculosis complex***	RQ-85-4M	50 tests	Manual
		RQ-85-6M	100 tests	
	Quantification standards for *Mycobacterium tuberculosis complex*	RQ-86-SM	12 runs	Manual

Respiratory infections

Product	Description	Code	Pkg	Application
REALQUALITY **ResP-PnJ** *	Identification and quantification (***standard*** included) of ***Pneumocystis jirovecii***	RQ-150-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **ResP-BORD** *	Identification of ***Bordetella pertussis***, ***Bordetella parapertussis*** and ***Bordetella holmesii***	RQ-147-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **ResP-HSM** *	Identification of ***Haemophilus influenzae***, ***Streptococcus pneumoniae*** and ***Moraxella catarrhalis***	RQ-148-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **ResP-HNS** *	Identification of ***Haemophilus influenzae***, ***Neisseria meningitidis*** and ***Streptococcus pneumoniae***	RQ-151-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY RQ-**ENTERO**	Identification of ***Enterovirus***	RQ-89-4M	50 tests	Manual
		RQ-89-6M	100 tests	
		RQ-89-4A	50 tests	GQ X120/Max/2050
		RQ-89-6A	100 tests	
	Quantification standards for Enterovirus	RQ-90-SM	12 runs	Manual
		RQ-90-SA	9 runs	GQ X120/Max/2050
REALQUALITY **ResP-Aria**	Identification of respiratory viruses ***Severe Acute Respiratory Syndrome Coronavirus 2*** (**SARS-CoV-2**), ***Influenza A, Influenza B*** and ***Respiratory Syncytial Virus*** (**RSV**)	RQ-133-6M	100 tests	Manual
		RQ-133-6A	100 tests	GQ X120
REALQUALITY **ResP-REM**	Identification of ***Respiratory Syncytial Virus*** (RSV), ***metapneumovirus*** (MPV) and ***enterovirus*** (EV)	RQ-134-6M	100 tests	Manual
		RQ-134-6A	100 tests	GQ X120/Max/2050
REALQUALITY **SARS-CoV-2 5G**	Identification of the ORF1ab, N and S genes of *Severe Acute Respiratory Syndrome coronavirus 2* (***SARS-CoV-2***)	RQ-140-4M	50 tests	Manual
		RQ-140-6M	100 tests	
		RQ-140-6A	100 tests	GQ X120/Max/2050
REALQUALITY **InFLU-Typing** *	Identification of ***Influenza* A (H1N1) pdm09**, **H3N2**, **H5N1** and **H7N9** subtypes	RQ-141-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **P-InFLU** *	Identification of ***Parainfluenza 1, Parainfluenza 2, Parainfluenza 3*** and ***Parainfluenza 4***	RQ-142-4A	48 tests	Manual and GQ X120/Max/2050
REALQUALITY **ResP-AMB** *	Identification of ***Adenovirus***, ***Metapneumovirus*** and ***Bocavirus***	RQ-143-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **ResP-RhinEV** *	Identification of ***Rhinovirus*** and ***Enterovirus***	RQ-144-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **Mers-CoV** *	Identification of ***MERS Coronavirus*** (MERS-CoV)	RQ-145-4A	48 tests	Manual and GQ X120/Max/2050
REALQUALITY **h-CoVs** *	Identification of ***Coronavirus* 229E**, **NL63**, **OC43**, **HKU1**	RQ-146-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **GAS** *	Identification of ***Streptococcus pyogenes*** (group A (beta-hemolytic) Streptococcus(Strep-A))	RQ-149-6A	96 tests	Manual and GQ X120/Max/2050

* *Lyophilized format*

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**	**14 GENOTYPES** Identification of **14 HPV genotypes with high oncogenic risk:** 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. **Genotyping of HPV 16 and HPV 18.**	RQ-97-4M	50 tests	Manual
		RQ-97-6M	100 tests	
		RQ-97R-4M	50 tests	Manual LC 480 II
		RQ-97R-6M	100 tests	
REALQUALITY **RQ-HPV Screen**	**14 GENOTYPES** Identification of **14 HPV genotypes with high oncogenic risk**: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. **Genotyping of HPV 16 and HPV 18.** Validated according to Meijer guidelines (Iacobellis et al., 2018; Meijer C. et al., 2009)	RQ-123-4M	50 tests	Manual
		RQ-123-6M	100 tests	
		RQ-123-4A	50 tests	GQ X120/Max/2050
		RQ-123-6A	100 tests	
REALQUALITY **RQ-HPV HR/LR Multiplex**	**22 GENOTYPES** Identification of **14 genotypes at high oncogenic risk, 6 at possible high oncogenic risk and 2 at low oncogenic risk** of *Human Papilloma Virus*. **Genotyping of HPV 6, HPV 11, HPV 16 and HPV 18**.	RQ-99-4M	50 tests	Manual
		RQ-99-6M	100 tests	
		RQ-99R-4M	50 tests	Manual LC 480 II
		RQ-99R-6M	100 tests	
		RQ-99-4A	50 tests	GQ X120/Max/2050
		RQ-99-6A	100 tests	
REALQUALITY **RQ-Multi HPV Detection**	**28 GENOTYPES** Identification of **14 genotypes at high oncogenic risk, 6 at possible high oncogenic risk and 8 at low oncogenic risk** of the *Human Papilloma Virus*. **Genotyping of HPV 16 and HPV 18.**	RQ-103-4M	50 tests	Manual
		RQ-103-6M	100 tests	
		RQ-103R-4M	50 tests	Manual LC 480 II
		RQ-103R-6M	100 tests	
		RQ-103-4A	50 tests	GQ X120/Max/2050
		RQ-103-6A	100 tests	
REALQUALITY **RQ-SevenSTI**	Identification of ***Chlamydia trachomatis***, ***Neisseria gonorrhoeae***, ***Mycoplasma genitalium***, ***Mycoplasma hominis***, ***Trichomonas vaginalis***, ***Ureaplasma urealyticum*** *and* ***Ureaplasma parvum***	RQ-127-4M	50 tests	Manual
		RQ-127-6M	100 tests	
		RQ-127-4A	50 tests	GQ X120/Max/2050
		RQ-127-6A	100 tests	
REALQUALITY **RQ-STI CT/NG/MG**	Identification of ***Chlamydia trachomatis***, ***Neisseria gonorrhoeae*** *and* ***Mycoplasma genitalium***	RQ-107-4M	50 tests	Manual
		RQ-107-6M	100 tests	
		RQ-107-4A	50 tests	GQ X120/Max/2050
		RQ-107-6A	100 tests	
REALQUALITY **RQ-STI CT**	Identification of ***Chlamydia trachomatis***	RQ-109-4M	50 tests	Manual
		RQ-109-6M	100 tests	
		RQ-109-4A	50 tests	GQ X120/Max/2050
		RQ-109-6A	100 tests	

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 ***Adenovirus***	RQ-93-4M	50 tests	Manual
		RQ-93-6M	100 tests	
		RQ-93-4A	50 tests	GQ X120/Max/2050
		RQ-93-6A	100 tests	
	Quantification standards for *Adenovirus*	RQ-94-SM	12 runs	Manual
		RQ-94-SA	9 runs	GQ X120/Max/2050
REALQUALITY **NoroV** *	Identification of ***Norovirus* (GI)** and ***Norovirus* (GII)**	RQ-153-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **AstroV** *	Identification of ***Astrovirus***	RQ-154-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **RotaV** *	Identification of ***Rotavirus A***	RQ-155-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **ETEC/EIEC** *	Identification of Enterotoxigenic *Escherichia coli* ***(ETEC)*** and Enteroinvasive *Escherichia coli* ***(EIEC)/Shigella***	RQ-156-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **EHEC/EPEC/EIEC** *	Identification of Enterohemorrhagic ***(EHEC),*** Shiga toxin producing ***(STEC),*** Enteropathogenic ***(EPEC)*** *Escherichia coli* and Enteroinvasive *Escherichia coli* ***(EIEC)/Shigella***	RQ-157-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **SCS/EIEC** *	Identification of ***Salmonella***, ***Campylobacter*** and *Shigella/Escherichia coli* **EIEC**	RQ-158-6A	96 tests	Manual and GQ X120/Max/2050
REALQUALITY **Gastro-P** *	Identification of ***Cryptosporidium***, ***Giardia lamblia*** and ***Entamoeba histolytica***	RQ-159-6A	96 tests	Manual and GQ X120/Max/2050

* ***Lyophilized format***

Fungal infections

Candida is a type of yeast that normally colonized the human body. Infections caused by Candida can range from mild conditions like oral or vaginal candidiasis to severe systemic infections. Candida is a significant contributor to nosocomial infections, especially in patients undergoing antibiotic or immunocompromised treatments.
Aspergillus is a type of filamentous fungi commonly found in the environment. Infections by Aspergillus, known as aspergillosis, can impact the respiratory system, particularly in immunocompromised patients, leading to symptoms such as fever, cough, and respiratory difficulties. These infections can also spread to other organs, posing a serious health risk.

Product	Description	Code	Pkg	Application
REALQUALITY **Candida Plus**	Identification of ***Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida spp.***	RQ-174-4M	50 tests	Manual
		RQ-174-6M	100 tests	
		RQ-174-4A	50 tests	GQ X120/Max/2050
		RQ-174-6A	100 tests	
REALQUALITY **Aspergillus**	Identification of ***Aspergillus fumigatus, Aspergillus terreus, Aspergillus spp.***	RQ-171-4M	50 tests	Manual
		RQ-171-6M	100 tests	
		RQ-171-4A	50 tests	GQ X120/Max/2050
		RQ-171-6A	100 tests	

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 **HIV-1 DNA**	RQ-125-4M	50 tests	Manual
		RQ-125-6M	100 tests	
	Quantification standards for HIV-1 DNA	RQ-126-SM	10 runs	
	Beta Globin Standard	RQ-128-SM	10 runs	

Antibiotic resistance

Antimicrobial resistance (AMR) poses a global threat to health and development, necessitating urgent actions across various sectors to achieve the Sustainable Development Goals (SDGs). The World Health Organization (WHO) has declared AMR as one of the top ten global public health threats faced by humanity.
Mismanagement and abuse of antimicrobials are key factors fostering the development of drug-resistant pathogens. The economic costs of AMR are substantial. Apart from causing deaths and disabilities, resistant infections lead to longer hospital stays, the use of more expensive drugs, and pose financial challenges for those affected.
https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
Strategies to reduce the transmission of genes associated with various antimicrobial resistances in healthcare facilities primarily focus on early identification of infected patients and carriers, along with the widespread implementation of contact precautions.

Product	Description	Code	Pkg	Application
REALQUALITY **Carba-Screen**	Identification of **Carbapenem Resistance Classes** (Carbapenemases Class B, Class A+D, Acinetobacter OXA) **-Screening-**	RQ-170-6M Var C1	100 tests	Manual
		RQ-170-6A Var C1	100 tests	GQ X120/Max/2050
	Identification of genes encoding resistance to **carbapenems** and **colistin** (IMP, VIM, NDM, KPC, OXA-48, MCR1,2,4) **-Identification-**	RQ-170-4M Var C3	50 tests	Manual
		RQ-170-4A Var C3	50 tests	GQ X120/Max/2050

"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 RQ-**TOXO**	Identification of ***Toxoplasma gondii***	RQ-117-4M	50 tests	Manual
		RQ-117-6M	100 tests	
		RQ-117-4A	50 tests	GQ X120/Max/2050
		RQ-117-6A	100 tests	
REALQUALITY **BAC** *	Identification of ***Borrelia spp.***, ***Anaplasma phagocitophylum*** and ***Coxiella burnetii***	RQ-160-6A	96 tests	Manual and GQ X120/Max/2050

* *Lyophilized format*

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 **THROMBO FII-FVL**	Identification and genotyping of the **Factor II G20210A** and **Factor V Leiden** mutations	RQ-177-4M	50 tests	Manual
		RQ-177-6M	100 tests	
		RQ-177-4A	50 tests	GQ X120/Max/2050
		RQ-177-6A	100 tests	
REALQUALITY **THROMBO MTHFR**	Identification and genotyping of the **MTHFR C677T** and **MTHFR A1298C** mutations	RQ-178-4M	50 tests	Manual
		RQ-178-6M	100 tests	
		RQ-178-4A	50 tests	GQ X120/Max/2050
		RQ-178-6A	100 tests	
REALQUALITY RS-**FACTOR V LEIDEN**	Identification and genotyping of the **G1691A mutation (Leiden)** in the gene coding for Coagulation Factor V	RQ-25-4M	50 tests	Manual
		RQ-25-6M	100 tests	
		RQ-25-4A	50 tests	GQ X120/Max/2050
		RQ-25-6A	100 tests	
REALQUALITY RS-**FACTOR V H1299R**	Identification and genotyping of the **H1299R** mutation (HR2 haplotype) in the gene coding for Coagulation Factor V	RQ-111-4M	50 tests	Manual
		RQ-111-6M	100 tests	
		RQ-111-4A	50 tests	GQ X120/Max/2050
		RQ-111-6A	100 tests	
REALQUALITY RQ-**FACTOR V Y1702C**	Identification and genotyping of the **Y1702C** mutation in the gene coding for Coagulation Factor V	RQ-69-4M	50 tests	Manual
		RQ-69-6M	100 tests	
		RQ-69-4A	50 tests	GQ X120/Max/2050
		RQ-69-6A	100 tests	
REALQUALITY RS-**FACTOR II G20210A**	Identification and genotyping of the **G20210A** mutation in the gene coding for Coagulation Factor II	RQ-27-4M	50 tests	Manual
		RQ-27-6M	100 tests	
		RQ-27-4A	50 tests	GQ X120/Max/2050
		RQ-27-6A	100 tests	
REALQUALITY RS-**MTHFR A1298C**	Identification and genotyping of the **A1298C** mutation in the gene coding for MTHFR	RQ-31-4M	50 tests	Manual
		RQ-31-6M	100 tests	
		RQ-31-4A	50 tests	GQ X120/Max/2050
		RQ-31-6A	100 tests	
REALQUALITY RS-**MTHFR C677T**	Identification and genotyping of the **C677T** mutation in the gene coding for MTHFR	RQ-29-4M	50 tests	Manual
		RQ-29-6M	100 tests	
		RQ-29-4A	50 tests	GQ X120/Max/2050
		RQ-29-6A	100 tests	
REALQUALITY RQ-**PAI-1 4G/5G**	Identification and genotyping of the **-675 4G/5G** polymorphism in the gene coding for the plasminogen activator type 1 inhibitor	RQ-119-4M	50 tests	Manual
		RQ-119-6M	100 tests	
		RQ-119-4A	50 tests	GQ X120/Max/2050
		RQ-119-6A	100 tests	
REALQUALITY RQ-**ACE (I/D)**	Identification and genotyping of the **insertion/deletion (I/D)** polymorphism in the **intron 16** of the gene coding for the angiotensin converting enzyme (ACE)	RQ-75-4M	50 tests	Manual
		RQ-75-6M	100 tests	
		RQ-75-4A	50 tests	GQ X120/Max/2050
		RQ-75-6A	100 tests	

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 **C282Y** mutation in the HFE gene	RQ-39-4M	50 tests	Manual
		RQ-39-6M	100 tests	
		RQ-39-4A	50 tests	GQ X120/Max/2050
		RQ-39-6A	100 tests	
REALQUALITY RS-**HEMO H63D**	Identification and genotyping of the **H63D** mutation in the HFE gene	RQ-41-4M	50 tests	Manual
		RQ-41-6M	100 tests	
		RQ-41-4A	50 tests	GQ X120/Max/2050
		RQ-41-6A	100 tests	
REALQUALITY RQ-**HEMO S65C**	Identification and genotyping of the **S65C** mutation in the HFE gene	RQ-43-4M	50 tests	Manual
		RQ-43-6M	100 tests	
		RQ-43-4A	50 tests	GQ X120/Max/2050
		RQ-43-6A	100 tests	

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 ***t(9;22) (q34;q11), variant p210 – BCR-ABL p210(M-bcr)*** Reverse transcription and PCR in **one step**	RQ-105-4M	50 tests	Manual
		RQ-105-6M	100 tests	
	Single-plasmid **quantification standards** for *BCR-ABL p210 (M-bcr), ABL* and *GUSB* transcripts	RQ-54-SM	6 runs	
REALQUALITY RQ-**BCR-ABL p190 One-Step**	Identification of translocation ***t(9;22) (q34;q11), variant p190 – BCR-ABL p190(m-bcr)*** Reverse transcription and PCR in **one step**	RQ-115-4M	50 tests	Manual
		RQ-115-6M	100 tests	
	Single-plasmid **quantification standards** for *BCR-ABL p190 (m-bcr), ABL* transcripts	RQ-116-SM	6 runs	
REALQUALITY RS-**WT-1**	Identification of the expression of **Wilms Tumor (WT 1) gene**	RQ-S57-48	48 tests	Manual
		RQ-S57-96	96 tests	
	Quantification standards for WT 1 and the ABL gene transcripts	RQ-58-ST	10 runs	

Oncohematology

Product	Description	Code	Pkg	Application
REALQUALITY RS-**AML1-ETO**	Identification of the **t(8;21) (q22;q22) translocation**	RQ-S59-48	48 tests	Manual
		RQ-S59-96	96 tests	
	Quantification standards for AML1-ETO and ABL transcripts	RQ-60-ST	10 runs	
REALQUALITY RS-**INV 16**	Identification of the **inv(16)(p13;q22) inversion**	RQ-S61-48	48 tests	Manual
		RQ-S61-96	96 tests	
	Quantification standards for INV-16 and ABL transcripts	RQ-62-ST	10 runs	
REALQUALITY RQ-**PML-RARa bcr1 One-Step**	Identification of translocation ***t(15;17) (q22;q21), variant bcr1 – PML-RARA bcr1***	RQ-179-4M	50 tests	Manual
		RQ-179-6M	100 tests	
	Quantification standards for *PML-RARA bcr1* and *ABL* transcripts	RQ-180-SM	6 runs	
REALQUALITY RQ-**PML-RARa bcr2 One-Step**	Identification of translocation ***t(15;17) (q22;q21), variant bcr2 – PML-RARA bcr2***	RQ-181-4M	50 tests	Manual
		RQ-181-6M	100 tests	
	Quantification standards for *PML-RARA bcr2* and *ABL* transcripts	RQ-182-SM	6 runs	
REALQUALITY RQ-**PML-RARa bcr3 One-Step**	Identification of translocation ***t(15;17) (q22;q21), variant bcr3 – PML-RARA bcr3***	RQ-183-4M	50 tests	Manual
		RQ-183-6M	100 tests	
	Quantification standards for *PML-RARA bcr3* and *ABL* transcripts	RQ-184-SM	6 runs	
p210 RNA Reference	**Reference RNA** for molecular identification and/or quantification of the **BCR-ABL p210 transcript**	RQ-185-SM	10 runs	Manual

Other reagents

Product	Description	Code	Pkg	Application
Rev-T Kit RQ variant	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.

REALQUALITY LC 2.0 Color compensation kit	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
REALQUALITY LC 480 Color compensation kit	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 **AB-THROMBO TYPE PLUS**	Simultaneous identification of mutations in the genes coding for **Factor V Leiden G1691A (Arg506Gln), Factor II G20210A, MTHFR C677T, MTHFR A1298C, PAI 1 4G/5G, Factor V (HR2) H1299R** 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

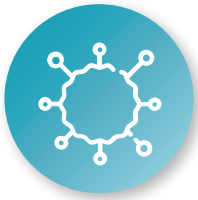
Some genetic disorders can predispose to the onset of celiac disease, microdeletions of the Y chromosome can instead lead to infertility. Molecular analysis of these genetic alterations makes it possible to accurately diagnose the predisposition to these pathologies.

Product	Description	Code	Pkg	Application
GENEQUALITY **AZF Y-TYPE**	Identification of **deletions at the AZF locus** 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 **CD-TYPE v2.0**	Identification of genetic susceptibility to **celiac disease** 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

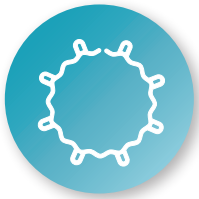
HCV



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 **genotypes 1-7** of the Hepatitis C virus (HCV) and **subtypes a and b of genotype 1**, 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

HPV



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: **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**	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

GENEQUALITY® Whole Exome Sequencing

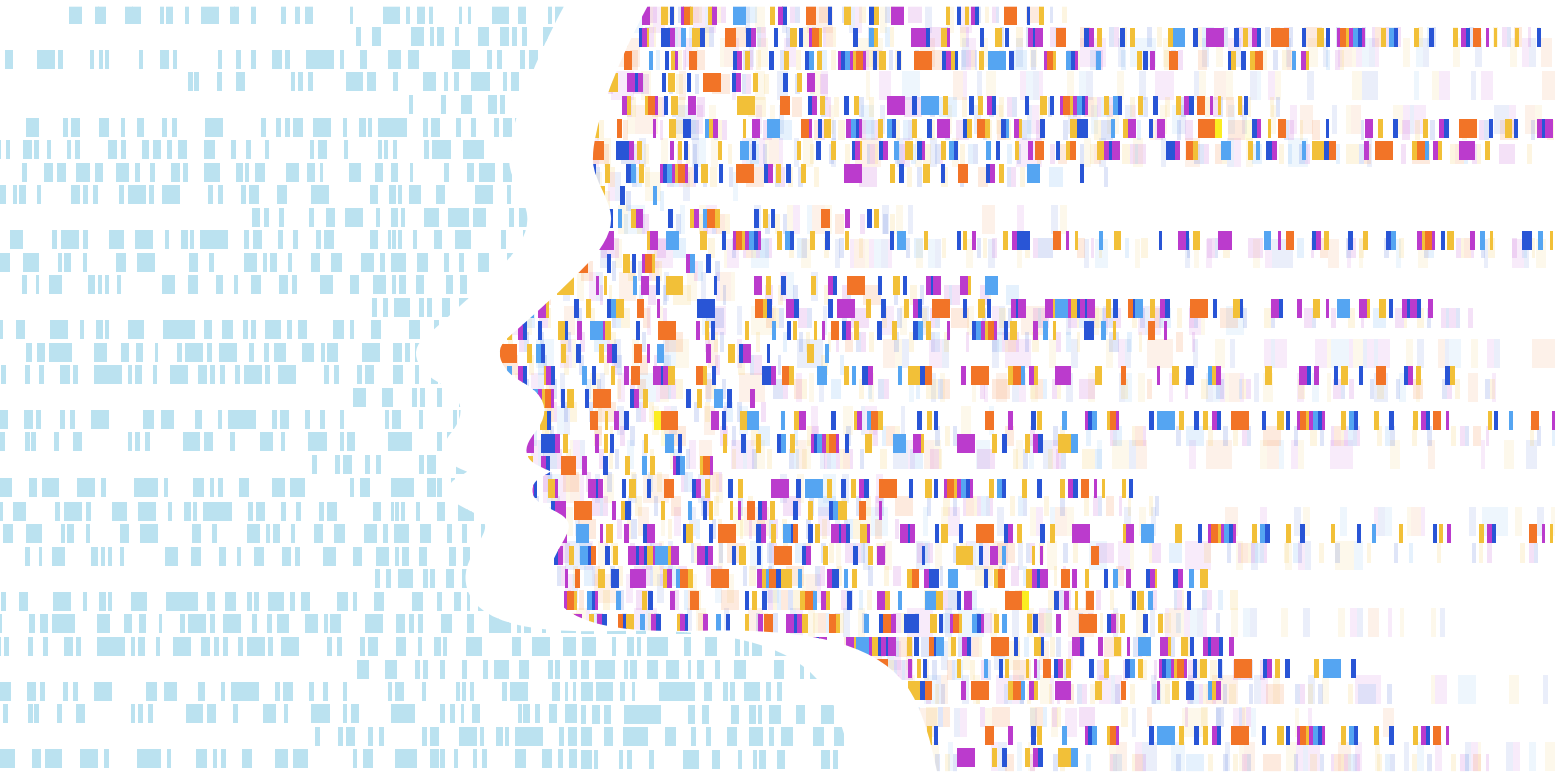
GENEQUALITY Library Prep, GENEQUALITY Purification Kit, and GENEQUALITY Unique Dual Indexes are in vitro diagnostic medical devices intended to be used together by qualified personnel for the preparation of libraries for subsequent diagnostic applications based on Next-Generation Sequencing (NGS) techniques. 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
GENEQUALITY® Library Prep	04-N01-6M	96 tests
GENEQUALITY® Purification kit	04-N02-6M	96 tests
GENEQUALITY® Unique Dual Indexes	04-N03-6M	96 tests
GENEQUALITY® Whole Exome Sequencing	04-NWE-6M	8x12 rxns

Next-Generation Sequencing

EU-IVDR



Instruments

Automated systems

Automated extraction and PCR setup

GENEQUALITY® X120

GENEQUALITY® X120 is a completely automated CE IVD 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.
- Extraction protocol is based on magnetic beads with preloaded cartridges.
- Full traceability of the entire workflow.
- Touch screen interface software.
- Decontamination control with the integrated UV lamp.
- Direct exportation of PCR configuration files.
- Bidirectional interface to the laboratory management system.

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

Automated systems

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).
- Simultaneous management of two distinct thermal amplification profiles.
- Extraction system based on the use of magnetic beads with preloaded cartridges.
- Complete traceability of the entire workflow.
- Software with touch screen interface.
- 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
GENEQUALITY® Max	"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
GENEQUALITY® X120 Pathogen kit	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
IC RNA (4,2 ml)	RNA internal control	05-76-04	100 tests
IC DNA (4,2 ml)	DNA internal control	05-78-04	100 tests
AMR Extraction Control	Internal control associated with the REALQUALITY Carba-Screen kit.	05-80-04	100 tests
GENEQUALITY® X120 LB-P	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
Work Plate	Work Plate, 2 mL, sterile for GENEQUALITY® X120	20-43001-0200	10 pcs
Elution Plate	Elution Plate, 1 mL, sterile for GENEQUALITY® X120	20-43001-1016	10 pcs
Filter tips, 300 uL	Filter tips, 300 uL for GENEQUALITY® X120	20-49008-0104	5760 pcs
Filter tips, 1000 uL	Filter tips, 1000 uL for GENEQUALITY® X120	20-49009-0104	3840 pcs
Filter tips, 50 uL	Filter tips, 50 uL for GENEQUALITY® X120	20-49010-0104	5760 pcs
"96-well PCR plate Aria Dx"	96-well PCR plate, with low border profile (for Real-Time Aria Dx Thermal Cycler)	AB-E1403-5200	10 pcs
Strips of 8 flat optical caps Aria Dx	Strips of 8 flat optical caps (for Real-Time Aria Dx Thermal Cycler)	AB-I1400-0900	125 pcs
96-well PCR plate, with low border profile	96-well PCR plate, with low border profile	AB-401491	25 pcs
Mx3000P Optical Strip Caps	Mx3000P Optical Strip Caps	AB-401425	120 pcs
96 well 0.1 mL white plates with barcode Bio-Rad CFX 96™	96 well 0.1 mL white plates (for Real-Time Bio-Rad CFX 96™ thermal cycler)	BP-B17489	25 pcs
Optical cap strip for Bio-Rad CFX 96™	Optical cap strips for PCR Real-Time PCR (for Bio-Rad CFX 96 Real-Time Thermal Cycler)	BP-B57801B	300 pcs
Waste bags	Waste bags for GENEQUALITY® X120	20-199202	25 pcs
2 mL microtube	2 mL microtube, Flat, no-grad, Sterile	20-72664	500 pcs
Screw cap for 2mL microtube	Screw cap for 2mL microtube	20-65716	500 pcs
Aluminium cover film	Aluminium cover film, -80°C to +120°C	20-94001-0216	100 pcs
Hamilton MIC Tubes & V-Caps	Hamilton MIC Tubes & V-Caps (GENEQUALITY® Max)	20-10110770	960 pcs

Automated systems

GENEQUALITY 2050
TwentyFifty

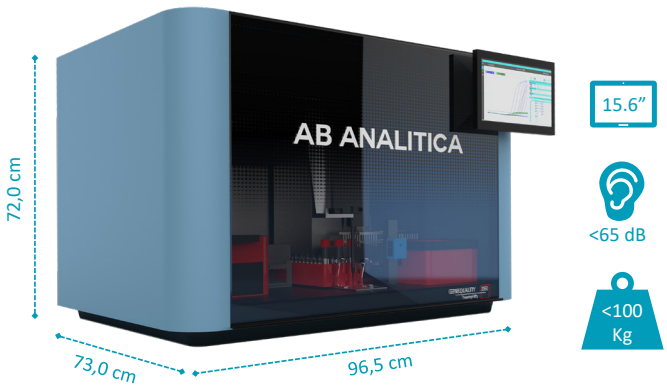
Fully Integrated System
Sample To Result

GENEQUALITY® TWENTYFIFTY (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
GENEQUALITY® 2050	Fully integrated Sample-To-Result Real-Time PCR system.	08-GQ2050-01	1 instrument
GENEQUALITY® 2050 Extraction	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

Real-Time PCR systems

AriaDx

Real-Time PCR thermal cycler from 1 to 6 channels configurable on site with modular optical cartridges (Agilent Technologies).

- Led optical technology.
- Ready-to-go instrument, no calibration required.
- Programming with touch screen interface.
- Possible normalization with reference dye (ROX™).
- Possibility to upgrade optical channels.

Agilent Technologies

This instrument can be sold exclusively in association with the AB ANALITICA kits.

Product	Description	Code	Pkg
AriaDx	Real-Time PCR thermal cycler with 4 channels (SYBR/FAM, ROX, HEX, CY5)	08-ARDX-01	1 instrument
AriaDx	Real-Time PCR thermal cycler with 5 channels (SYBR/FAM, ROX, HEX, CY5, CY3)	08-ARDX-02	1 instrument
AriaDx	Real-Time PCR thermal cycler with 6 channels (SYBR/FAM, ROX, HEX, CY5, CY3, ATTO425)	08-ARDX-03	1 instrument

Mic qPCR Cycler

Real-Time PCR rotor cycler with 4 optical channels (Bio Molecular Systems).

- *48 position rotor.*
- *Thermal system based on magnetic induction technology.*
- *Reaction volumes up to 30 uL.*
- *No need for color compensation and calibration.*
- *User specific settings and flexible system configurations.*

bms bio molecular systems

This instrument can be sold exclusively in association with the AB ANALITICA kits and in some geographic areas only.

Product	Description	Code	Pkg
Mic qPCR Cycler	Rotor Real-Time PCR thermal cycler with 4 optical channels	08-MIC	1 pcs

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

Breath Test

BREATHQUALITY UBT

^{13}C-UREA Breath test for diagnosis of gastroduodenal infection by Helicobacter pylori.

Oral solution, single dose (75 mg ^{13}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
BREATHQUALITY - UBT	Breath test for in vivo diagnosis of gastroduodenal infection by Helicobacter pylori. Oral solution, single dose (75 mg 13C 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
AB 13C-AMINOPIRINA	**^{13}C Aminopyrine:** Substrate for study of liver function	13-01A-75
AB 13C-METACETINA	**^{13}C Methacetin:** Substrate for study of liver function	13-02A-75
AB 13C-TRIGLICERIDI MISTI	**Mixed ^{13}C Triglycerides:** Substrate for study of pancreatic lipase activity in the duodenum	13-07A-250
AB 13C-ACIDO OTTANOICO	**^{13}C Octanoic Acid:** Substrate for evaluation of gastric emptying	13-09A-100

Notes

Notes

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