

VIASURE

RT-PCR Complete Solution

Molecular Diagnostic workflow
for your lab

certest



Molecular Diagnostics



Optimise the performance
of your laboratory with
**VIASURE Complete
Solution**



Gastrointestinal infections



Respiratory infections



Antimicrobial resistance



Tropical & Vector-Borne transmission diseases



Sexual Health

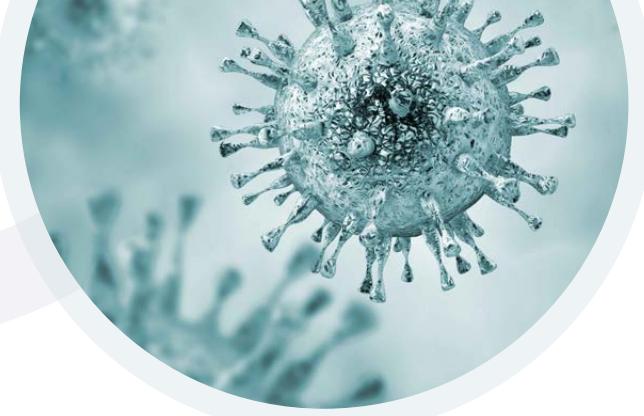


Immuno-supressed and Meningitis



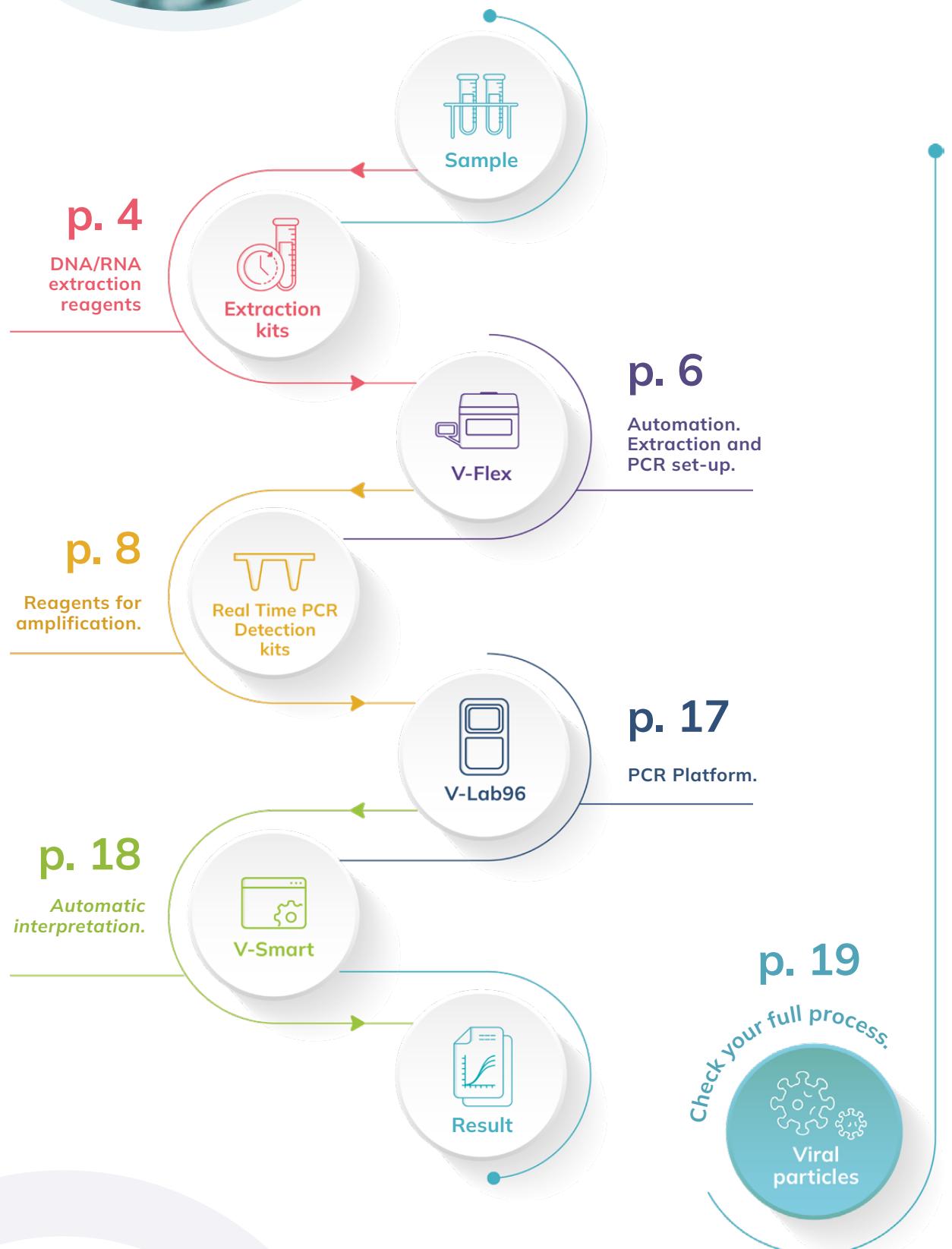
Non infectious diseases





VIASURE

RT-PCR Complete Solution



VIASURE Resp. viruses Quick Lysis Reagent



Lyophilised reagents in individualised vials for rapid cell lysis. Compatible with VIASURE Real Time PCR products, including SARS-CoV-2 detection kits.



Ready to use.



**Quick sample processing
10 minutes.**



High Specificity and Sensitivity.

Detection up to 5 copies/qPCR reaction.

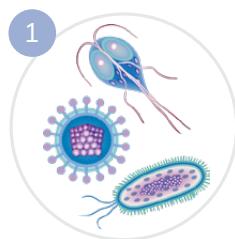


Compatible with:

- Nasopharyngeal and oropharyngeal swabs
- Saliva.



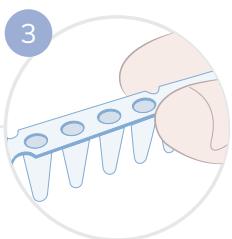
No freezing during transport and storage.



SAMPLE COLLECTION



RAPID LYSIS: RNA RELEASE



AMPLIFICATION

Reference	Description
VS-ERN0148	VIASURE Resp. viruses Quick Lysis Reagent, 4x12 tubes, 48 prep.

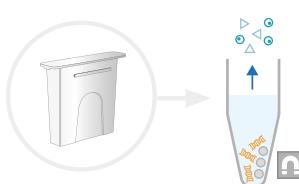
VIASURE Extraction Kits



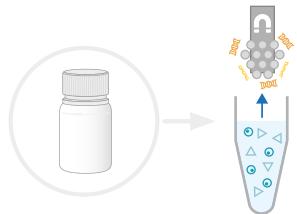
-  Simultaneous processing of **different types of biological samples**.
-  **Magnetic beads technology**
-  **Starting sample volume:** 200 µl
Elution volume: 100 µl
-  **Simultaneous extraction of DNA and RNA from viruses, bacteria, parasites and fungi from different clinical samples.**

► Formats

V-FLEX



OPEN FORMAT



VIASURE DNA/RNA Pathogen Extraction Kit



Swabs, saliva, sputum, faeces, and urine.

Reference	Description
VS-EAP0296FX	VIASURE DNA/RNA Pathogens Extraction Kit VIASURE V-Flex, 96 prep
VS-EAP0296OP	VIASURE DNA/RNA Pathogens Extraction Kit VIASURE Open Format, 96 prep

VIASURE Blood Pathogens Extraction Kit



Optimised for whole blood, plasma, serum, blood and cerebrospinal fluid cultures.

Reference	Description
VS-EAB0196FX	VIASURE Blood Pathogens Extraction Kit for VIASURE V-Flex, 96 prep
VS-EAB0196OP	VIASURE Blood Pathogens Extraction Kit for VIASURE Open Format, 96 prep

V-Flex

Automated solution for nucleic acid extraction and PCR set-up.



Set-up flexible for different needs.



Fully automated (from 1 to 96 samples) and PCR set-up.



Flexible set-up for **different users and requirements**.



Intuitive - user friendly integrated Software.



Configure different **VIASURE PCR Kits** one run.



DNA/RNA purification from a wide range of samples.



Easy and fully traceable sample handling.



Full LIS compatibility and integration.



Exclusive design for **minimum maintenance**.



► Features

Power & Connectivity

100-240 VAC ($\pm 10\%$) / 50/60 Hz

USB-C

LAN port (RJ45, Ethernet)

Dimensions and Weight

Weight 151 kg

Size (L x W x H) 782 x 1190 x 1094 mm

Environmental conditions

Temperature * 15–32°C (59–90°F)

Humidity * 30–80% relative (non-condensing) at 30°C (86°F)

Altitude * 0–2000 m above sea level

Temperature in the workplace 1–60°C (34–140°F)

Ovvoltage category II

Pollution degree 2

* Indoor only

V-Flex

Instrument Integrated Modules

UVC Light UV-C emitting lamp for decontamination of the inside of the instrument housing and work deck.

Loading ID Loading ID module includes up to six dedicated grid positions for loading and scanning the barReference labels

Integrated computer & Touch Screen User interaction touch screen display. No need of extra laptop / PC.

Termoshaker Integrated Heating/Shaking device

HEPA filter unit (HEFU) Air flow can be adjusted to blow filtered air in the enclosure or extract air by passing the filter.

Cooling Module Cooling block for elution plate.

Pipetting System

Volume Range 1 μ l to 5000 μ l

Process Security cLLD (capacitive Liquid Level detection)

Precision (CV) 1 μ l: $\leq 5\%$ | 200 μ l: $\leq 2\%$ | 1000 μ l: $\leq 2\%$



VIASURE Real Time PCR Detection Kits



Gastrointestinal infections

► Multiplex

Reference	Description
AEY	Aeromonas + Yersinia enterocolitica
BLD	Blastocystis hominis + Dientamoeba fragilis
CDA	Clostridium difficile toxins A+B
CLA	H. pylori + Clarithromycin resistance
CLJ	Campylobacter coli, C. lari & C. jejuni
ECT	E. coli typing (2 wells): (E. coli ETEC + EIEC) + (E. coli EHEC, EPEC & EIEC)
EEE	E. coli EHEC, EPEC & EIEC
ESE	E. coli ETEC + EIEC
KGE	Cryptosporidium, Giardia & E. histolytica
NOR	Norovirus GI + GII
SCS	Salmonella, Campylobacter & Shigella/EIEC
SCY	Salmonella, Campylobacter & Yersinia enterocolitica

► Monoplex

Reference	Description
ADV	Adenovirus
ATV	Astrovirus
CAM	Campylobacter
CDS	Clostridium difficile
CIA	Clostridium difficile toxins A/B
CTB	Clostridium difficile toxB
DIE	Dientamoeba fragilis
ETD	Entamoeba dispar
ETH	Entamoeba histolytica
GIA	Giardia lamblia
KRY	Cryptosporidium
NOG	Norovirus GI
NOP	Norovirus GII
PYR	Helicobacter pylori
RTV	Rotavirus
SAV	Sapovirus
SAM	Salmonella
SHY	Shigella/EIEC (Enteroinvasive Escherichia coli)
YER	Yersinia enterocolitica

► Panels

Targets	GP01	GP02	GP03	GP04
Adenovirus	●			
Aeromonas spp. + Yersinia enterocolitica		●	●	
Astrovirus	●			
Blastocystis hominis + Dientamoeba fragilis		●		
Campylobacter coli, C. lari & C. jejuni				●
Clostridium difficile		●		
Clostridium difficile toxB		●		
Clostridium difficile toxins A + B				●
Cryptosporidium, Giardia & E. histolytica	●	●		
E. coli ETEC + EIEC		●	●	
E. coli EHEC, EPEC & EIEC		●	●	●
Norovirus GI + GII	●			
Rotavirus	●			
Salmonella, Campylobacter & Y. enterocolitica	●			●
Salmonella, Campylobacter & Shigella/EIEC		●	●	
Sapovirus	●			
Shigella/EIEC	●			



Panel GP01

Multiplex diagnostic: a unique thermal protocol, for multiple parameters to be detected simultaneously



Respiratory infections

► Multiplex

Reference	Description
ABC	Flu A, Flu B & SARS-CoV-2
ABR	Flu A, Flu B & RSV
AMB	Adenovirus, Metapneumovirus & Bocavirus
ASP	Aspergillus differentiation (A. fumigatus, A. flavus, A. terreus)
BDT	Bordetella (B. pertussis, B. parapertussis & B. holmesii)
CML	C. pneumoniae, M. pneumoniae & L. pneumophila
CFR	SARS-CoV-2, Flu & RSV
COR	Coronavirus (229E, NL63, OC43 &HKU1)
ERNCO2	Quick SARS-CoV-2 (Resp. Viruses Quick Lysis + SARS-CoV-2)
HSM	H. influenzae, S. pneumoniae & M. catarrhalis
HXN	Flu Typing II (H1N1, H5N1, H3N2 & H7N9)
H13	Flu Typing I (H1N1 + H3N2)
IAB	Flu A + Flu B
MER	MERS Coronavirus (2 wells)
MTD	M. tuberculosis complex + Non-tuberculosis mycobacteria
NCO2	SARS-CoV-2 (ORF1ab & N genes)
NCO3	SARS-CoV-2 (N1 + N2)
NCO4	SARS-CoV-2 Triplex (ORF1ab, E & N genes)
PIZ	Parainfluenza (2 wells): (1, 3 & 2, 4)
RHE	Rhinovirus + Enterovirus
RPA	Respiratory Viral Panel I (2 wells): (Flu A, Flu B & RSV) + (H1N1, H5N1, H3N2 & H7N9)
RSV	RSV A + B
SUK2	SARS-CoV-2 del 69/70, ORF1ab & N genes
VAI	SARS-CoV-2 Variant II (P681R, L452R, E484Q)
VAO	SARS-CoV-2 Variant III (Q954H, A2710T)
VAR	SARS-CoV-2 Variant I (E484K, K417N, K417T, N501Y)

► Monoplex

Reference	Description
BVS	Bocavirus
GAS	Group A Streptococcus
HNV	Influenza A(H1N1)pdm09
JIR	Pneumocystis jirovecii (q)
LGN	Legionella pneumophila
MPV	Human metapneumovirus
MTC	M. Tuberculosis complex
RSA	RSV A
RSB	RSV B
YIA	Influenza A
YIB	Influenza B

(q) Quantitative

► Panels

Targets	RP01	RP02	RP03	RP04	RP05	RP06
Adenovirus, Metapneumovirus & Bocavirus	●	●	●	●	●	●
C. pneumoniae, M. pneumoniae & L. pneumophila		●	●			
Coronavirus (229E, NL63, OC43 & HKU1)	●	●	●	●	●	●
SARS-CoV-2 (ORF1ab & N genes)						●
Flu A + Flu B		●		●		
Flu A, Flu B & RSV	●		●		●	●
Flu Typing I (H1N1 & H3N2)			●			●
Flu Typing II (H1N1, H5N1, H3N2 & H7N9)		●				
H. influenzae, S. pneumoniae & M. catarrhalis			●		●	
Influenza H1N1				●		
MERS Coronavirus (2 wells)	●●					
Parainfluenza (1, 3 & 2, 4) (2 wells)	●●	●●	●●	●●	●●	●●
Rhinovirus + Enterovirus	●		●	●	●	●
RSV A + B		●		●		
Legionella pneumophila					●	

NEW

Work flow

**01**

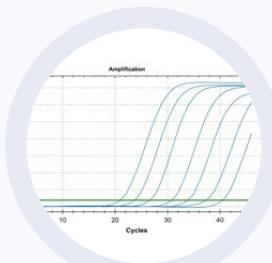
Add 15 µL of rehydration buffer into each well.

**02**

Add 5 µL of: DNA/RNA sample / Positive control / Negative control.

**03**

Place the strips in the thermal cycler and run the specified protocol.

**04**

Analysis of results..



Tropical & Vector-Borne transmission diseases

► Multiplex

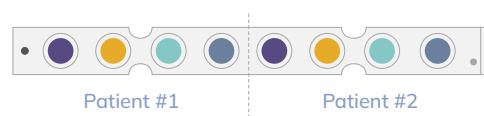
Reference	Description
BAC	Borrelia, Anaplasma & C. burnetii
DES	Dengue Serotyping (2 wells): (Dengue 1, 4 & 2, 3)
MAD	Malaria differentiation (2 wells): (P. malariae, P. knowlesi & P. ovale) + (P. falciparum + P. vivax)
TBD	Tick Borne Diseases (3 wells): (Borrelia, Anaplasma & C. burnetii) + (Rickettsia, Babesia & Ehrlichia) + (TBEV)
ZDC	Zika, Dengue & Chikungunya Virus

► Monoplex

Reference	Description
CCV	Crimean-Congo Hemorrhagic Fever Virus
CHA	Trypanosoma cruzi (Chagas)
CHI	Chikungunya Virus
DEN	Dengue Virus
FEV	Yellow Fever Virus
JEV	Japanese Encephalitis Virus
LEI	Leishmania
MAL	Malaria (q)
MPX	Monkeypox Virus
MYV	Mayaro Virus
TGO	Toxoplasma gondii (1)
WNV	West Nile Virus
ZIK	Zika Virus

► Panel

Targets	TP01
Zika, Dengue & Chikungunya Virus	●
West Nile Virus	●
Yellow Fever Virus	●
Mayaro Virus	●



Patient #1

Patient #2

(q) Quantitative

(1) Research Use Only



► Multiplex

Reference	Description
CGT	C. albicans, G. vaginalis & T. vaginalis
CTN	N. gonorrhoeae + C. trachomatis
HHT	Herpes virus 1, Herpes virus 2 & Treponema pallidum
HPV	Human Papilloma Virus 16 + 18
HRP	High Risk Papilloma (2 wells): (16), (18) & (35/58/66) + (33/45/51), (52/59/68) & (31/39/56)
MGR	Macrolide resistance-associated mutations (23S rRNA)
NCR	Neisseria gonorrhoeae ciprofloxacin resistant
STD	Sexually transmitted diseases (2 wells): (N. gonorrhoeae, C. trachomatis & M. genitalium) + (T. vaginalis, U. urealyticum, U. parvum & M. hominis)

► Monoplex

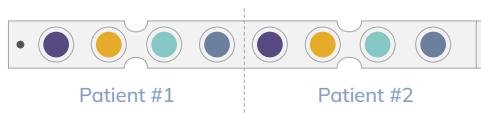
Reference	Description
AVA	Atopobium vaginae (1)
CAU	Candida auris (1)
GBS	Streptococcus B
LGV	C. trachomatis (LGV)
TPA	Treponema pallidum

► Panels

Targets	SP01	SP02 (1)
N. gonorrhoeae, C. trachomatis & M. genitalium	●	
T. vaginalis, U. urealyticum, U. parvum & M. hominis	●	
Herpes virus 1, Herpes virus 2 & Treponema pallidum	●	
C. albicans, G. vaginalis & T. vaginalis	●	
Human Papillomavirus Genotyping (16, 18, 31, 35)		●
Human Papillomavirus Genotyping (33, 59, 56, 58)		●
Human Papillomavirus Genotyping (68, 73, 26, 82)		●
Human Papillomavirus Genotyping (51, 69, 39, 66)		●
Human Papillomavirus Genotyping (53, 52, 45)		●
Human Papillomavirus Genotyping (11, 70, 43)		●
Human Papillomavirus Genotyping (42, 40, 54)		●
Human Papillomavirus Genotyping (61, 44, 6)		●

Real Time PCR Detection kits

Panel SP01



Panel SP02



(1) Research Use Only



Immunosupressed and Meningitis

► Multiplex

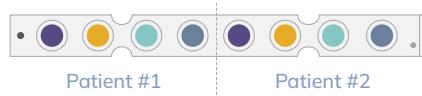
Reference	Description
BJV	BK + JC Virus
HHZ	Herpes Virus 1, Herpes Virus 2 & Varicela Zoster Virus
HHV	Human Herpes Virus 6, 7 & 8
MEP	Mumps, Enterovirus & Parechovirus
NEU	Adenovirus, CMV, EBV & Parvovirus B19 (1)
HNS	H. influenzae, N. meningitidis & S. pneumoniae
SLE	S. agalactiae, L. monocytogenes & E. coli

► Monoplex

Reference	Description
BKQ	BK Virus (q)
CMV	Cytomegalovirus (q)
EBV	Epstein-Barr Virus (1) (q)
HBV	Hepatitis B Virus (1) (q)

► Panel

Targets	MP01 (1)
Human Herpes Virus 6, 7 & 8	●
Herpes Virus 1, Herpes Virus 2 & Varicela Zoster Virus	●
Mumps, Enterovirus & Parechovirus	●
Adenovirus, CMV, EBV & Parvovirus B19	●



Non infectious diseases

► Multiplex

Reference	Description
CEL	HLA celiac (2 wells): (DQA1*05, DQB1*03:02, DQB1*02 & HBB gene (-globin)) & (DQA1*02, DQA1*03 & no DQB1*02)
RNP	Control RNase P (1)

(q) Quantitative

(1) Research Use Only



Antimicrobial resistance and sepsis

► Multiplex

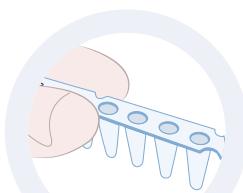
Reference	Description
VAN	Vancomycin resistance
EFF	Enterococcus faecalis + Enterococcus faecium
MSA	Methicillin-resistant Staphylococcus aureus (2 wells): (MRSA, MSSA and/or MRCoNS)
CPE	Carbapenemase-producing Enterobacteriaceae (2 wells): (NDM + VIM) + (OXA, KPC & IMP)
BLC	CTX, TEM, SHV & mcr
EAC	Enterobacter, A. baumannii & E. coli
PKP	P. aeruginosa, K. pneumoniae & P. mirabilis
CLA	H. pylori + Clarithromycin resistance
MGR	Macrolide resistance-associated mutations (23S rRNA)
NCR	Neisseria gonorrhoeae ciprofloxacin resistant



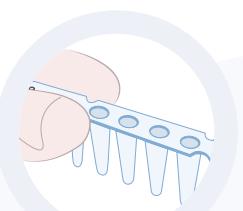
Genetic diseases



Plates in low (0,1 ml)
and high (0,2 ml) profile



Low Profile strip
(0,1 ml)



High Profile strip
(0,2 ml)



2ml Tube
(Only for Multiplex and Monoplex Kits)



Rotor-Gene Tube

Available formats



▶ Compatibility guidance

Please, verify the table and **check the specifications of your equipment before running the RT-PCR**. If the equipment does not appear in the list below, contact your supplier.

Low Profile Cyclers (0,1ml)		High Profile Cyclers (0,2ml)	
Manufacturer	Model	Manufacturer	Model
Applied Biosystems	AriaMx/AriaDx Real-Time PCR System	Abbott	Abbott m2000 ⁽⁶⁾
	7500 Fast / 7500 Fast Dx Real-Time PCR System ⁽¹⁾⁽⁶⁾	Agilent	Mx3000P™ / Mx 3005P™
	QuantStudio™ 12K Flex 96-well Fast	Analytik Jena	qTower ⁽⁷⁾
	QuantStudio™ 6 Flex 96-well Fast		7300 ⁽³⁾⁽⁶⁾
	QuantStudio™ 7 Flex 96-well Fast		7500 ⁽⁶⁾
	QuantStudio™ 3 Fast Real-Time PCR System		7900 HT ⁽²⁾
	QuantStudio™ 5 Fast / QuantStudio™ 5 Real-Time PCR System		ABI PRISM 7000 ⁽²⁾
	StepOne Plus™ Real-Time PCR System ⁽²⁾		ABI PRISM 7700 ⁽²⁾
	StepOne™ ^{(2), (3)}	Applied Biosystems	QuantStudio™ 12K Flex 96-well
	ViiA™ 7 Fast		QuantStudio™ 6 Flex 96-well
Azure Biosystems	Azure Cielo 3 ⁽⁴⁾		QuantStudio™ 7 Flex 96-well
	Azure Cielo 6		QuantStudio™ 3 Real-Time PCR System
BIONEER	Exicycler™ 96 Fast		QuantStudio™ 5 Fast / QuantStudio™ 5 Real-Time PCR System
Bio-Rad	CFX96TM / CFX96TM IVD Real-Time PCR Detection System		ViiA™ 7 Real-Time PCR System
	Mini OpticonTM Real-Time PCR Detection System ⁽⁴⁾	BIOER	QuantGene 9600
	CFX Opus 96	BIONEER	Exicycler™ 96
Roche	LightCycler® 480 Real-Time PCR System ⁽⁶⁾⁽⁷⁾		CFX96TM Deep Well / CFX96TM Deep Well IVD
	LightCycler® 96 Real-Time PCR System		iCycler iQTM Real-Time PCR Detection System
	Cobas z480 Analyzer ⁽⁶⁾⁽⁷⁾	Bio-Rad	iCycler iQTM5 Real-Time PCR Detection System
Special Formats ⁽⁵⁾			My iQTM Real-Time PCR Detection System ⁽⁴⁾
Manufacturer	Model		My iQTM2 Real-Time PCR Detection System ⁽⁴⁾
Bio Molecular Systems	Mic Real Time PCR Cycler	DNA-Technology	DTprime
Cepheid	SmartCycler®		DTlite
Qiagen	Rotor-Gene® Q	Eppendorf	Mastercycler™ ep realplex
		Qiagen	QIAquant 96 ⁽⁷⁾
		VIASURE	V-Lab96

(1) Select Ramp Speed "Standard" in New Experiment/Advanced Set-up/Experiment Properties. When using the Applied Biosystems 7500 Fast with strips it is recommended to place a plate holder to reduce the risk of crushed tube (Ref. PN 4388506)..

(2) No Cy5 caption.

(3) No ROX caption.

(4) Only FAM and HEX caption.

(5) The product must be reconstituted following the appropriate procedure (see Test procedure) and transferred to the specific tubes for Mic, SmartCycler®, Rotor-Gene® Q.

(6) A special grid is needed to fit these real-time PCR kits.

(7) Specific compensation color is required.

V-Lab96

Viasure Real Time PCR platform

VIASURE V-Lab96 allows users to analyze 96 samples simultaneously for qualitative and quantitative Real Time PCR.



Improved optical system for **high specificity and sensitive** detection.



Reduced operating time.



High sample throughput in diagnostic lab applications.



Data registering and accounting in electronic format for LIS connection.



Power-off protection



Integrated 10.4-inch touch screen.



Compatible with all VIASURE Real Time PCR Detection Kits.



Qualitative & Quantitative data analysis.



Automatic interpretation and analysis of results



V-Smart

Automatic interpretation

VIASURE V-Smart allows the analyse and interpretation of the VIASURE Real Time PCR assays.

The **VIASURE V-Smart** software facilitates the conversion of the PCR raw data into test results with minimal manual intervention.



**Intuitive and easy to use
user-friendly interface**



**Machine-learning
based**



**Automatic results PCR
interpretation**



LIS connection & Report



**Big range of RT-PCR
Thermocyclers**



PCR platforms compatibility

- Agilent Technologies
- Applied Biosystems
- BIO-RAD
- DNA-Technology
- VIASURE 48/VIASURE 96
- Qiagen-Rotorgene
- Roche
- Neos
- V-Lab96

VIASURE RNA Viral Particles

Monitor the whole process, from nucleic acid extraction to amplification.



► Available Kits

Reference	Description
VS-VP1NCO	VIASURE Viral SARS-CoV-2 Positive Control Kit
VS-VP1SUK	VIASURE Viral SARS-CoV-2 Alpha (B.1.1.7) Positive Control Kit
VS-VP1SSA	VIASURE Viral SARS-CoV-2 Beta (B.1.351) Positive Control Kit
VS-VP1SBR	VIASURE Viral SARS-CoV-2 Gamma (P.1) Positive Control Kit
VS-VP1SDL	VIASURE Viral SARS-CoV-2 Delta (B.1.617.2) Positive Control Kit
VS-VP1SWT	VIASURE Viral SARS-CoV-2 Total Positive Control Kit
VS-VP1ABR	VIASURE Viral ABR Positive Control Kit
VS-VP1YIA	VIASURE Viral Influenza A (H1N1) Positive Control Kit
VS-VP1YIB	VIASURE Viral Influenza B Positive Control Kit
VS-VP1ZIKRUO	VIASURE Viral Zika Total Positive Control Reagents RUO
VS-VP1DEB	VIASURE Viral Dengue 2 Positive Control Kit
VS-VP1DTTRUO	VIASURE Viral Dengue 1, 2, 3 & 4 Total Positive Control Reagents RUO
VS-VP1CHI	VIASURE Viral Chikungunya Positive Control Kit
VS-VP1CHTRUO	VIASURE Viral Chikungunya Total Positive Control Reagents RUO
VS-VP1WNTRUO	VIASURE Viral West Nile Virus Total Positive Control Reagents RUO



How do these controls help you in the lab process?



Monitor instrument performance.



Improve the diagnosis process: nucleic acid extraction, amplification, and detection quality.



Allow you to obtain comparable results between different assays and platforms.



Validate and verify different assays complying with regulatory requirements.

VIASURE RT-PCR Complete Solution

provides a perfect combination of products and tools for your lab.



“Ready & Easy-to-use” kits.
Lyophilised reagents



Shipping and storage at room temperature.
Shelf-life: 24 months



Validated according to ISO 13485
and CE marked



Unique thermal protocol: multiple parameters simultaneously in a single PCR

VIASURE
by certest

Certest Biotec, S.L.

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VIASURE/GEN-1223EN

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