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-supressed and Meningitis
- Non infectious diseases

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.

RESULT

Viral Particles

Check your full process.
p. 19

VIASURE Resp. viruses Quick Lysis Reagent

Quick

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

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

Quick sample processing (10 min).

Ready to use. No specific equipment required.

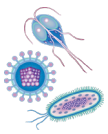
Compatible with **transport media** without guanidium salts.

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

Compatible with different biological matrices:

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

Workflow:

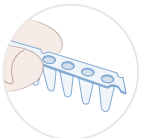


1. Sample collection:

- 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.

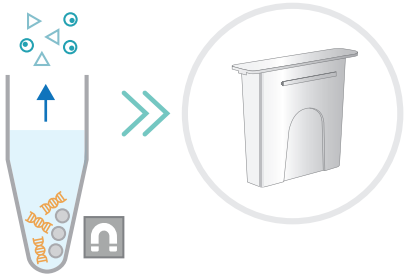
The extraction kit **has been optimized for two type of magnetic separation methods:** VIASURE V-Flex and KingFisher® Flex (other platforms ongoing).

Automate

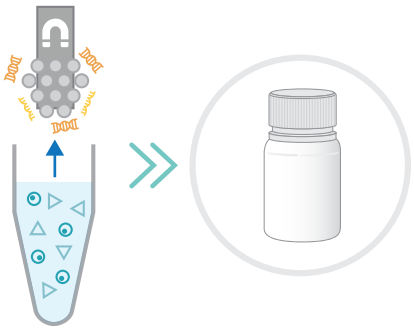
Advantages:

- **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.

Fully automated (Up to 96 samples) extraction and PCR set-up.

Flexible configuration for **different users and requirements**.

Intuitive - user friendly integrated Software.

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

DNA/RNA purification from a wide range of samples.

Easy and fully traceable sample handling.

Full LIS Compatible and integration

Exclusive designed for **minimum maintenance**.

V-Flex

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
Bacteria	SCY	Salmonella, Campylobacter & Yersinia enterocolitica
	SCS	Salmonella, Campylobacter & Shigella/EIEC
	CLJ	Campylobacter coli, C. lari & C. jejuni
	AEY	Aeromonas + Yersinia enterocolitica
	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
	CDA	Clostridium difficile toxins A+B
Parasites	KGE	Cryptosporidium, Giardia & E. histolytica
	BLD	Blastocystis hominis + Dientamoeba fragilis

2. Monoplex

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

3. Gastrointestinal Panels

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

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
	ABR	Flu A, Flu B & RSV
	RSV	RSV A + B
	H13	Flu Typing I (H1N1 + H3N2)
	HXN	Flu Typing II (H1N1, H5N1, H3N2 & H7N9)
	RPA	Respiratory Viral Panel I (2 wells): (Flu A, Flu B & RSV) + (H1N1, H5N1, H3N2 & H7N9)
	PIZ	Parainfluenza (2 wells): (1, 3 & 2, 4)
	AMB	Adenovirus, Metapneumovirus & Bocavirus
	RHE	Rhinovirus + Enterovirus
	MER	MERS Coronavirus (2 wells)
	COR	Coronavirus (229E, NL63, 0C43 &HKU1)
	NCO2	SARS-CoV-2 (ORF1ab & N genes)
	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, E4849)
	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)
	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
	MPV	Human metapneumovirus
	YIA	Influenza A
	HNV	Influenza A(H1N1)pdm09
	YIB	Influenza B
	RSA	RSV A
	RSB	RSV B
Bacteria	LGN	Legionella pneumophila
	MTC	M. Tuberculosis complex
	GAS	Group A Streptococcus
Fungi	JIR	Pneumocystis jirovecii *(q)*

(q) Quantitative.

3. Respiratory Panels

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

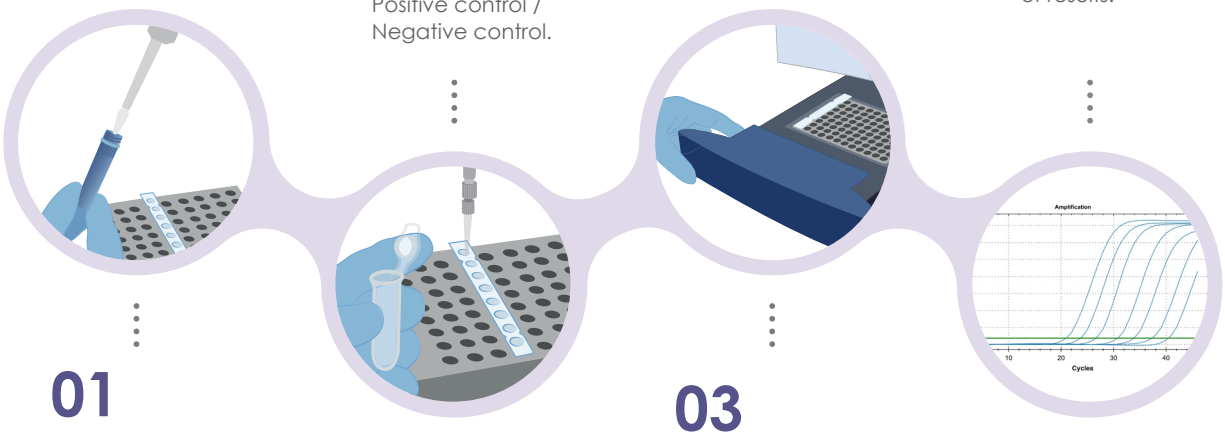
Workflow

01

Add 15 µl of rehydration buffer into each well.

02

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



03

Load the strips into the thermocycler and run the specified protocol.

04

Analysis of results.

Tropical & Vector-Borne transmission diseases

1. Multiplex

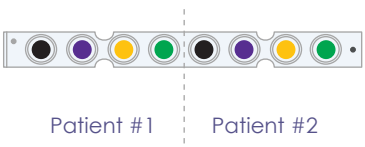
Reference	Description
ZDC	Zika, Dengue & Chikungunya Virus
DES	Dengue Serotyping (2 wells): (Dengue 1, 4 & 2, 3)
TBD	Tick Borne Diseases (3 wells): (Borrelia, Anaplasma & Coxiella) + (Rickettsia, Babesia & Ehrlichia) + (TBEV)
BAC	Borrelia, Anaplasma & Coxiella
MAD	Malaria differentiation (2 wells): (P.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

2. Monoplex

Type	Reference	Description
Virus	ZIK	Zika Virus
	DEN	Dengue Virus
	CHI	Chikungunya Virus
	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

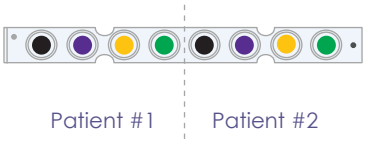
Reference	Description
STD	Sexually transmitted diseases (2 wells): (N. gonorrhoeae, C. trachomatis & M. genitalium) + (T. vaginalis, U. urealyticum, U. parvum & M. hominis)
CTN	N. gonorrhoeae + C. trachomatis
HHT	Herpes virus 1, Herpes virus 2 & Treponema pallidum
CGT	C. albicans, G. vaginalis & T. vaginalis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

2. Monoplex

Reference	Description
GBS	Streptococcus B
TPA	Treponema pallidum
LGV	C. trachomatis (LGV)

3. Sexual health Panel

Targets	SP01
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	●



Immunosupressed 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
	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

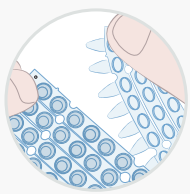
Reference	Description
CEL	HLA celiac (2 wells): (DQA1*05, DQB1*03:02, DQB1*02 & HBB gene (β-globin)) & (DQA1*02, DQA1*03 & no DQB1*02)

Coming soon...

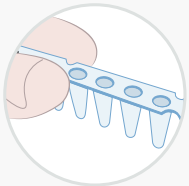
Urinary Tract Infections

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).

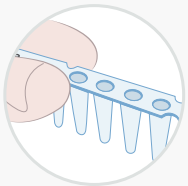
Available formats:



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
Applied Biosystems	7500 Fast / 7500 Fast Dx Real-Time PCR System [1] [6]
	QuantStudio™ 12K Flex 96-well Fast
	QuantStudio™ 6 Flex 96-well Fast
	QuantStudio™ 7 Flex 96-well Fast
	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	CFX96TM / CFX96TM IVD Real-Time PCR Detection System
	Mini OpticonTM Real-Time PCR Detection System [4]
Roche	LightCycler ® 480 Real-Time PCR System [6] [7]
	LightCycler ® 96 Real-Time PCR System
	Cobas z480 Analyzer [6][7]

Special Formats [5]

Manufacturer	Model
Bio Molecular Systems	Mic Real Time PCR Cycler
Cepheid	SmartCycler®
Qiagen	Rotor-Gene® Q

High Profile Cyclers (0,2ml)

Manufacturer	Model
Abbott	Abbott m2000 [6]
Agilent	Mx3000P™/ Mx 3005P™
Analytik Jena	qTower [7]
Applied Biosystems	7300 [3] [6]
	7500 [6]
	7900 HT [2]
	ABI PRISM 7000 [2]
	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]
	QuantStudio™ 5 Fast/ QuantStudio™ 5 Real-Time PCR System
	ViiA™ 7 Real-Time PCR System
BIOER	QuantGene 9600
BIONEER	Exicycler™ 96
Bio-Rad	CFX96TM Deep Well / CFX96TM Deep Well IVD
	iCycler iQTM Real-Time PCR Detection System
	iCycler iQTM5 Real-Time PCR Detection System
	My iQTM Real-Time PCR Detection System [4]
	My iQTM2 Real-Time PCR Detection System [4]
DNA-Technology	DTprime
	DTlite
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 or geneLEAD VIII System.

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

(7) Specific compensation color is required.

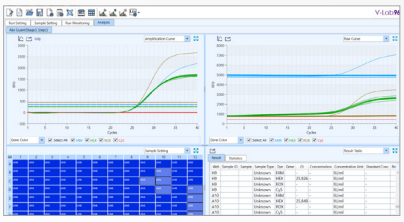
V-Lab96

Viasure Real Time PCR platform

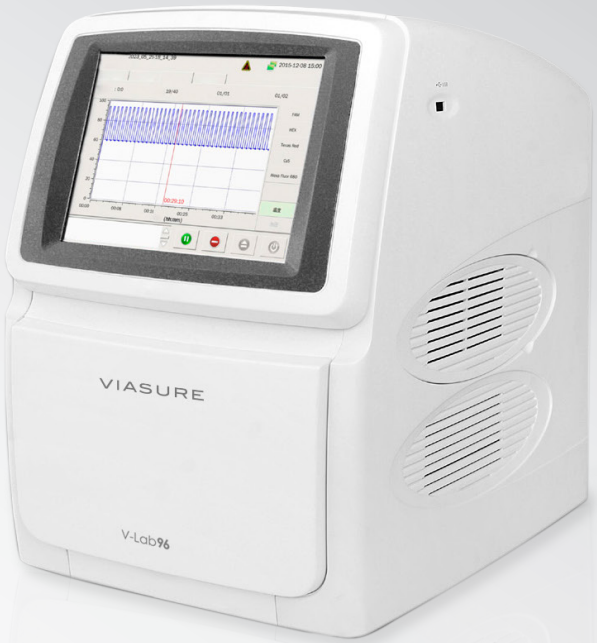
Advanced system with 96-well block for diagnostic applications.

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.



- 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 conexion.
- **Power-off protection.** Avoid the loss of experimental data and waste of reagents due to abrupt power-off.

V-Lab96

- **Analysis performed in a closed test tube** to minimize possible contamination of further experiments.
- Integrated 10.4" **TouchScreen.**
- **Compatible with all VIASURE Real Time PCR Detection Kits.**
- Qualitative & Quantitative data analysis.
- **Automatic interpretation** and analysis of results

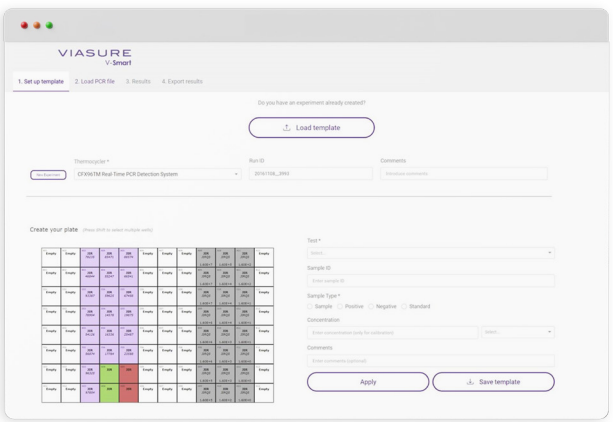
V-Smart

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:

1. Reconstitution of the viral Positive Control
2. Nucleic acid extraction
3. Amplification
4. Result interpretation

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

Service and support:
Our expert team focuses on **quality, attention and detail.**

One step ahead

VIASURE

CerTest BIOTEC

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

SGS MDSAP

VIASURE/GEN-0722EN