



RealCycler

Real-Time PCR products



I will go anywhere provided it is forward.

Dr. Livingstone

Products Portfolio

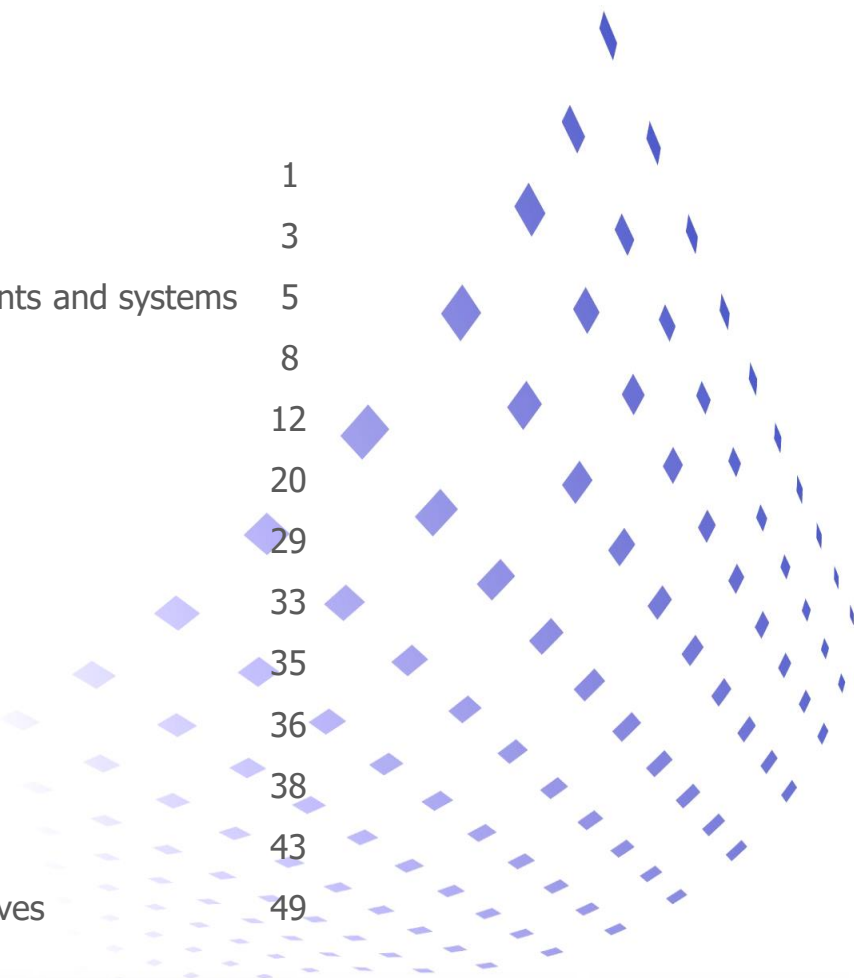
PROGENIE
MOLECULAR



RealCycler®

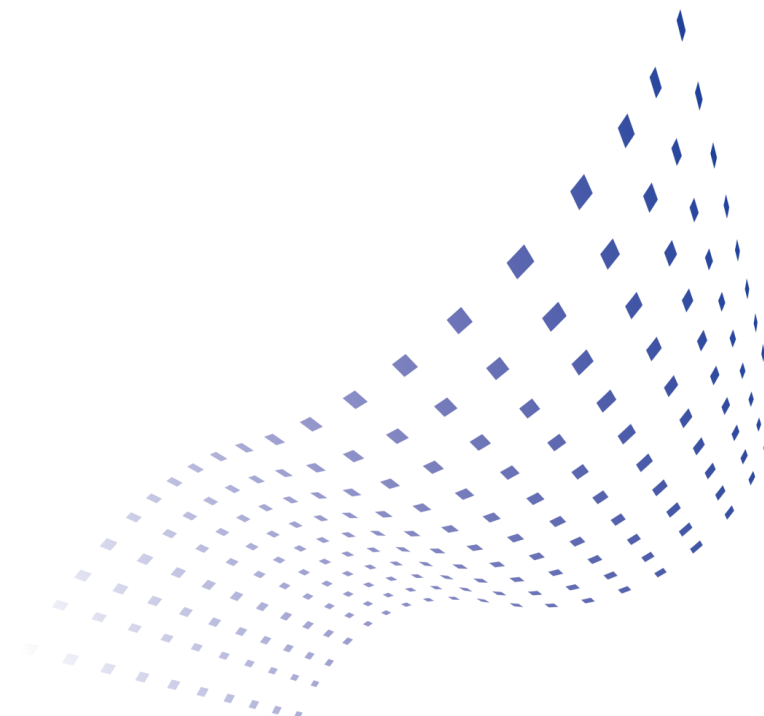
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Available formats

(same reagent in different presentations)



AVAILABLE FORMATS

(same reagent in different presentations)

Monotest CFX96



Monotest ABI



Monotest Flash 20



Universal



Chic-Out



Exclusive for CFX96 (Bio-Rad) instrument.

Prealiquoted in specific tubes.

Ready to add DNA/RNA and amplify.

Ideal for laboratories with high workload looking to minimize hands-on time.

Number of tests:
32 tests (ref. -CFX32)
96 tests (ref. -CFX96)

Instruments that use standard 0,2 ml PCR tubes.

Prealiquoted in 0,2 ml microtubes, ready to add DNA/RNA and amplify.

Ideal for laboratories with high workload looking to minimize hands-on time.

Number of tests:
32 tests (ref. -ABI32)
96 tests (ref. -ABI96)

Exclusive for Flash 20 instrument

Prealiquoted in specific tubes.

Ready to add DNA/RNA and amplify.

Ideal for laboratories with high workload looking to minimize hands-on time.

Number of tests:
24 tests (ej. CORO)

Compatible with most real-time PCR instruments.

Ideal for laboratories with a high or very high workload in which the aim is to minimize the cost in terms of time of handling reagents.

Ideal for automated equipment.

Number of tests:
30 tests (ref. -U)
60 tests (ref. -G)
100 tests (ref. -C)
1000 tests (ref. -M)

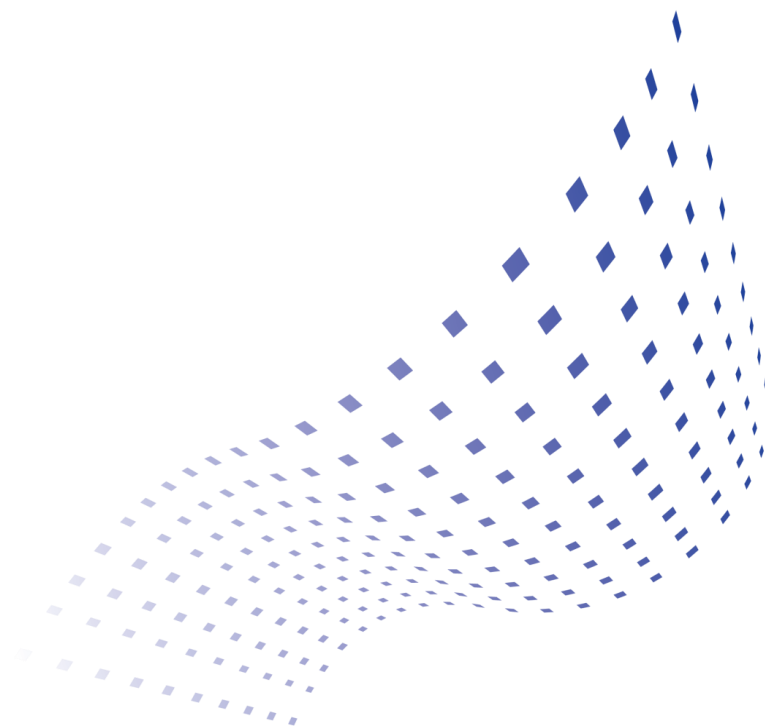
Compatible with most real-time PCR instruments.

Internal control CHIC (Competitive Heterologous Internal Control) supplied separately from the reaction mix to monitor the nucleic acids extraction.

Ideal for laboratories with a high or very high workload in which the aim is to minimize the cost in terms of time of handling reagents.

Number of tests:
30 tests (ref. -UX)
60 tests (ref. -GX)

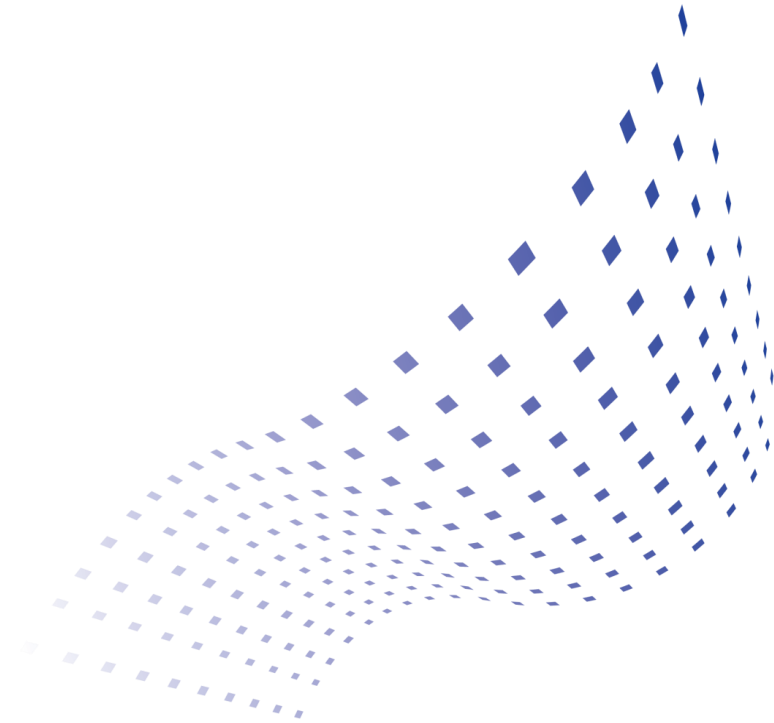
Validated qPCR instruments and systems



Validated qPCR instruments and systems

<p>Andana® 1216 (Progenie molecular)</p>	<p>Flash20™ (Coyote Bioscience)</p>	<p>QuantStudio™ 5 (ThermoFisher Scientific)</p>
		
<p>CFX96 (Bio-Rad)</p>	<p>Mic qPCR Cycler (Bio Molecular Systems)</p>	<p>SLAN®-96P Real-Time PCR System® (Sansure)</p>
		
<p>ABI 7500 (Thermo Fisher Scientific)</p>	<p>AriaDx® (Agilent Technologies)</p>	<p>RotorGene Q (Qiagen)</p>
		



Validated nucleic acid extraction instruments and systems



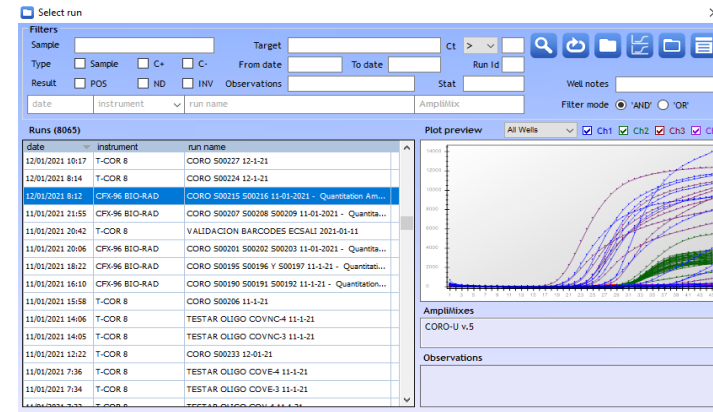
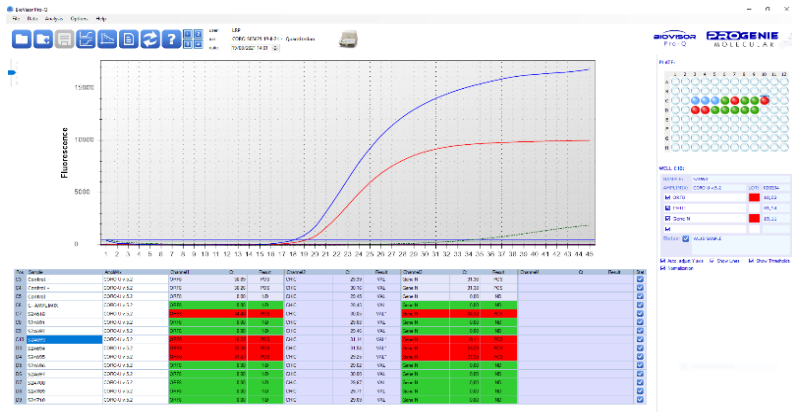
Validated nucleic acid extraction instruments and systems

Maxwell® 16 Instrument (Promega)	Maxwell® RSC Instrument (Promega)	Maxwell® RSC 48 Instrument (Promega)
 <p>The Maxwell 16 Instrument is a compact, white and black laboratory device with a front-loading sample tray and a control panel on top.</p>	 <p>The Maxwell RSC Instrument is a white and black laboratory device with a front-loading sample tray. It is shown alongside several clear plastic extraction tubes.</p>	 <p>The Maxwell RSC 48 Instrument is a larger white and black laboratory device with a top-mounted touchscreen display and a barcode scanner on the right side.</p>
MagCore® Automated Nucleic Acid Extractor (RBCBioscience)		QIAcube (Qiagen)
 <p>The MagCore Automated Nucleic Acid Extractor is a white laboratory instrument with a large front-loading window. It is shown next to its distinctive orange and white carrying case.</p>		 <p>The QIAcube is a white and blue laboratory instrument with a large front-loading window. It is shown with various extraction reagents and tubes.</p>

Validated nucleic acid extraction instruments and systems

KingFisher™ Flex Purification System (Thermo Scientific™)	BioRobot® EZ1™ (Qiagen)
 <p>The image shows the KingFisher Flex Purification System, a blue and white laboratory instrument with a circular sample tray. To its right are several bottles and boxes of reagents, including one labeled 'Applied Biosystems'.</p>	 <p>The image shows the BioRobot EZ1, a tall, white, vertical laboratory instrument. To its left are various reagent bottles and boxes, including one labeled 'Qiagen'.</p>
MagNA Pure. Roche Molecular Systems	NucliSENS® easyMAG®. bioMérieux
 <p>The image shows the MagNA Pure, a white and blue laboratory instrument with a large transparent window. To its right are boxes and bottles of reagents.</p>	 <p>The image shows the NucliSENS easyMAG, a white and blue laboratory instrument with a curved top and a transparent window. To its right are boxes and bottles of reagents.</p>

BIOVISOR Pro-Q



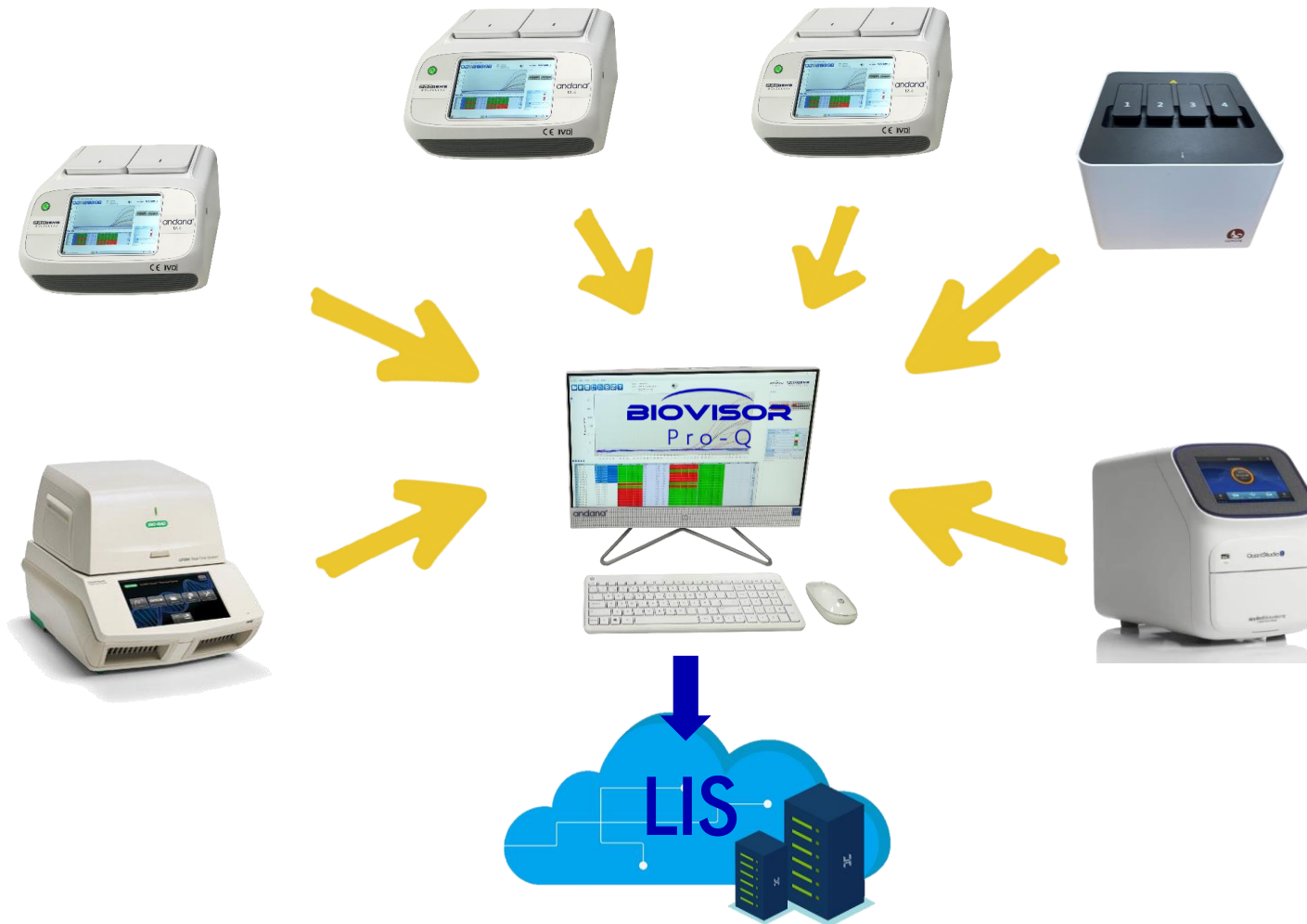
The **BioVisor® Pro-Q** software allows the automatic interpretation and prevalidation of the results obtained with the *RealCycler* products.

The **BioVisor® Pro-Q** imports the fluorescence data from the Real-time PCR instrument, it analyses it automatically and it issues a report with the results, or it exports them to a document in .csv or LIS format.

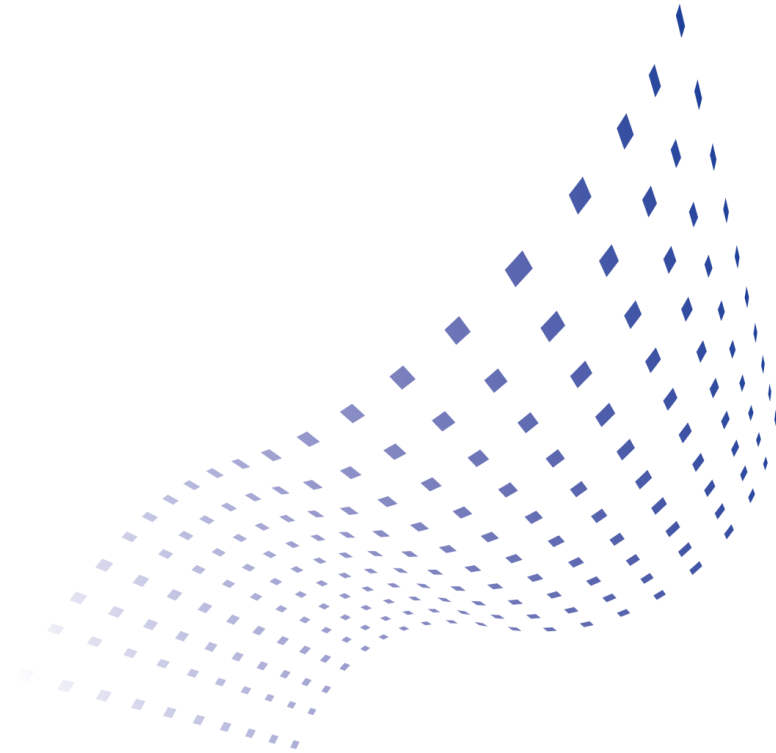
Specifications:

- CE-IVD marked.
- Users and licenses management.
- Management of all the runs from the different instruments in a single database.
- Predetermined fluorescence thresholds for each reference.
- Normalization of fluorescence values.
- Validation of the internal control of the sample.
- Series validation depending on the controls result.
- Monitoring of inhibitions.
- Allows the simultaneous quantification of several pathogens.
- Automatic calculation of the load of pathogen in the sample.
- Generation of a report with the results.
- Storage of runs, calibration curves and results.
- Connectivity with several instruments in a local area network and remotely.
- Validated instruments:
 - CFX96 (Bio-Rad)
 - QuantStudio (Thermo Fisher Scientific)
 - ABI7500 (Applied Biosystems, ThermoFisher Scientific)
 - MIC (Biomolecular Systems)
 - T-COR 8 (Cirrus Dx)
 - RotorGene (Qiagen)
 - SmartCycler (Cepheid)
 - SLAN-96P (SanSure Biotech)

Management of all PCR results on a single platform



List of references



Infectious meningoencephalitis

Application	Format	Ref.	Tests
Cytomegalovirus² DNA detection	Monotest CFX	CMVH-CFX32	32
	Monotest ABI	CMVH-ABI32	32
	Monotest Flash 20	CMVH	24
	Universal	CMVH-U	30
		CMVH-G	60
	Chic-Out	CMVH-UX	30
		CMVH-GX	60
Enterovirus (EV) RNA detection	Monotest CFX	ENTV-CFX32	32
	Monotest ABI	ENTV-ABI32	32
	Monotest Flash 20	ENTV	24
	Universal	ENTV-U	30
		ENTV-G	60
	Chic-Out	ENTV-UX	30
		ENTV-GX	60
Enterovirus (EV) + Herpes Simplex Virus (HSV-1 + HSV-2) + Varicella-Zoster Virus (VZV) DNA+RNA detection	Monotest CFX	ENHEVA-CFX32	32
	Monotest ABI	ENHEVA-ABI32	32
	Monotest Flash 20	ENHEVA	24
	Universal	ENHEVA-U	30
		ENHEVA-G	60
	Chic-Out	ENHEVA-UX	30
		ENHEVA-GX	60

Infectious meningoencephalitis

Application	Format	Ref.	Tests
Enterovirus (EV) + Parechovirus RNA detection	Monotest CFX	EVPA-CFX32	32
	Monotest ABI	EVPA-ABI32	32
	Monotest Flash 20	EVPA	24
	Universal	EVPA-U	30
		EVPA-G	60
	Chic-Out	EVPA-UX	30
		EVPA-GX	60
Enterovirus (EV) + Parechovirus + Mumps virus RNA detection	Monotest CFX	EVPEPA-CFX32	32
	Monotest ABI	EVPEPA-ABI32	32
	Monotest Flash 20	EVPEPA	24
	Universal	EVPEPA-U	30
		EVPEPA-G	60
	Chic-Out	EVPEPA-UX	30
		EVPEPA-GX	60
Enterovirus (EV) + Parechovirus + Mumps virus / Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) + Varicella-Zoster Virus (VZV) DNA+RNA detection	Monotest CFX	MENVIR-CFX32	16+16
	Monotest ABI	MENVIR-ABI32	16+16
	Monotest Flash 20	MENVIR	12+12
	Universal	MENVIR-U	15+15
		MENVIR-G	30+30
	Chic-Out	MENVIR-UX	15+15
		MENVIR-GX	30+30

Infectious meningoencephalitis

Application	Format	Ref.	Tests
Epstein-Barr Virus (EBV) DNA detection	Monotest CFX	EBAR-CFX32	32
	Monotest ABI	EBAR-ABI32	32
	Monotest Flash 20	EBAR	24
	Universal	EBAR-U	30
		EBAR-G	60
	Chic-Out	EBAR-UX	30
		EBAR-GX	60
Epstein-Barr Virus (EBV) + Cytomegalovirus (CMV)¹ DNA detection	Monotest CFX	CMEB-CFX32	32
	Monotest ABI	CMEB-ABI32	32
	Monotest Flash 20	CMEB	24
	Universal	CMEB-U	30
		CMEB-G	60
	Chic-Out	CMEB-UX	30
		CMEB-GX	60
Epstein-Barr Virus (EBV) + Cytomegalovirus (CMV) + Herpesvirus type 6 (HHV-6)¹ DNA detection	Monotest CFX	EBCMVI-CFX32	32
	Monotest ABI	EBCMVI-ABI32	32
	Monotest Flash 20	EBCMVI	24
	Universal	EBCMVI-U	30
		EBCMVI-G	60
	Chic-Out	EBCMVI-UX	30
		EBCMVI-GX	60

Infectious meningoencephalitis

Application	Format	Ref.	Tests
<i>Escherichia coli</i> + <i>Streptococcus agalactiae</i> + <i>Listeria monocytogenes</i> DNA detection	Monotest CFX	ECSALI-CFX32	32
	Monotest ABI	ECSALI-ABI32	32
	Monotest Flash 20	ECSALI	24
	Universal	ECSALI-U	30
		ECSALI-G	60
	Chic-Out	ECSALI-UX	30
		ECSALI-GX	60
Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) DNA detection	Monotest CFX	HSVT-CFX32	32
	Monotest ABI	HSVT-ABI32	32
	Monotest Flash 20	HSVT	24
	Universal	HSVT-U	30
		HSVT-G	60
	Chic-Out	HSVT -UX	30
		HSVT-GX	60
Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) + Varicella-Zoster Virus (VZV) DNA detection	Monotest CFX	HSVTVA-CFX32	32
	Monotest ABI	HSVTVA-ABI32	32
	Monotest Flash 20	HSVTVA	24
	Universal	HSVTVA-U	30
		HSVTVA-G	60
	Chic-Out	HSVTVA-UX	30
		HSVTVA-GX	60

Infectious meningoencephalitis

Application	Format	Ref.	Tests
Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) + Varicella-Zoster Virus (VZV) / Epstein-Barr Virus (EBV) + Cytomegalovirus (CMV) + Herpesvirus type 6 (HHV-6)¹ DNA detection	Monotest CFX	HERPLX-CFX32	16+16
	Monotest ABI	HERPLX-ABI32	16+16
	Monotest Flash 20	HERPLX	12+12
	Universal	HERPLX-U	15+15
		HERPLX-G	30+30
	Chic-Out	HERPLX-UX	15+15
HERPLX-GX		30+30	
Herpesvirus type 6 (HHV-6) DNA detection	Monotest CFX	HHVI-CFX32	32
	Monotest ABI	HHVI-ABI32	32
	Monotest Flash 20	HHVI	24
	Universal	HHVI-U	30
		HHVI-G	60
	Chic-Out	HHVI-UX	30
HHVI-GX		60	
Herpesvirus type 6 (HHV-6) + Herpesvirus type 7 (HHV-7) + Herpesvirus type 8 (HHV-8) DNA detection	Monotest CFX	HSV678-CFX32	32
	Monotest ABI	HSV678-ABI32	32
	Monotest Flash 20	HSV678	24
	Universal	HSV678-U	30
		HSV678-G	60
	Chic-Out	HSV678-UX	30
HSV678-GX		60	

Infectious meningoencephalitis

Application	Format	Ref.	Tests
<i>Listeria monocytogenes</i> DNA detection	Monotest CFX	LIST-CFX32	32
	Monotest ABI	LIST-ABI32	32
	Monotest Flash 20	LIST	24
	Universal	LIST-U	30
		LIST-G	60
	Chic-Out	LIST-UX	30
		LIST -GX	60
Lymphocytic Choriomeningitis Virus (LCMV) RNA detection	Monotest CFX	LCMV-CFX32	32
	Monotest ABI	LCMV-ABI32	32
	Monotest Flash 20	LCMV	24
	Universal	LCMV-U	30
		LCMV-G	60
	Chic-Out	LCMV-UX	30
		LCMV-GX	60
<i>Neisseria meningitidis</i> + <i>Streptococcus pneumoniae</i> DNA detection	Monotest CFX	MENE-CFX32	32
	Monotest ABI	MENE-ABI32	32
	Monotest Flash 20	MENE	24
	Universal	MENE-U	30
		MENE-G	60
	Chic-Out	MENE-UX	30
		MENE-GX	60

Infectious meningoencephalitis

Application	Format	Ref.	Tests
<i>Neisseria meningitidis + Streptococcus pneumoniae + Haemophilus influenzae</i> DNA detection	Monotest CFX	MENEHI-CFX32	32
	Monotest ABI	MENEHI-ABI32	32
	Monotest Flash 20	MENEHI	24
	Universal	MENEHI-U	30
		MENEHI-G	60
	Chic-Out	MENEHI-UX	30
MENEHI-GX		60	
<i>Neisseria meningitidis + Streptococcus pneumoniae + Listeria monocytogenes</i> DNA detection	Monotest CFX	MENELI-CFX32	32
	Monotest ABI	MENELI-ABI32	32
	Monotest Flash 20	MENELI	24
	Universal	MENELI-U	30
		MENELI-G	60
	Chic-Out	MENELI-UX	30
MENELI-GX		60	
<i>Neisseria meningitidis + Streptococcus pneumoniae + Listeria monocytogenes / Enterovirus (EV) + Herpes Simplex Virus (HSV-1 + HSV-2) + Varicella-Zoster Virus (VZV)</i> DNA+RNA detection	Monotest CFX	MEBAVI-CFX32	16+16
	Monotest ABI	MEBAVI-ABI32	16+16
	Monotest Flash 20	MEBAVI	12+12
	Universal	MEBAVI-U	15+15
		MEBAVI-G	30+30
	Chic-Out	MEBAVI-UX	15+15
MEBAVI-GX		30+30	

Infectious meningoencephalitis

Application	Format	Ref.	Tests
<i>Streptococcus agalactiae</i> DNA detection	Monotest CFX	SAGA-CFX32	32
	Monotest ABI	SAGA-ABI32	32
	Monotest Flash 20	SAGA	24
	Universal	SAGA-U	30
		SAGA-G	60
	Chic-Out	SAGA-UX	30
		SAGA-GX	60
Toscana virus RNA detection	Monotest CFX	TOSC-CFX32	32
	Monotest ABI	TOSC-ABI32	32
	Monotest Flash 20	TOSC	24
	Universal	TOSC-U	30
		TOSC-G	60
	Chic-Out	TOSC-UX	30
		TOSC-GX	60
Varicella-Zoster Virus (VZV) DNA detection	Monotest CFX	VARI-CFX32	32
	Monotest ABI	VARI-ABI32	32
	Monotest Flash 20	VARI	24
	Universal	VARI-U	30
		VARI-G	60
	Chic-Out	VARI-UX	30
		VARI-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
Adenovirus (ADV) DNA detection	Monotest CFX	ADNV-CFX32	32
	Monotest ABI	ADNV-ABI32	32
	Monotest Flash 20	ADNV	24
	Universal	ADNV-U	30
		ADNV-G	60
	Chic-Out	ADNV-UX	30
ADNV-GX		60	
Aspergillus fumigatus DNA detection	Monotest CFX	FUMI-CFX32	32
	Monotest ABI	FUMI-ABI32	32
	Monotest Flash 20	FUMI	24
	Universal	FUMI-U	30
		FUMI-G	60
	Chic-Out	FUMI-UX	30
FUMI-GX		60	
Bocavirus (HBoV) + Adenovirus (ADV) DNA detection	Monotest CFX	BOAD-CFX32	32
	Monotest ABI	BOAD-ABI32	32
	Monotest Flash 20	BOAD	24
	Universal	BOAD-U	30
		BOAD-G	60
	Chic-Out	BOAD-UX	30
BOAD-GX		60	

Respiratory tract infections

Application	Format	Ref.	Tests
<i>Bordetella holmesii + Bordetella parapertussis + Bordetella pertussis</i> DNA detection	Monotest CFX	BHOLPP-CFX32	32
	Monotest ABI	BHOLPP-ABI32	32
	Monotest Flash 20	BHOLPP	24
	Universal	BHOLPP-U	30
		BHOLPP-G	60
	Chic-Out	BHOLPP-UX	30
		BHOLPP-GX	60
	<i>Bordetella pertussis + Bordetella parapertussis</i> DNA detection	Monotest CFX	BORD-CFX32
Monotest ABI		BORD-ABI32	32
Monotest Flash 20		BORD	24
Universal		BORD-U	30
		BORD-G	60
Chic-Out		BORD-UX	30
		BORD-GX	60
<i>Candida albicans + Candida parapsilosis + Candida glabrata</i> DNA detection		Monotest CFX	ALPAGL-CFX32
	Monotest ABI	ALPAGL-ABI32	32
	Monotest Flash 20	ALPAGL	24
	Universal	ALPAGL-U	30
		ALPAGL-G	60
	Chic-Out	ALPAGL-UX	30
		ALPAGL-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
Coronavirus SARS-CoV-2 (ORF8 + E gene) FAM+ATTO647N RNA detection	Monotest CFX	CORO-CFX32 v.5	32
		CORO-CFX96 v.5	96
	Monotest ABI	CORO-ABI32 v.5	32
		CORO-ABI96 v.5	96
	Monotest Flash 20	CORO v.5	24
	Universal	CORO-U v.5	30
		CORO-G v.5	60
	Chic-Out	CORO-UX v.5	30
		CORO-GX v.5	60
	Coronavirus SARS-CoV-2 (ORF8 + N gene) FAM+TxR RNA detection	Monotest CFX	CORO-CFX32 v.5.2
CORO-CFX96 v.5.2			96
Monotest ABI		CORO-ABI32 v.5.2	32
		CORO-ABI96 v.5.2	96
Monotest Flash 20		CORO v.5.2	24
Universal		CORO-U v.5.2	30
		CORO-G v.5.2	60
Chic-Out		CORO-UX v.5.2	30
		CORO-GX v.5.2	60

Respiratory tract infections

Application	Format	Ref.	Tests
Coronavirus SARS-CoV-2 (ORF8 + E gene) FAM+FAM RNA detection	Monotest CFX	CORO-CFX32 v.5.3	32
		CORO-CFX96 v.5.3	96
	Monotest ABI	CORO-ABI32 v.5.3	32
		CORO-ABI96 v.5.3	96
	Monotest Flash 20	CORO v.5.3	24
	Universal	CORO-U v.5.3	30
		CORO-G v.5.3	60
	Chic-Out	CORO -UX v.5.3	30
		CORO-GX v.5.3	60
	Coronavirus SARS-CoV-2 + Flu B + Flu A + Respiratory Syncytial Virus (RSV) RNA detection	Monotest CFX	COROFLUR-CFX32
COROFLUR-CFX96			96
Monotest ABI		COROFLUR-ABI32	32
		COROFLUR-ABI96	96
Universal		COROFLUR-U	30
		COROFLUR-G	60
		COROFLUR-C	100
		COROFLUR-M	1000
Chic-Out		COROFLUR-UX	30
		COROFLUR-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
<i>Coxiella burnetii</i> DNA detection	Monotest CFX	COXI-CFX32	32
	Monotest ABI	COXI-ABI32	32
	Monotest Flash 20	COXI	24
	Universal	COXI-U	30
		COXI-G	60
	Chic-Out	COXI-UX	30
		COXI-GX	60
Flu A + Flu B RNA detection	Monotest CFX	GRIP-CFX32	32
	Monotest ABI	GRIP-ABI32	32
	Monotest Flash 20	GRIP	24
	Universal	GRIP-U	30
		GRIP-G	60
	Chic-Out	GRIP-UX	30
		GRIP-GX	60
Flu A + Flu B / Flu A H1N1 RNA detection	Monotest CFX	GRHI-CFX32	16+16
	Monotest ABI	GRHI-ABI32	16+16
	Monotest Flash 20	GRHI	12+12
	Universal	GRHI-U	15+15
		GRHI-G	30+30
	Chic-Out	GRHI-UX	15+15
		GRHI-GX	30+30

Respiratory tract infections

Application	Format	Ref.	Tests
Flu A + Flu B + Respiratory Syncytial Virus (RSV) RNA detection	Monotest CFX	FLURSV-CFX32	32
	Monotest ABI	FLURSV-ABI32	32
	Monotest Flash 20	FLURSV	24
	Universal	FLURSV-U	30
		FLURSV-G	60
	Chic-Out	FLURSV-UX	30
		FLURSV-GX	60
Seasonal Flu A (H1) + Seasonal Flu A (H3) RNA detection	Monotest CFX	FLUS-CFX32	32
	Monotest ABI	FLUS-ABI32	32
	Monotest Flash 20	FLUS	24
	Universal	FLUS-U	30
		FLUS-G	60
	Chic-Out	FLUS-UX	30
		FLUS-GX	60
Legionella pneumophila DNA detection	Monotest CFX	LEGI-CFX32	32
	Monotest ABI	LEGI-ABI32	32
	Monotest Flash 20	LEGI	24
	Universal	LEGI-U	30
		LEGI-G	60
	Chic-Out	LEGI-UX	30
		LEGI-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
<i>Mycoplasma pneumoniae + Chlamydophila pneumoniae</i> ¹ DNA detection	Monotest CFX	MYCH-CFX32	32
	Monotest ABI	MYCH-ABI32	32
	Monotest Flash 20	MYCH	24
	Universal	MYCH-U	30
		MYCH-G	60
	Chic-Out	MYCH-UX	30
		MYCH-GX	60
<i>Mycoplasma pneumoniae + Chlamydophila pneumoniae + Legionella spp.</i> ¹ DNA detection	Monotest CFX	MYCHLE-CFX32	32
	Monotest ABI	MYCHLE-ABI32	32
	Monotest Flash 20	MYCHLE	24
	Universal	MYCHLE-U	30
		MYCHLE-G	60
	Chic-Out	MYCHLE-UX	30
		MYCHLE-GX	60
<i>Mycobacterium tuberculosis complex</i> DNA detection	Monotest CFX	MTBC-CFX32	32
	Monotest ABI	MTBC-ABI32	32
	Monotest Flash 20	MTBC	24
	Universal	MTBC-U	30
		MTBC-G	60
	Chic-Out	MTBC-UX	30
		MTBC-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
<i>Pneumocystis jirovecii</i> DNA detection	Monotest CFX	PJIR-CFX32	32
	Monotest ABI	PJIR-ABI32	32
	Monotest Flash 20	PJIR	24
	Universal	PJIR-U	30
		PJIR-G	60
	Chic-Out	PJIR-UX	30
		PJIR-GX	60
<i>Pseudomonas aeruginosa</i> DNA detection	Monotest CFX	PAER-CFX32	32
	Monotest ABI	PAER-ABI32	32
	Monotest Flash 20	PAER	24
	Universal	PAER-U	30
		PAER-G	60
	Chic-Out	PAER-UX	30
		PAER-GX	60
<i>Pseudomonas aeruginosa + Acinetobacter baumannii + Staphylococcus aureus</i> DNA detection	Monotest CFX	PACISA-CFX32	32
	Monotest ABI	PACISA-ABI32	32
	Monotest Flash 20	PACISA	24
	Universal	PACISA-U	30
		PACISA-G	60
	Chic-Out	PACISA-UX	30
		PACISA-GX	60

Respiratory tract infections

Application	Format	Ref.	Tests
<p><i>Pseudomonas aeruginosa + Acinetobacter baumannii-Stenotrophomonas maltophilia + Staphylococcus aureus</i> DNA detection</p>	Monotest CFX	PAMASA-CFX32	32
	Monotest ABI	PAMASA-ABI32	32
	Monotest Flash 20	PAMASA	24
	Universal	PAMASA-U	30
		PAMASA-G	60
	Chic-Out	PAMASA-UX	30
		PAMASA-GX	60
<p><i>Streptococcus agalactiae</i> DNA detection</p>	Monotest CFX	SAGA-CFX32	32
	Monotest ABI	SAGA-ABI32	32
	Monotest Flash 20	SAGA	24
	Universal	SAGA-U	30
		SAGA-G	60
	Chic-Out	SAGA-UX	30
		SAGA-GX	60
<p><i>Streptococcus pneumoniae</i> DNA detection</p>	Monotest CFX	NEUM-CFX32	32
	Monotest ABI	NEUM-ABI32	32
	Monotest Flash 20	NEUM	24
	Universal	NEUM-U	30
		NEUM-G	60
	Chic-Out	NEUM-UX	30
		NEUM-GX	60

Sexually transmitted diseases

Application	Format	Ref.	Tests
<i>Candida albicans + Candida parapsilosis + Candida glabrata</i> DNA detection	Monotest CFX	ALPAGL-CFX32	32
	Monotest ABI	ALPAGL-ABI32	32
	Monotest Flash 20	ALPAGL	24
	Universal	ALPAGL-U	30
		ALPAGL-G	60
	Chic-Out	ALPAGL-UX	30
		ALPAGL-GX	60
<i>Candida sp.</i> DNA detection	Monotest CFX	CAND-CFX32	32
	Monotest ABI	CAND-ABI32	32
	Monotest Flash 20	CAND	24
	Universal	CAND-U	30
		CAND-G	60
	Chic-Out	CAND-UX	30
		CAND-GX	60
<i>Candida sp. + Trichomonas vaginalis + Gardnerella vaginalis</i> DNA detection	Monotest CFX	CSTVGV-CFX32	32
	Monotest ABI	CSTVGV-ABI32	32
	Monotest Flash 20	CSTVGV	24
	Universal	CSTVGV-U	30
		CSTVGV-G	60
	Chic-Out	CSTVGV-UX	30
		CSTVGV-GX	60

Sexually transmitted diseases

Application	Format	Ref.	Tests
<i>Chlamydia trachomatis</i> L serovar² DNA detection	Monotest CFX	CHSL-CFX32	32
	Monotest ABI	CHSL-ABI32	32
	Monotest Flash 20	CHSL	24
	Universal	CHSL-U	30
		CHSL-G	60
	Chic-Out	CHSL-UX	30
		CHSL-GX	60
Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) DNA detection	Monotest CFX	HSVT-CFX32	32
	Monotest ABI	HSVT-ABI32	32
	Monotest Flash 20	HSVT	24
	Universal	HSVT-U	30
		HSVT-G	60
	Chic-Out	HSVT-UX	30
		HSVT-GX	60
<i>Mycoplasma genitalium</i> DNA detection	Monotest CFX	MYGE-CFX32	32
	Monotest ABI	MYGE-ABI32	32
	Monotest Flash 20	MYGE	24
	Universal	MYGE-U	30
		MYGE-G	60
	Chic-Out	MYGE-UX	30
		MYGE-GX	60

Sexually transmitted diseases

Application	Format	Ref.	Tests
<p><i>Mycoplasma genitalium + Trichomonas vaginalis + Chlamydia trachomatis L serovar¹</i> DNA detection</p>	Monotest CFX	MGTVCL-CFX32	32
	Monotest ABI	MGTVCL-ABI32	32
	Monotest Flash 20	MGTVCL	24
	Universal	MGTVCL-U	30
		MGTVCL-G	60
	Chic-Out	MGTVCL-UX	30
		MGTVCL-G	60
<p><i>Mycoplasma genitalium + Trichomonas vaginalis + Ureaplasma urealyticum-Ureaplasma parvum</i> DNA detection</p>	Monotest CFX	MGTVUS-CFX32	32
	Monotest ABI	MGTVUS-ABI32	32
	Monotest Flash 20	MGTVUS	24
	Universal	MGTVUS-U	30
		MGTVUS-G	60
	Chic-Out	MGTVUS-UX	30
		MGTVUS-GX	60
<p><i>Mycoplasma hominis + Ureaplasma parvum / Mycoplasma genitalium + Trichomonas vaginalis + Ureaplasma urealyticum</i> DNA detection</p>	Monotest CFX	GENI-CFX32	16+16
	Monotest ABI	GENI-ABI32	16+16
	Monotest Flash 20	GENI	12+12
	Universal	GENI-U	15+15
		GENI-G	30+30
	Chic-Out	GENI-UX	15+15
		GENI-GX	30+30

Sexually transmitted diseases

Application	Format	Ref.	Tests
<p><i>Neisseria gonorrhoeae</i> + <i>Mycoplasma genitalium</i> + <i>Chlamydia trachomatis</i>¹ DNA detection</p>	Monotest CFX	NGMGCL-CFX32	32
	Monotest ABI	NGMGCL-ABI32	32
	Monotest Flash 20	NGMGCL	24
	Universal	NGMGCL-U	30
		NGMGCL-G	60
	Chic-Out	NGMGCL-UX	30
		NGMGCL-GX	60
<p><i>Treponema pallidum</i> + <i>Haemophilus ducreyi</i> DNA detection</p>	Monotest CFX	TPHD-CFX32	32
	Monotest ABI	TPHD-ABI32	32
	Monotest Flash 20	TPHD	24
	Universal	TPHD-U	30
		TPHD-G	60
	Chic-Out	TPHD-UX	30
		TPHD-GX	60
<p><i>Treponema pallidum</i> + Herpes Simplex Virus (HSV-1 + HSV-2) + <i>Chlamydia trachomatis</i> L serovar¹ DNA detection</p>	Monotest CFX	ULCGEN-CFX32	32
	Monotest ABI	ULCGEN-ABI32	32
	Monotest Flash 20	ULCGEN	24
	Universal	ULCGEN-U	30
		ULCGEN-G	60
	Chic-Out	ULCGEN-UX	30
		ULCGEN-GX	60

Sexually transmitted diseases

Application	Format	Ref.	Tests
<i>Treponema pallidum</i> + <i>Haemophilus ducreyi</i> / <i>Chlamydia trachomatis</i> L serovar² DNA detection	Monotest CFX	THLV-CFX32	16+16
	Monotest ABI	THLV-ABI32	16+16
	Monotest Flash 20	THLV	12+12
	Universal	THLV-U	15+15
		THLV-G	30+30
	Chic-Out	THLV-UX	15+15
		THLV-GX	30+30

Congenital and perinatal infections

Application	Format	Ref.	Tests
Cytomegalovirus² DNA detection	Monotest CFX	CMVH-CFX32	32
	Monotest ABI	CMVH-ABI32	32
	Monotest Flash 20	CMVH	24
	Universal	CMVH-U	30
		CMVH-G	60
	Chic-Out	CMVH-UX	30
		CMVH-GX	60
Herpesvirus type 1 (HSV-1) + Herpesvirus type 2 (HSV-2) DNA detection	Monotest CFX	HSVT-CFX32	32
	Monotest ABI	HSVT-ABI32	32
	Monotest Flash 20	HSVT	24
	Universal	HSVT-U	30
		HSVT-G	60
	Chic-Out	HSVT-UX	30
		HSVT-GX	60

<p><i>Plasmodium sp.</i> DNA detection</p>	Monotest CFX	PLAS-CFX32	32
	Monotest ABI	PLAS-ABI32	32
	Monotest Flash 20	PLAS	24
	Universal	PLAS-U	30
		PLAS-G	60
	Chic-Out	PLAS-UX	30
		PLAS-GX	60
	<p><i>Toxoplasma gondii</i>² DNA detection</p>	Monotest CFX	TGON-CFX32
Monotest ABI		TGON-ABI32	32
Monotest Flash 20		TGON	24
Universal		TGON-U	30
		TGON-G	60
Chic-Out		TGON-UX	30
		TGON-GX	60
<p><i>Trypanosoma cruzi</i> DNA detection</p>		Monotest CFX	CHAG-CFX32
	Monotest ABI	CHAG-ABI32	32
	Monotest Flash 20	CHAG	24
	Universal	CHAG-U	30
		CHAG-G	60
	Chic-Out	CHAG-UX	30
		CHAG-GX	60

Gastrointestinal infections

Application	Format	Ref.	Tests
Clostridium difficile toxin B (TcdB) and binary toxin (CDT) DNA detection	Monotest CFX	CDIF-CFX32	32
	Monotest ABI	CDIF-ABI32	32
	Monotest Flash 20	CDIF	24
	Universal	CDIF-U	30
		CDIF-G	60
	Chic-Out	CDIF-UX	30
		CDIF-GX	60
Mumps virus RNA detection	Monotest CFX	PAPE-CFX32	32
	Monotest ABI	PAPE-ABI32	32
	Monotest Flash 20	PAPE	24
	Universal	PAPE-U	30
		PAPE-G	60
	Chic-Out	PAPE-UX	30
		PAPE-GX	60
Salmonella sp. DNA detection	Monotest CFX	SALM-CFX32	32
	Monotest ABI	SALM-ABI32	32
	Monotest Flash 20	SALM	24
	Universal	SALM-U	30
		SALM-G	60
	Chic-Out	SALM-UX	30
		SALM-GX	60

Opportunistic and nosocomial infections

Application	Format	Ref.	Tests
<i>Candida auris</i> DNA detection	Monotest CFX	AURI-CFX32	32
	Monotest ABI	AURI-ABI32	32
	Monotest Flash 20	AURI	24
	Universal	AURI-U	30
		AURI-G	60
	Chic-Out	AURI-UX	30
		AURI-GX	60
JC Polyomavirus (JCV) + BK Polyomavirus (BKV) DNA detection	Monotest CFX	POLI-CFX32	32
	Monotest ABI	POLI-ABI32	32
	Monotest Flash 20	POLI	24
	Universal	POLI-U	30
		POLI-G	60
	Chic-Out	POLI-UX	30
		POLI-GX	60
<i>Pseudomonas aeruginosa</i> DNA detection	Monotest CFX	PAER-CFX32	32
	Monotest ABI	PAER-ABI32	32
	Monotest Flash 20	PAER	24
	Universal	PAER-U	30
		PAER-G	60
	Chic-Out	PAER-UX	30
		PAER-GX	60

Opportunistic and nosocomial infections

Application	Format	Ref.	Tests
<i>Pseudomonas aeruginosa + Acinetobacter baumannii + Staphylococcus aureus</i> DNA detection	Monotest CFX	PACISA-CFX32	32
	Monotest ABI	PACISA-ABI32	32
	Monotest Flash 20	PACISA	24
	Universal	PACISA-U	30
		PACISA-G	60
	Chic-Out	PACISA-UX	30
		PACISA-GX	60
<i>Pseudomonas aeruginosa + Acinetobacter baumannii-Stenotrophomonas maltophilia + Staphylococcus aureus</i> DNA detection	Monotest CFX	PAMASA-CFX32	32
	Monotest ABI	PAMASA-ABI32	32
	Monotest Flash 20	PAMASA	24
	Universal	PAMASA-U	30
		PAMASA-G	60
	Chic-Out	PAMASA-UX	30
		PAMASA-GX	60
<i>Pseudomonas aeruginosa + Enterobacteriaceae + Staphylococcus aureus</i> DNA detection	Monotest CFX	PAENSA-CFX32	32
	Monotest ABI	PAENSA-ABI32	32
	Monotest Flash 20	PAENSA	24
	Universal	PAENSA-U	30
		PAENSA-G	60
	Chic-Out	PAENSA-UX	30
		PAENSA-GX	60

Opportunistic and nosocomial infections

Application	Format	Ref.	Tests
<i>Toxoplasma gondii</i> ² DNA detection	Monotest CFX	TGON-CFX32	32
	Monotest ABI	TGON-ABI32	32
	Monotest Flash 20	TGON	24
	Universal	TGON-U	30
		TGON-G	60
	Chic-Out	TGON-UX	30
		TGON-GX	60

Systemic infections

Application	Format	Ref.	Tests
<i>Bartonella sp.+ Bartonella henselae</i> DNA detection	Monotest CFX	BART-CFX32	32
	Monotest ABI	BART-ABI32	32
	Monotest Flash 20	BART	24
	Universal	BART-U	30
		BART-G	60
	Chic-Out	BART-UX	30
		BART-GX	60
<i>Borrelia burgdorferi</i> DNA detection	Monotest CFX	BBUR-CFX32	32
	Monotest ABI	BBUR-ABI32	32
	Monotest Flash 20	BBUR	24
	Universal	BBUR-U	30
		BBUR-G	60
	Chic-Out	BBUR-UX	30
		BBUR-GX	60

Systemic infections

Application	Format	Ref.	Tests
Ebola Zaire virus² RNA detection	Monotest CFX	EBOL-CFX32	32
	Monotest ABI	EBOL-ABI32	32
	Monotest Flash 20	EBOL	24
	Universal	EBOL-U	30
		EBOL-G	60
	Chic-Out	EBOL-UX	30
		EBOL-GX	60
Hepatitis B Virus (HBV)² DNA detection	Monotest CFX	HEPB-CFX32	32
		HEPB-CFX96	96
	Monotest ABI	HEPB-ABI32	32
		HEPB-ABI96	96
	Monotest Flash 20	HEPB	24
	Universal	HEPB-U	60
	Hepatitis C Virus (HCV)² RNA detection	Monotest CFX	HEPC-CFX32
HEPC-CFX96			96
Monotest ABI		HEPC-ABI32	32
		HEPC-ABI96	96
Monotest Flash 20		HEPC	24
Universal		HEPC-U	60

Systemic infections

Application	Format	Ref.	Tests
Kingella kingae DNA detection	Monotest CFX	KING-CFX32	32
	Monotest ABI	KING-ABI32	32
	Monotest Flash 20	KING	24
	Universal	KING-U	30
		KING-G	60
	Chic-Out	KING-UX	30
		KING-GX	60
Leishmania donovani complex DNA detection	Monotest CFX	DONO-CFX32	32
	Monotest ABI	DONO-ABI32	32
	Monotest Flash 20	DONO	24
	Universal	DONO-U	30
		DONO-G	60
	Chic-Out	DONO-UX	30
		DONO-GX	60
Measles virus RNA detection	Monotest CFX	SARA-CFX32	32
	Monotest ABI	SARA-ABI32	32
	Monotest Flash 20	SARA	24
	Universal	SARA-U	30
		SARA-G	60
	Chic-Out	SARA-UX	30
		SARA-GX	60

Systemic infections

Application	Format	Ref.	Tests
Monkeypox virus DNA detection	Monotest CFX	MONK-CFX32	32
	Monotest ABI	MONK-ABI32	32
	Monotest Flash 20	MONK	24
	Universal	MONK-U	30
		MONK-G	60
	Chic-Out	MONK-UX	30
		MONK-GX	60
Parvovirus B19 DNA detection	Monotest CFX	PARV-CFX32	32
	Monotest ABI	PARV-ABI32	32
	Monotest Flash 20	PARV	24
	Universal	PARV-U	30
		PARV-G	60
	Chic-Out	PARV-UX	30
		PARV-GX	60
Plasmodium sp. DNA detection	Monotest CFX	PLAS-CFX32	32
	Monotest ABI	PLAS-ABI32	32
	Monotest Flash 20	PLAS	24
	Universal	PLAS-U	30
		PLAS-G	60
	Chic-Out	PLAS-UX	30
		PLAS-GX	60

Systemic infections

Application	Format	Ref.	Tests
<i>Tropheryma whipplei</i> DNA detection	Monotest CFX	TRWH-CFX32	32
	Monotest ABI	TRWH-ABI32	32
	Monotest Flash 20	TRWH	24
	Universal	TRWH-U	30
		TRWH-G	60
	Chic-Out	TRWH-UX	30
		TRWH-GX	60
<i>Trypanosoma cruzi</i> DNA detection	Monotest CFX	CHAG-CFX32	32
	Monotest ABI	CHAG-ABI32	32
	Monotest Flash 20	CHAG	24
	Universal	CHAG-U	30
		CHAG-G	60
	Chic-Out	CHAG-UX	30
		CHAG-GX	60
West Nile virus RNA detection	Monotest CFX	WNVI-CFX32	32
	Monotest ABI	WNVI-ABI32	32
	Monotest Flash 20	WNVI	24
	Universal	WNVI-U	30
		WNVI-G	60
	Chic-Out	WNVI-UX	30
		WNVI-GX	60

Bacterial resistances

Application	Format	Ref.	Tests
blaCTX-M1 + blaCTX-M2 + blaCTX-M9 DNA detection	Monotest CFX	BLACTX-CFX32	32
	Monotest ABI	BLACTX-ABI32	32
	Monotest Flash 20	BLACTX	24
	Universal	BLACTX-U	30
		BLACTX-G	60
	Chic-Out	BLACTX-UX	30
BLACTX-GX		60	
blaIMP + blaNDM DNA detection	Monotest CFX	IMND-CFX32	32
	Monotest ABI	IMND-CFX32	32
	Monotest Flash 20	IMND	24
	Universal	IMND-U	30
		IMND-G	60
	Chic-Out	IMND-UX	30
IMND-GX		60	
blaIMP + blaNDM-1 + MCR-1 / blaOXA + blaCTX-M + blaVIM + blaKPC / S. aureus + PVL + vanA-vanB + mecA-mecC DNA detection	Universal	MDRORG-U	10+10+10
		MDRORG-G	20+20+20
	Chic-Out	MDRORG-UX	10+10+10
		MDRORG-GX	20+20+20

Bacterial resistances

Application	Format	Ref.	Tests
blaIMP + blaNDM-1 + MCR-1 / blaOXA + blaCTX-M + blaVIM + blaKPC DNA detection	Monotest CFX	MDRO-CFX32	16+16
	Monotest ABI	MDRO-ABI32	16+16
	Universal	MDRO-U	15+15
		MDRO-G	30+30
	Chic-Out	MDRO-UX	15+15
		MDRO-GX	30+30
blaIMP + blaNDM / blaOXA + blaCTX-M + blaVIM + blaKPC DNA detection	Monotest CFX	INOCVK-CFX32	
	Monotest ABI	INOCVK-ABI32	
	Universal	INOCVK-U	15+15
		INOCVK-G	30+30
	Chic-Out	INOCVK-UX	15+15
		INOCVK-GX	30+30
blaIMP + blaVIM DNA detection	Monotest CFX	IMVI-CFX32	32
	Monotest ABI	IMVI-ABI32	32
	Monotest Flash 20	IMVI	24
	Universal	IMVI-U	30
		IMVI-G	60
	Chic-Out	IMVI-UX	30
IMVI-GX		60	

Bacterial resistances

Application	Format	Ref.	Tests
blaKPC + blaNDM DNA detection	Monotest CFX	KPND-CFX32	32
	Monotest ABI	KPND-ABI32	32
	Monotest Flash 20	KPND	24
	Universal	KPND-U	30
		KPND-G	60
	Chic-Out	KPND-UX	30
		KPND-GX	60
blaOXA + blaVIM DNA detection	Monotest CFX	OXVI-CFX32	32
	Monotest ABI	OXVI-ABI32	32
	Monotest Flash 20	OXVI	24
	Universal	OXVI-U	30
		OXVI-G	60
	Chic-Out	OXVI-UX	30
		OXVI-GX	60
blaOXA + blaVIM + blaKPC DNA detection	Monotest CFX	OXVIKP-CFX32	32
	Monotest ABI	OXVIKP-ABI32	32
	Monotest Flash 20	OXVIKP	24
	Universal	OXVIKP-U	30
		OXVIKP-G	60
	Chic-Out	OXVIKP-UX	30
		OXVIKP-GX	60

Bacterial resistances

Application	Format	Ref.	Tests
blaOXA + blaVIM + blaKPC + blaNDM DNA detection	Monotest CFX	OXVIKPN-D-CFX32	32
	Monotest ABI	OXVIKPN-D-ABI32	32
	Universal	OXVIKPN-D-U	30
		OXVIKPN-D-G	60
	Chic-Out	OXVIKPN-D-UX	30
		OXVIKPN-D-GX	60
mecA gene + <i>Staphylococcus aureus</i> DNA detection	Monotest CFX	SAMA-CFX32	32
	Monotest ABI	SAMA-ABI32	32
	Monotest Flash 20	SAMA	24
	Universal	SAMA-U	30
		SAMA-G	60
	Chic-Out	SAMA-UX	30
		SAMA-GX	60

Bacterial resistances

Application	Format	Ref.	Tests
mecA gene + Panton-Valentine leukocidin toxin (PVL) + <i>Staphylococcus aureus</i> DNA detection	Monotest CFX	SAMAPV-CFX32	32
	Monotest ABI	SAMAPV-ABI32	32
	Monotest Flash 20	SAMAPV	24
	Universal	SAMAPV-U	30
		SAMAPV-G	60
	Chic-Out	SAMAPV-UX	30
		SAMAPV-GX	60
Panton-Valentine leukocidin toxin (PVL) + <i>Staphylococcus aureus</i> DNA detection	Monotest CFX	SAPV-CFX32	32
	Monotest ABI	SAPV-ABI32	32
	Monotest Flash 20	SAPV	24
	Universal	SAPV-U	30
		SAPV-G	60
	Chic-Out	SAPV-UX	30
		SAPV-GX	60
Plasmid AmpC-type β-lactamases: blaACC + blaEBC / blaCIT + blaDHA DNA detection	Monotest CFX	AMPC-CFX32	16+16
	Monotest ABI	AMPC-ABI32	16+16
	Monotest Flash 20	AMPC	12+12
	Universal	AMPC-U	15+15
		AMPC-G	30+30
	Chic-Out	AMPC-UX	15+15
		AMPC-GX	30+30

Bacterial resistances

Application	Format	Ref.	Tests
Plasmid AmpC-type β-lactamases: blaCIT + blaDHA + blaACC-blaEBC DNA detection	Monotest CFX	CIDHAE-CFX32	32
	Monotest ABI	CIDHAE-ABI32	32
	Monotest Flash 20	CIDHAE	24
	Universal	CIDHAE-U	30
		CIDHAE-G	60
	Chic-Out	CIDHAE-UX	30
CIDHAE-GX		60	
<i>Pseudomonas aeruginosa</i> + <i>Acinetobacter baumannii</i> + <i>Staphylococcus aureus</i> / blaOXA + blaCTX-M + blaVIM + blaKPC DNA detection	Monotest CFX	DRPROA-CFX32	16+16
	Monotest ABI	DRPROA-ABI32	16+16
	Universal	DRPROA-U	15+15
		DRPROA-G	30+30
	Chic-Out	DRPROA-UX	15+15
		DRPROA-GX	30+30
<i>Pseudomonas aeruginosa</i> + <i>Acinetobacter baumannii</i>-<i>Stenotrophomonas maltophilia</i> + <i>Staphylococcus aureus</i> / blaOXA + blaCTX-M + blaVIM + blaKPC / blaIMP + blaNDM + vanA-vanB + mecA-mecC DNA detection	Universal	REZERO-U	10+10+10
		REZERO-G	20+20+20
	Chic-Out	REZERO-UX	10+10+10
		REZERO-GX	20+20+20
<i>Pseudomonas aeruginosa</i> + <i>Enterobacteriaceae</i> + <i>Staphylococcus aureus</i> / blaOXA + blaCTX-M + blaVIM + blaKPC / blaIMP + blaNDM + vanA-vanB + mecA-mecC DNA detection	Universal	ENZERO-U	10+10+10
		ENZERO-G	20+20+20
	Chic-Out	ENZERO-UX	10+10+10
		ENZERO-GX	20+20+20

Controls and standards for calibration curves

Application	Ref.	Tests
Adenovirus DNA quantification	ADVQ	1
Aspergillus fumigatus DNA quantification	FUMQ	1
BK Polyomavirus (BKV) DNA quantification	BKVQ	1
Bordetella parapertussis DNA quantification	BPAQ	1
Bordetella pertussis DNA quantification	BPEQ	1
Cytomegalovirus (CMV)² DNA quantification	CMVQ	1
Epstein-Barr Virus (EBV) DNA quantification	EBVQ	1
Haemophilus influenzae DNA quantification	HAEQ	1
Hepatitis B Virus (HBV)² DNA quantification	HBVQ	1
Hepatitis C Virus (HCV)² RNA quantification	HCVQ	1
Herpesvirus type 1 (HSV-1) DNA quantification	HV1Q	1
Herpesvirus type 2 (HSV-2) DNA quantification	HV2Q	1
Herpesvirus type 6 (HHV-6) DNA quantification	HV6Q	1

Controls and standards for calibration curves

Application	Ref.	Tests
JC Polyomavirus (JCV) DNA quantification	JCVQ	1
Parvovirus B19 DNA quantification	B19Q	1
<i>Pneumocystis jirovecii</i> DNA quantification	PJIQ	1
<i>Staphylococcus aureus</i> DNA quantification	AURQ	1
<i>Streptococcus pneumoniae</i> DNA quantification	NEUQ	1
<i>Ureaplasma urealyticum</i> DNA quantification	UREQ	1
Varicella-Zoster Virus (VZV) DNA quantification	VZVQ	1

¹ CE mark does not currently include the detection of *Chlamydia trachomatis* L serovar, *Chlamydia pneumoniae* and Cytomegalovirus. The results obtained with the kits for these pathogens must be considered only for clinical research purposes.

² For research use only.

Bureau Veritas Certification

Certificación
Concedida a
PROGENIE MOLECULAR, S.L.U.

EDIFICIO PROGENIE, C/ VALLE DE LA BALLESTERA, 56 - 46015 - VALENCIA - ESPAÑA

Bureau Veritas Certification certifica que el Sistema de Gestión ha sido auditado y encontrado conforme con los requisitos de la norma:

NORMA

ISO 9001:2015



El Sistema de Gestión se aplica a:

SERVICIOS DE ANÁLISIS CLÍNICOS EN LAS ÁREAS DE GENÉTICA, VIROLOGÍA, SEROLOGÍA, MICROBIOLOGÍA MOLECULAR E IDENTIFICACIÓN DE ADN (PRUEBAS PATERNIDAD). DISEÑO, DESARROLLO, PRODUCCIÓN Y COMERCIALIZACIÓN DE REACTIVOS PARA DIAGNÓSTICO "IN VITRO" E INVESTIGACIÓN BASADOS EN BIOLOGÍA MOLECULAR.

Número del Certificado:	ES128643 - 1
Aprobación original:	25-05-2010
Auditoría de certificación/renovación:	15-03-2022
Caducidad de ciclo anterior:	25-05-2022
Certificado en vigor:	26-05-2022
Caducidad del certificado:	25-05-2025

Este certificado está sujeto a los términos y condiciones generales y particulares de los servicios de certificación

Bureau Veritas Iberia S.L.
C/ Valperilla Primera 22-24, Edificio Casba, 28109 Alcobendas - Madrid, España

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Bureau Veritas Certification

Certificación
Concedida a
PROGENIE MOLECULAR, S.L.U.

EDIFICIO PROGENIE, C/ VALLE DE LA BALLESTERA, 56 - 46015 - VALENCIA - ESPAÑOL

Bureau Veritas Certification certifica que el Sistema de Gestión de la Calidad de Productos Sanitarios ha sido auditado y encontrado conforme con los requisitos de la norma:

NORMA

ISO 13485:2016
(UNE-EN ISO 13485:2018)


El Sistema de Gestión se aplica a:

DISEÑO, DESARROLLO, PRODUCCIÓN Y COMERCIALIZACIÓN DE REACTIVOS PARA DIAGNÓSTICO "IN VITRO" E INVESTIGACIÓN, BASADOS EN BIOLOGÍA MOLECULAR.

Número del certificado:	ES128643-1
Aprobación original:	25-05-2010
Auditoría de transición: / Auditoría de certificación/renovación:	15-03-2022
Caducidad de ciclo anterior:	25-05-2022
Certificado en vigor:	26-05-2022
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Bureau Veritas Iberia S.L.
C/ Valperilla Primera 22-24, Edificio Casba, 28109 Alcobendas - Madrid, España



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PERMISO

LICENCIA SANITARIA PREVIA DE FUNCIONAMIENTO DE INSTALACIONES DE PRODUCTOS SANITARIOS

Haciendo uso de las atribuciones que me están conferidas, de conformidad con lo dispuesto en el Real Decreto 1275/2011, de 16 de septiembre, por el que se crea la Agencia estatal "Agencia Española de Medicamentos y Productos Sanitarios" y se aprueba su estatuto y en el Real Decreto 1662/2000, de 29 de septiembre, sobre productos sanitarios para diagnóstico "In Vitro", a propuesta del Departamento de Productos Sanitarios.

Emite nueva licencia por: ACTUALIZACIÓN DE DATOS

Fecha de licencia iniciada: 09 de mayo de 2011 Fecha de última modificación: 18 de julio de 2017

DENOMINACIÓN DE LA EMPRESA PROGENIE MOLECULAR	CIF / NIF B97262158	NÚMERO DE LICENCIA 6067-PS
DOMICILIO SOCIAL E INSTALACIÓN C/ VALLE DE LA BALLESTERA 56, 46015 VALENCIA		
ACTIVIDADES PROPIAS FABRICACIÓN E IMPORTACIÓN		
TIPO DE PRODUCTO FABRICACIÓN: Reactivos y kits: KITS DE DIAGNÓSTICO IN VITRO POR PCR IMPORTACIÓN: Reactivos y kits: KITS DE DIAGNÓSTICO IN VITRO		
ACTIVIDADES CONCERTADAS -----		
TÉCNICO RESPONSABLE (DNI) D/Dª LAURA RUIZ PALMERO (52975377Y)	TITULACIÓN LICENCIADO EN BIOLOGÍA DOCTORA EN BIQUÍMICA Y BIOLOGÍA MOLECULAR	

Esta licencia tendrá validez durante cinco años a partir de la fecha 30 de marzo de 2016, siempre que no varien las condiciones en las que se concede. Podrá ser revalidada a solicitud del interesado, formulada con anterioridad al último trimestre de su vigencia.

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS


Fdo. Helena Crespo Sánchez-Ezarraga

Formado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios Localizador: 310483704
Fecha de la firma: 31/07/2017
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