

VIASURE

Complete Solution

Molecular Diagnostic workflow
for your lab

CerTest
BIOTEC





“ **VIASURE Complete Solution**
helps to achieve a better molecular
diagnostic workflow.

Welcome to the VIASURE experience!

Solutions for:



Gastrointestinal
infections



Respiratory
infections



Antimicrobial
resistance



Tropical &
Vector-Borne
transmission
diseases



Sexual
Health



Immuno-suppressed
and Meningitis



Non infectious
diseases



+25,000m²

MOLECULAR DIAGNOSTICS



VIASURE Complete Solution

SAMPLE



Extraction kit

p. 4

Quick and Automate
RNA/DNA extraction kits.



V-Flex

p. 6

Nucleic acid
extraction and
PCR set-up.



Real Time PCR
Detection kits

p. 8

Lyophilized product.
Ready & Easy-to-use.



V-Lab96

p. 17

Run your Real Time PCR.



V-Smart

p. 18

Automatic
interpretation.

Viral Particles



Check your
full process.

p. 19

RESULT

VIASURE Resp. viruses Quick Lysis Reagent



Designed to quickly process respiratory samples as nasopharyngeal and oropharyngeal swabs and saliva.

Compatible with VIASURE Real Time PCR Kits, including SARS-CoV-2 detection kits. Very easy transport and storage, not freeze required.



Quick sample processing (10 min).



High Specificity and Sensitivity. Detection up to **5 copies/qPCR** reaction.



Ready to use. No specific equipment required.



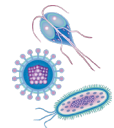
Compatible with different biological matrices:



Compatible with **transport media** without guanidium salts.

- **Nasopharyngeal** and oropharyngeal swabs in transport medium.
- **Saliva** without preservatives.

▶ Workflow:



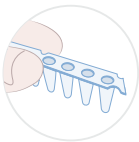
1. Sample collection:

- Nasopharyngeal and oropharyngeal swabs.
- Saliva without preservatives.



2. Quick Lysis Reagent:

1. Rehydrate VIASURE Quick Lysis Reagent.
2. Add the sample.
3. Incubate for 10 minutes at 100°C.



3. Molecular diagnosis method:

Add the supernatant to VIASURE products.

▶ References:

Code	Description
VS-ERN0112	VIASURE Resp. viruses Quick Lysis Reagent, 1x12 tubes, 12 prep.
VS-ERN0148	VIASURE Resp. viruses Quick Lysis Reagent, 4x12 tubes, 48 prep.

VIASURE DNA/RNA Pathogen Extraction Kit



Extract from various biological samples: swabs, saliva, sputum, bronchoalveolar lavages, fecal and urine samples.

Based on magnetic particles, which allows its automation for high throughput analysis, reducing hands-on-time and improving reproducibility.

The extraction kit **has been optimized for two type of magnetic separation methods:** VIASURE V-Flex and KingFisher® Flex (other platforms ongoing).

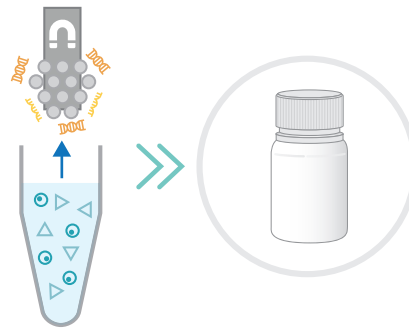
▶ Advantages:

- ✓ **Adaptable for high and low throughputs.**
- ✓ **Simultaneous processing of different kind of clinical samples.**
- ✓ **Simultaneous processing of various potential infectious diseases.**

▶ Formats:



V-Flex



Open Format

▶ Features:

VIASURE DNA/RNA Pathogen Extraction Kit	
Technology	Magnetic beads
Sample material	Swabs, saliva, sputum, feces, and urine. Compatible with inactivating transport buffers including guanidine salts
Sample/Elution volume	200 µl/ 100 µl
Target molecules	DNA and RNA
Compatible platforms	VIASURE V-Flex System and KingFisher® Flex
Formats	VIASURE V-Flex System Cartridges (96 prep.) or Open Format bottles (96 prep.)

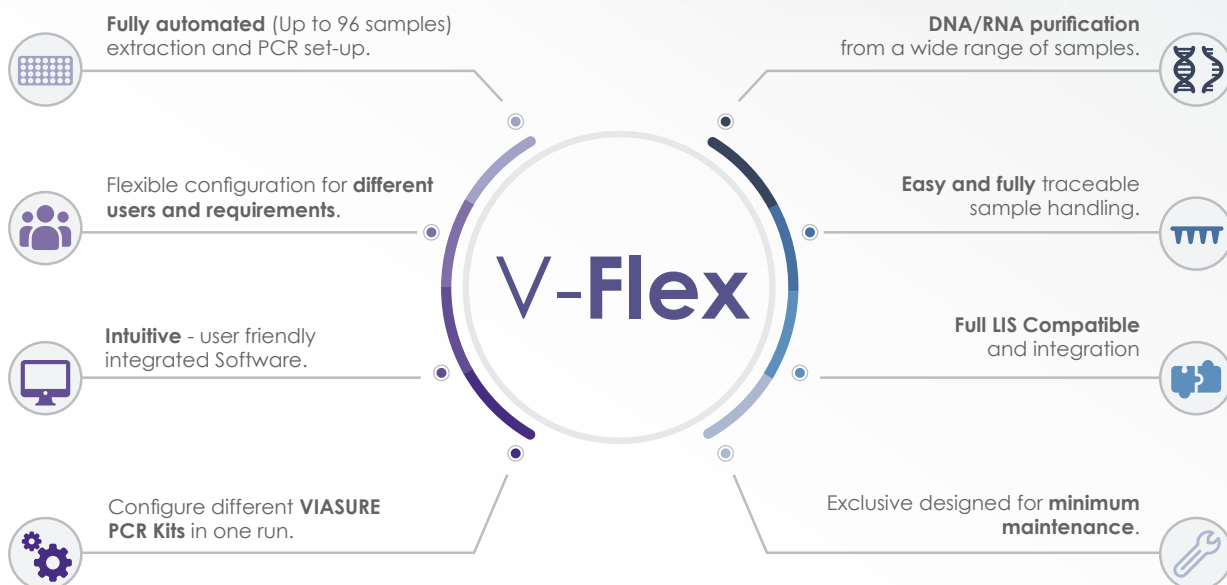
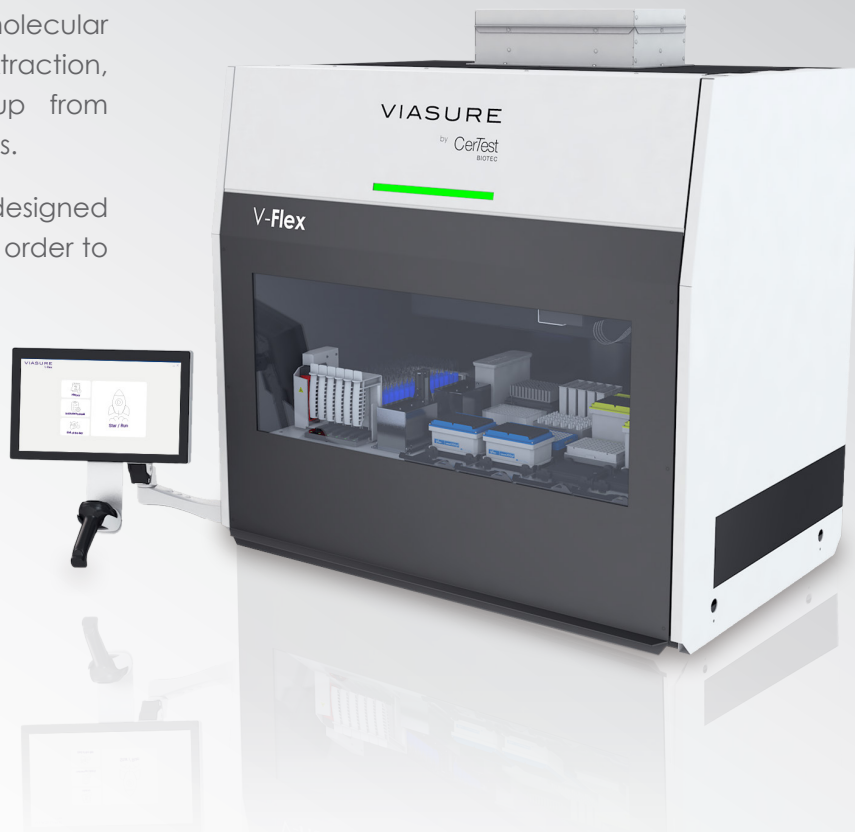
V-Flex

Automated solution for Molecular Biology.
Nucleic acid extraction and PCR set-up.

The **VIASURE V-FLEX system** is a new fully automated solution in molecular biology for nucleic acid extraction, purification and PCR set-up from biological matrix and samples.

The instrument has been designed with **flexible configuration**, in order to meet different user needs.

VIASURE V-Flex optimizes and improves users **walk away** experience.



► Features

Power & Connectivity

- 100-240 VAC (± 10%) / 50/60 Hz
- USB-C
- LAN port (RJ45, Ethernet)

Dimension and Weight

	4 Channel arm	8 Channel Arm
Weight	145 kg	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
Transport temperature	-20 to 60°C (-4 to 140°F)
Transport humidity	20–80% relative (non-condensing)
Storage temperature	1–60°C (34–140°F)
Storage humidity	30–80% relative (non-condensing) at 30°C (86°F)
Overvoltage category	II
Pollution degree	2

* Indoor only

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 barcode labels
Integrated computer & Touch Screen	User interaction touch screen display. No need of extra laptop / PC.
ThermoShaker	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 µl to 5000 µl
Process Security	cLLD (capacitive Liquid Level detection)
Precision (CV)	1 µl: ≤ 5% 200 µl: ≤ 2% 1000 µl: ≤ 2%

“Flexible configuration for different requirements.”

VIASURE Real Time PCR Detection Kits



Gastrointestinal infections

1. Multiplex

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

2. Monoplex

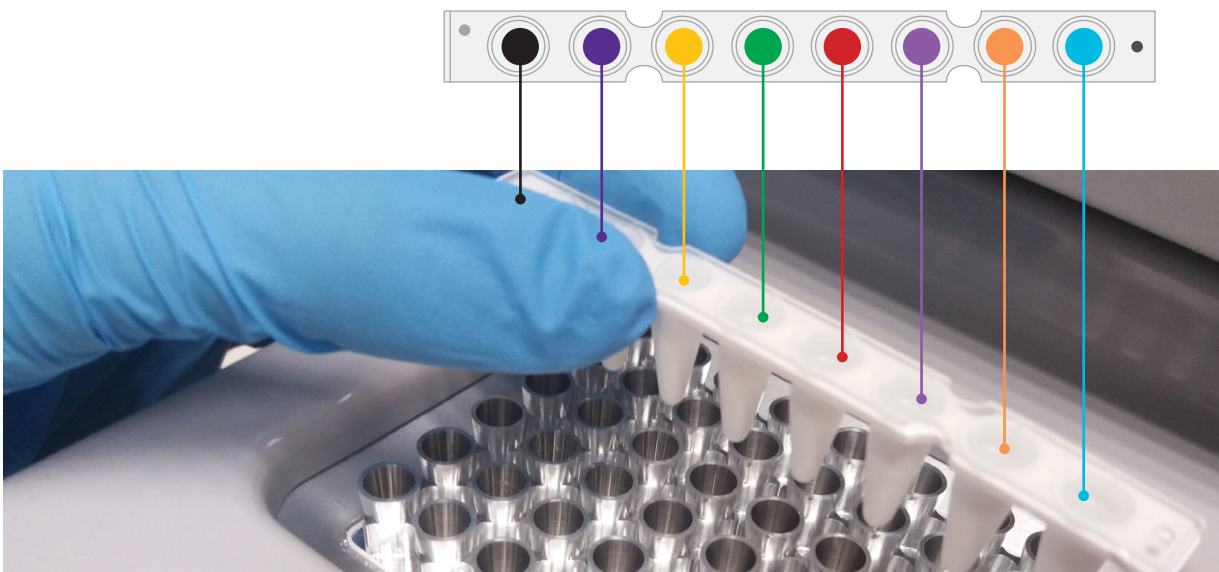
Type	Reference	Description
Virus	ADV	Adenovirus - IVD
	ATV	Astrovirus - IVD
	NOG	Norovirus GI - IVD
	NOP	Norovirus GII - IVD
	RTV	Rotavirus - IVD
	SAV	Sapovirus - IVD
Bacteria	CAM	Campylobacter - IVD
	CDS	Clostridium difficile - IVD
	CTB	Clostridium difficile toxB - IVD
	CIA	Clostridium difficile toxins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

3. Gastrointestinal 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	○			

Real Time PCR Detection Kits

Simultaneous detection of multiple targets in a broad range of multiplexing diagnostic panels.





Respiratory infections

1. Multiplex

Type	Reference	Description
Virus	IAB	Flu A + Flu B - IVD
	ABR	Flu A, Flu B & RSV - IVD
	RSV	RSV A + B- IVD
	H13	Flu Typing I (H1N1 + H3N2)
	HXN	Flu Typing II (H1N1, H5N1, H3N2 & H7N9) - IVD
	RPA	Respiratory Viral Panel I (2 wells): (Flu A, Flu B & RSV) + (H1N1, H5N1, H3N2 & H7N9)
	PIZ	Parainfluenza (2 wells): (1, 3 & 2, 4) - IVD
	AMB	Adenovirus, Metapneumovirus & Bocavirus - IVD
	RHE	Rhinovirus + Enterovirus - IVD
	MER	MERS Coronavirus (2 wells)
	COR	Coronavirus (229E, NL63, OC43 & HKU1)
	NCO2	SARS-CoV-2 (ORF1ab & N genes) - IVD
	NCO3	SARS-CoV-2 (N1 + N2)
	NCO4	SARS-CoV-2 Triplex (ORF1ab, E & N genes)
	ABC	Flu A, Flu B & SARS-CoV-2
	CFR	SARS-CoV-2, Flu & RSV
	SUK1	SARS-CoV-2 & UK Variant (S UK, S & N genes)
	SUK2	SARS-CoV-2 del 69/70, ORF1ab & N genes
	VAR	SARS-CoV-2 Variant I (E484K, K417N, K417T, N501Y)
	VAI	SARS-CoV-2 Variant II (P681R, L452R, E484Y)
VAO	SARS-CoV-2 Variant III (Q954H, A2710T)	
ERNCO2	Quick SARS-CoV-2 (Resp. Viruses Quick Lysis + SARS-CoV-2)	
Bacteria	BDT	Bordetella (B. pertussis, B. parapertussis & B. holmesii) - IVD
	CML	C. pneumoniae, M. pneumoniae & L. pneumophila
	HSM	H. influenzae, S. pneumoniae & M. catarrhalis
	MTD	M. Tuberculosis complex + Non-tuberculosis mycobacteria
Fungi	ASP	Aspergillus differentiation

SARS-CoV-2



2. Monoplex

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

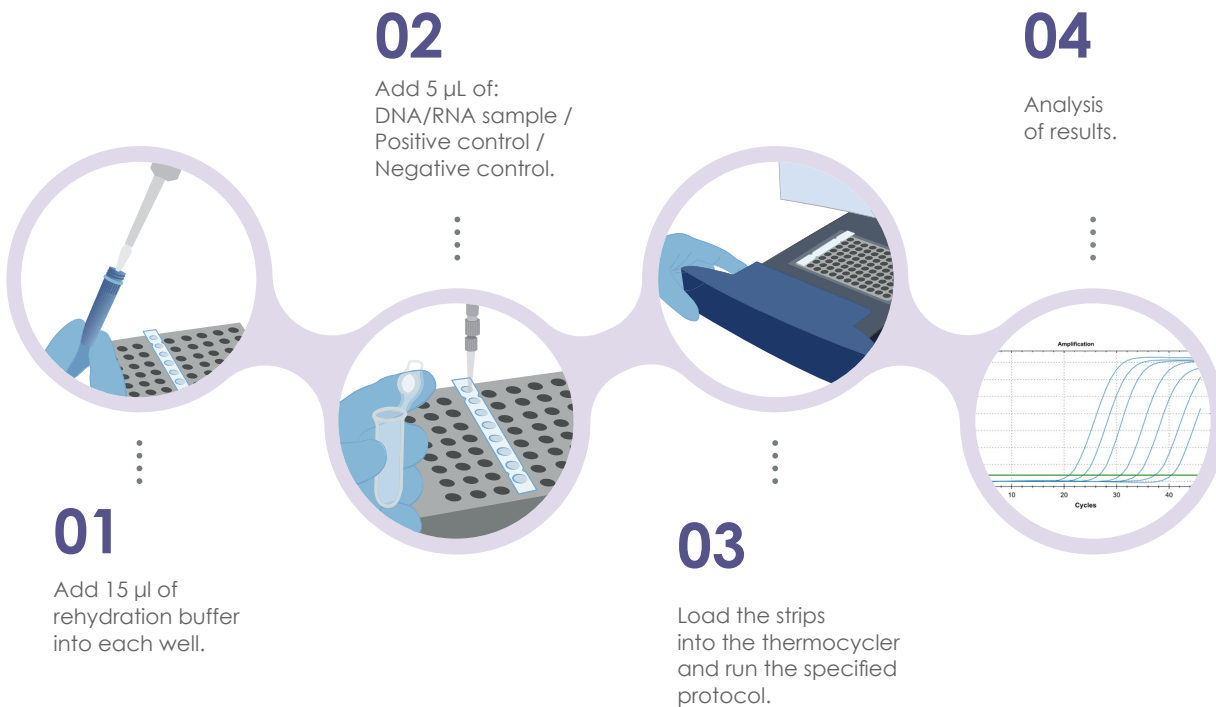
(q) Quantitative.

3. Respiratory Panels

Targets	RP01	RP02	RP03	RP04	RP05
Adenovirus, Metapneumovirus & Bocavirus	○	○	○	○	○
C. pneumoniae, M. pneumoniae & L. pneumophila		○	○		
Coronavirus (229, NL63, OC43 & HKU1)	○	○	○	○	○
Flu A + Flu B		○		○	
Flu A, Flu B & RSV	○		○		○
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					○

Real Time PCR Detection Kits

► Workflow





Tropical & Vector-Borne transmission diseases

1. Multiplex

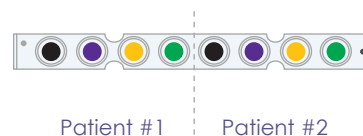
Reference	Description
ZDC	Zika, Dengue & Chikungunya Virus - IVD
DES	Dengue Serotyping (2 wells): (Dengue 1, 4 & 2, 3)
TBD	Tick Borne Diseases (3 wells): IVD (Borrelia, Anaplasma & Coxiella) + (Rickettsia, Babesia & Ehrlichia) + (TBEV)- IVD
BAC	Borrelia, Anaplasma & Coxiella
MAD	Malaria differentiation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

2. Monoplex

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

3. Tropical Panel

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



(q) Quantitative.



Sexual health

1. Multiplex

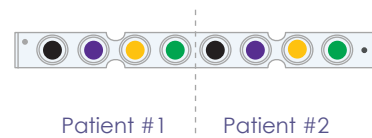
Reference	Description
STD	Sexually transmitted diseases (2 wells): (<i>N. gonorrhoeae</i> , <i>C. trachomatis</i> & <i>M. genitalium</i>) + (<i>T. vaginalis</i> , <i>U. urealyticum</i> , <i>U. parvum</i> & <i>M. hominis</i>)
CTN	<i>N. gonorrhoeae</i> + <i>C. trachomatis</i>
HHT	Herpes virus 1, Herpes virus 2 & <i>Treponema pallidum</i>
CGT	<i>C. albicans</i> , <i>G. vaginalis</i> & <i>T. vaginalis</i>
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
NCR	<i>Neisseria gonorrhoeae</i> ciprofloxacin resistant

2. Monoplex

Reference	Description
GBS	<i>Streptococcus B</i>
TPA	<i>Treponema pallidum</i>
LGV	<i>C. trachomatis</i> (LGV)

3. Sexual health Panel

Targets	SP01
<i>N. gonorrhoeae</i> , <i>C. trachomatis</i> & <i>M. genitalium</i>	●
<i>T. vaginalis</i> , <i>U. urealyticum</i> , <i>U. parvum</i> & <i>M. hominis</i>	●
Herpes virus 1, Herpes virus 2 & <i>Treponema pallidum</i>	●
<i>C. albicans</i> , <i>G. vaginalis</i> & <i>T. vaginalis</i>	●





Immunosuppressed and Meningitis

1. Multiplex

Type	Reference	Description
Virus	BJV	BK + JC Virus
	HHZ	Herpes Virus 1, Herpes Virus 2 & Varicela Zoster Virus
	HHV	Human Herpes Virus 6, 7 & 8 - IVD
	MEP	Mumps, Enterovirus & Parechovirus
Bacteria	HNS	H. influenzae, N. meningitidis & S. pneumoniae
	SLE	S. agalactiae, L. monocytogenes & E. coli

2. Monoplex

Type	Reference	Description
Virus	CMV	Cytomegalovirus (q)
	BKQ	BK Virus



Antimicrobial resistance and sepsis

1. 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
NCR	Neisseria gonorrhoeae ciprofloxacin resistant

➔ Coming soon:

- Beta-lactamases (TCX-M, TEM, SHY & Colistin)

(q) Quantitative.



Non infectious diseases

1. Multiplex

Reference	Description
CEL	HLA celiac (2 wells): (DQA1*05, DQB1*03:02, DQB1*02 & HBB gene (β -globin)) & (DQA1*02, DQA1*03 & no DQB1*02)

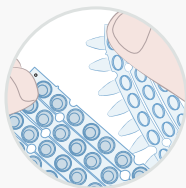
 **Coming soon...**



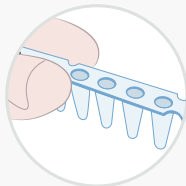
Urinary Tract Infections

UTIs are common infections that happen when bacteria, often from the skin or rectum, enter the urethra and infect the urinary tract. The infections can affect several parts of the urinary tract, but the most common type is a bladder infection (cystitis).

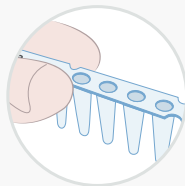
► Available formats:



Plates in low (0.1ml) and high (0.2ml) profile



Low Profile strip (0.1ml)



High Profile strip (0.2ml)



2ml Tube (Only for Multiplex and Monoplex Kits)



Rotor-Gene Tube (Only for Multiplex and Monoplex Kits)

► 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)	
Manufacturer	Model
Agilent Technologies	AriaMx/AriaDx Real-Time PCR System
	7500 Fast / 7500 Fast Dx Real-Time PCR System ⁽¹⁾ ⁽⁴⁾
	QuantStudio™ 12K Flex 96-well Fast
	QuantStudio™ 6 Flex 96-well Fast
	QuantStudio™ 7 Flex 96-well Fast
Applied Biosystems	QuantStudio™ 3 Fast Real-Time PCR System ⁽³⁾
	QuantStudio™ 5 Fast/ QuantStudio™ 5 Real-Time PCR System
	StepOne Plus™ Real-Time PCR System ⁽²⁾
	StepOne™ ⁽²⁾ , ⁽³⁾
	ViiA™ 7 Fast
Azure Biosystems	Azure Cielo 3 ⁽⁴⁾
	Azure Cielo 6
BIONEER	Exicycler™ 96 Fast
Bio-Rad	CFX96™ / CFX96™ IVD Real-Time PCR Detection System
	Mini Opticon™ Real-Time PCR Detection System ⁽⁴⁾
Roche	LightCycler® 480 Real-Time PCR System ⁽⁴⁾ ⁽⁷⁾
	LightCycler® 96 Real-Time PCR System
	Cobas z480 Analyzer ⁽⁴⁾ ⁽⁷⁾

Special Formats ⁽⁵⁾	
Manufacturer	Model
Bio Molecular Systems	Mic Real Time PCR Cyclers
Cepheid	SmartCycler®
Qiagen	Rotor-Gene® Q

High Profile Cyclers (0,2ml)	
Manufacturer	Model
Abbot	Abbot m2000 ⁽⁴⁾
Agilent	Mx3000P™/ Mx 3005P™
Analytik Jena	qTower ⁽⁷⁾
	7300 ⁽³⁾ ⁽⁴⁾
	7500 ⁽⁴⁾
	7900 HT ⁽²⁾
	ABI PRISM 7000 ⁽²⁾
Applied Biosystems	ABI PRISM 7700 ⁽²⁾
	QuantStudio™ 12K Flex 96-well
	QuantStudio™ 6 Flex 96-well
	QuantStudio™ 7 Flex 96-well
	QuantStudio™ 3 Real-Time PCR System ⁽²⁾
BIOER	QuantStudio™ 5 Fast/ QuantStudio™ 5 Real-Time PCR System
	ViiA™ 7 Real-Time PCR System
	QuantGene 9600
BIONEER	Exicycler™ 96
Bio-Rad	CFX96™ Deep Well / CFX96™ Deep Well IVD
	iCycler iQ™ Real-Time PCR Detection System
	iCycler iQ™5 Real-Time PCR Detection System
	My iQ™ Real-Time PCR Detection System ⁽⁴⁾
DNA-Technology	My iQ™2 Real-Time PCR Detection System ⁽⁴⁾
	DPrime
Eppendorf	DTitle
	Mastercycler™ ep <i>realplex</i>
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 or geneLEAD VIII System.

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

(7) Specific compensation color is required.

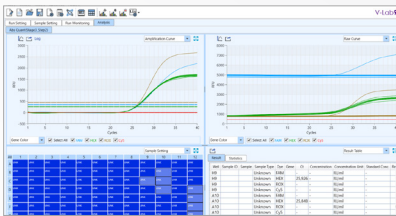
V-Lab96

Viasure Real Time PCR platform

Advanced system with 96-well block for diagnostic applications.

Open platform for in vitro diagnostics.

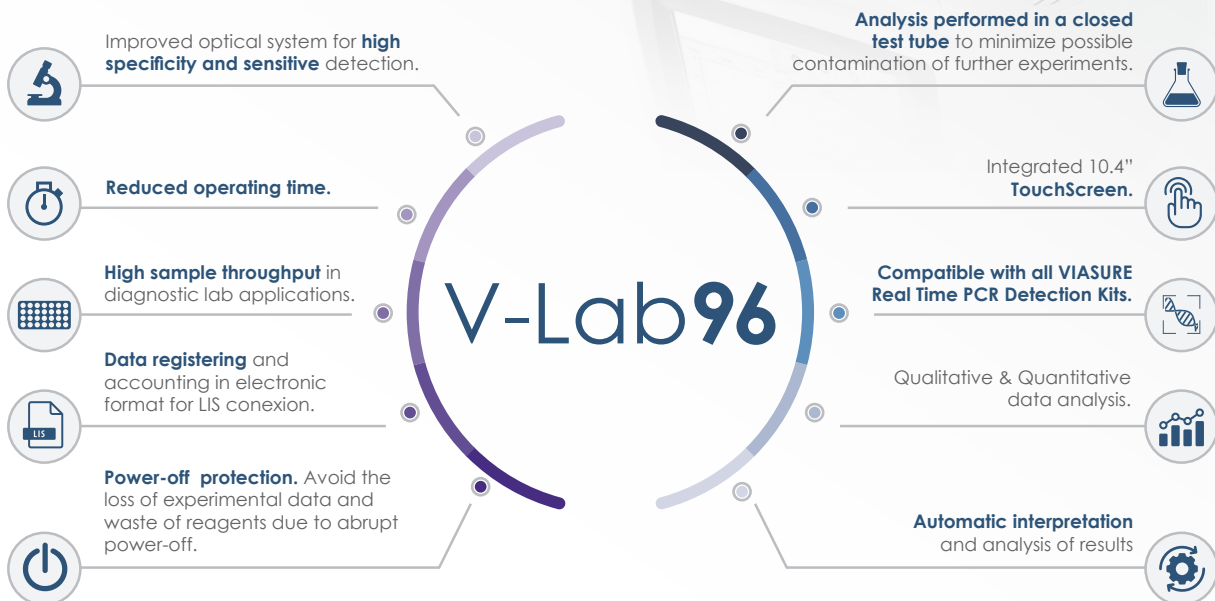
VIASURE V-Lab96 allows users to analyze 96 samples simultaneously for qualitative and quantitative Real Time PCR.



VIASURE V-Lab96 software screen.



V-Lab



V-Smart

Easy & automatic interpretation

Make your analysis easier.



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.



Easy to use



Automatic results PCR interpretation



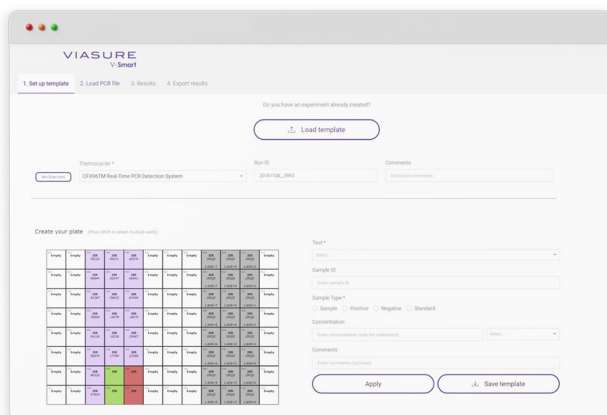
Big range of RT-PCR Thermocyclers



LIS connection & Report



Machine-learning based

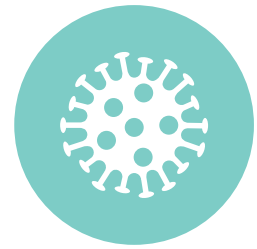


Supported qPCR systems

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

VIASURE RNA Viral Particles

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



► Available Kits:

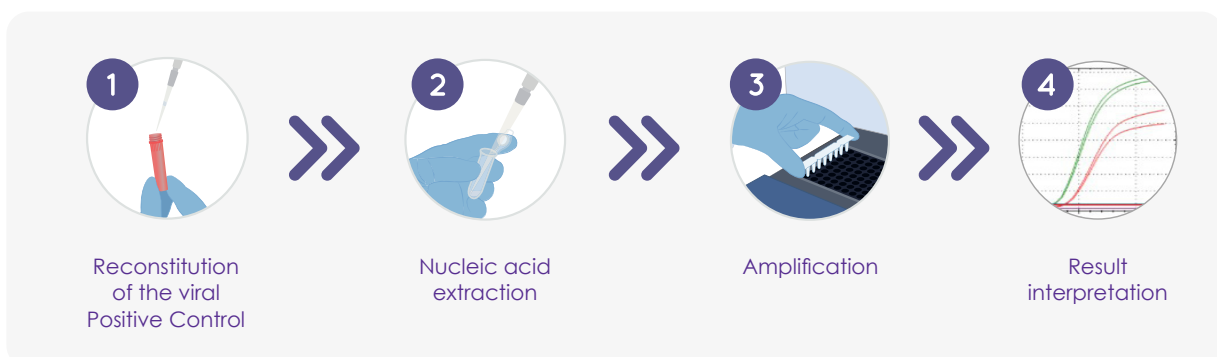
Reference	Description
VS-VP1NCO	VIASURE Viral SARS-CoV-2 Positive Control Kit
VS-VP1SUK	VIASURE Viral SARS-CoV-2 Alpha (B.1.1.7) Positive Control Kit
VS-VP1SSA	VIASURE Viral SARS-CoV-2 Beta (B.1.351) Positive Control Kit
VS-VP1SBR	VIASURE Viral SARS-CoV-2 Gamma (P.1) Positive Control Kit
VS-VP1SWT	VIASURE 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-VP1DEB	VIASURE Viral Dengue 2 Positive Control Kit
VS-VP1CHI	VIASURE Viral Chikungunya Positive Control Kit
VS-VP1SDL	VIASURE Viral SARS-CoV-2 Delta (B.1.617.2) Positive Control Kit



► 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**.

► Test procedure:



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CerTest Biotec, S.L.

Pol. Industrial Río Gállego II · Calle J, Nº1
50840, San Mateo de Gállego, Zaragoza (Spain)

Tel. (+34) 976 520 354

Fax (+34) 976 106 268

viasure@certest.es

www.certest.es



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