

# VIASURE

## Complete Solution

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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



**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

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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.



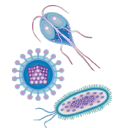
**Compatible** with different biological matrices:



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

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

## ▶ Workflow:



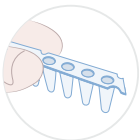
### 1. Sample collection:

- 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).

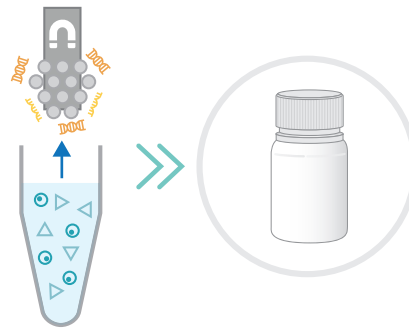
## ▶ Advantages:

- ✓ **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.)

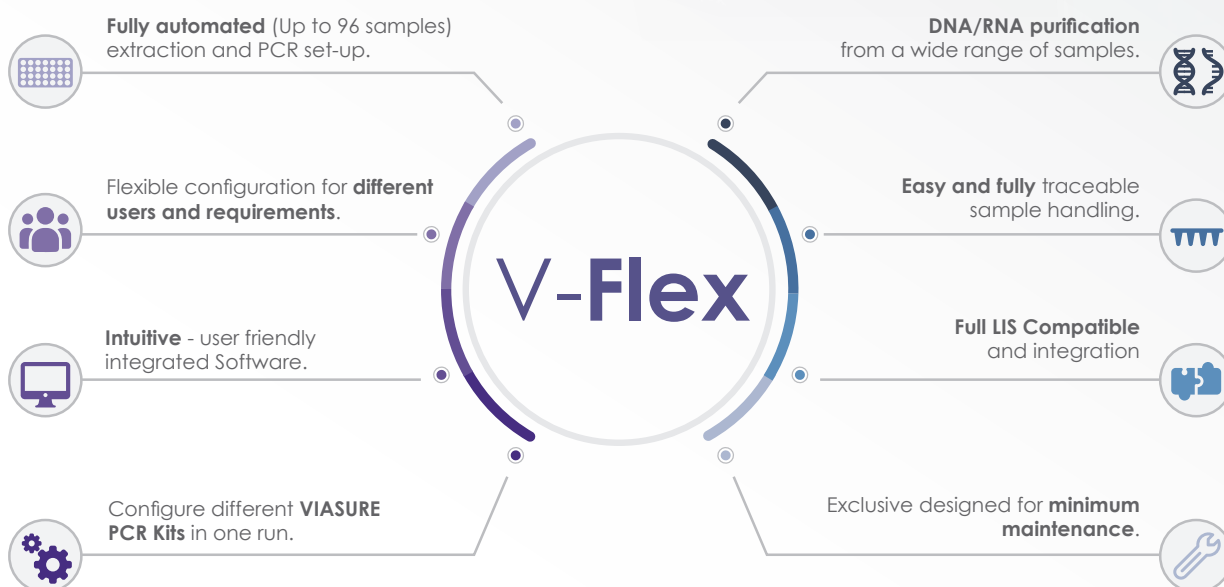
# V-Flex

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
<b>Weight</b>	145 kg	151 kg
<b>Size</b> (L x W x H)	782 x 1190 x 1094 mm	

### Environmental conditions

<b>Temperature *</b>	15–32°C (59–90°F)
<b>Humidity *</b>	30–80% relative (non-condensing) at 30°C (86°F)
<b>Altitude *</b>	0–2000 m above sea level
<b>Transport temperature</b>	-20 to 60°C (-4 to 140°F)
<b>Transport humidity</b>	20–80% relative (non-condensing)
<b>Storage temperature</b>	1–60°C (34–140°F)
<b>Storage humidity</b>	30–80% relative (non-condensing) at 30°C (86°F)
<b>Overvoltage category</b>	II
<b>Pollution degree</b>	2

\* Indoor only

### Instrument Integrated Modules

<b>UVC Light</b>	UV-C emitting lamp for decontamination of the inside of the instrument housing and work deck.
<b>Loading ID</b>	Loading ID module includes up to six dedicated grid positions for loading and scanning the barcode labels
<b>Integrated computer &amp; Touch Screen</b>	User interaction touch screen display. No need of extra laptop / PC.
<b>ThermoShaker</b>	Integrated Heating/Shaking device

### Pipetting System

<b>Volume Range</b>	1 µl to 5000 µl
<b>Process Security</b>	cLLD (capacitive Liquid Level detection)
<b>Precision (CV)</b>	1 µl: ≤ 5%   200 µl: ≤ 2%   1000 µl: ≤ 2%

### Extra Options

<b>HEPA filter unit (HEFU)</b>	Air flow can be adjusted to blow filtered air in the enclosure or extract air by passing the filter.
<b>Cooling Module</b>	Cooling blocks for micro-plates, tubes or reservoirs.

“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
Parasites	CDA	Clostridium difficile toxins A+B
	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	○			
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
	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, OC43 & 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, E484Q)
VAO	SARS-CoV-2 Variant III (Q954H, A2710T)	
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

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)

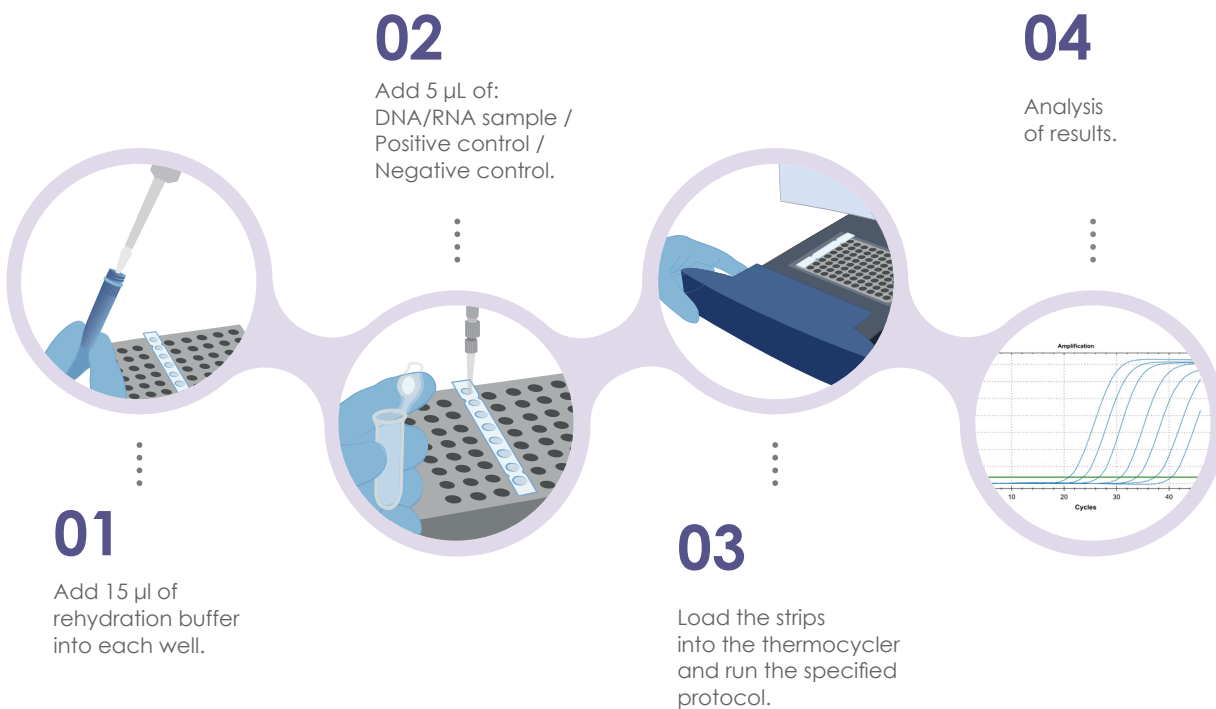
(q) Quantitative.

### 3. Respiratory Panels

Targets	RP01	RP02	RP03	RP04	RP05
Adenovirus, Metapneumovirus & Bocavirus	○	○	○	○	○
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

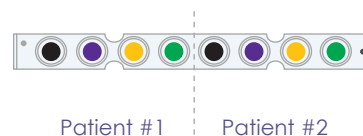
Type	Reference	Description
	ZDC	Zika, Dengue & Chikungunya Virus
	DES	Dengue Serotyping (2 wells): (Dengue 1, 4 & 2, 3)
	TBD	Tick Borne Diseases (3 wells): (Borrelia, Anaplasma & Coxiella) + (Rickettsia, Babesia & Ehrlichia) + (TBEV)
	BAC	Borrelia, Anaplasma & Coxiella
	MAD	Malaria differentiation (2 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
Parasites	CHA	Trypanosoma cruzi (Chagas)
	MAL	Malaria (q)
	LEI	Leishmania

### 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)
HHT	Herpes virus 1, Herpes virus 2 & Treponema pallidum
CGT	C. albicans, G. vaginalis & T. vaginalis
HPV	Human Papiloma Virus 16 + 18
HRP	High Risk Papilloma (2 wells): (16), (18) & (35/58/66) + (33/45/51), (52/59/68) & (31/39/56)
CTN	N. gonorrhoeae + C. trachomatis

**➔ Coming soon:**

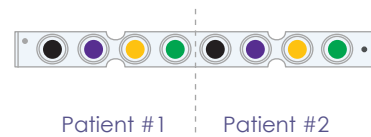
- Low Risk Papilloma: (40/43/61/70), (6/11) & (42/44/54) (2 wells)
- Neisseria gonorrhoeae ciprofloxacin resistant

## 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	●



Real Time PCR Detection Kits



## Immunosuppressed and Meningitis

### 1. Multiplex

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

### 2. Monoplex

Type	Reference	Description
Virus	CMV	Cytomegalovirus (q)

➔ **Coming soon:**

- BK virus (q)



## Antimicrobial resistance

### 1. Multiplex

Reference	Description
VAN	Vancomycin resistance
CLA	H. pylori + Clarithromycin resistance
MSA	Methicillin-resistant Staphylococcus aureus (2 wells): (MRSA, MSSA and/or MRCoNS)
CPE	Carbapenemase-producing Enterobacteriaceae (2 wells): (NDM + VIM) + (OXA, KPC & IMP)

➔ **Coming soon:**

- Enterococcus faecalis, Enterococcus faecium & Vancomycin resistance
- Beta-lactamases (TCX-M, TEM, SHY & Colistin)
- Neisseria gonorrhoeae ciprofloxacin resistant

(q) Quantitative.



## Non infectious diseases

### 1. Multiplex

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

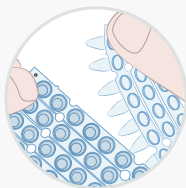
 **Coming soon...**



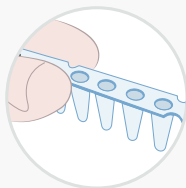
### Urinary Tract Infections

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).

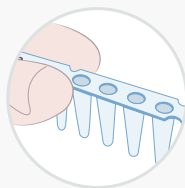
### ► Available formats:



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 <sup>(1)</sup> <sup>(4)</sup>
	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 <sup>(3)</sup>
	QuantStudio™ 5 Fast/ QuantStudio™ 5 Real-Time PCR System
	StepOne Plus™ Real-Time PCR System <sup>(2)</sup>
	StepOne™ <sup>(2)</sup> , <sup>(3)</sup>
	ViiA™ 7 Fast
Azure Biosystems	Azure Cielo 3 <sup>(4)</sup>
	Azure Cielo 6
BIONEER	Exicycler™ 96 Fast
Bio-Rad	CFX96™ / CFX96™ IVD Real-Time PCR Detection System
	Mini Opticon™ Real-Time PCR Detection System <sup>(4)</sup>
Roche	LightCycler® 480 Real-Time PCR System <sup>(4)</sup> <sup>(7)</sup>
	LightCycler® 96 Real-Time PCR System
	Cobas z480 Analyzer <sup>(4)</sup> <sup>(7)</sup>

Special Formats <sup>(5)</sup>	
Manufacturer	Model
Bio Molecular Systems	Mic Real Time PCR Cyclor
Cepheid	SmartCycler®
Qiagen	Rotor-Gene® Q

High Profile Cyclers (0,2ml)	
Manufacturer	Model
Abbot	Abbot m2000 <sup>(4)</sup>
Agilent	Mx3000P™/ Mx 3005P™
Analytik Jena	qTower <sup>(7)</sup>
	7300 <sup>(3)</sup> <sup>(4)</sup>
	7500 <sup>(4)</sup>
	7900 HT <sup>(2)</sup>
	ABI PRISM 7000 <sup>(2)</sup>
Applied Biosystems	ABI PRISM 7700 <sup>(2)</sup>
	QuantStudio™ 12K Flex 96-well
	QuantStudio™ 6 Flex 96-well
	QuantStudio™ 7 Flex 96-well
	QuantStudio™ 3 Real-Time PCR System <sup>(2)</sup>
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 <sup>(4)</sup>
DNA-Technology	My iQ™2 Real-Time PCR Detection System <sup>(4)</sup>
	DPrime
Eppendorf	DTitle
	Mastercycler™ ep <i>realplex</i>
Qiagen	QIAquant 96 <sup>(7)</sup>
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.



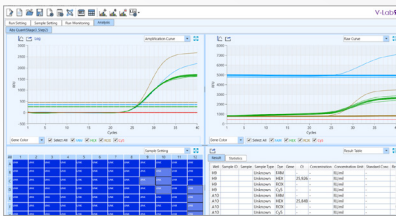
# V-Lab96

## Viasure Real Time PCR platform

Advanced system with 96-well block for diagnostic applications.

## Open platform for in vitro diagnostics.

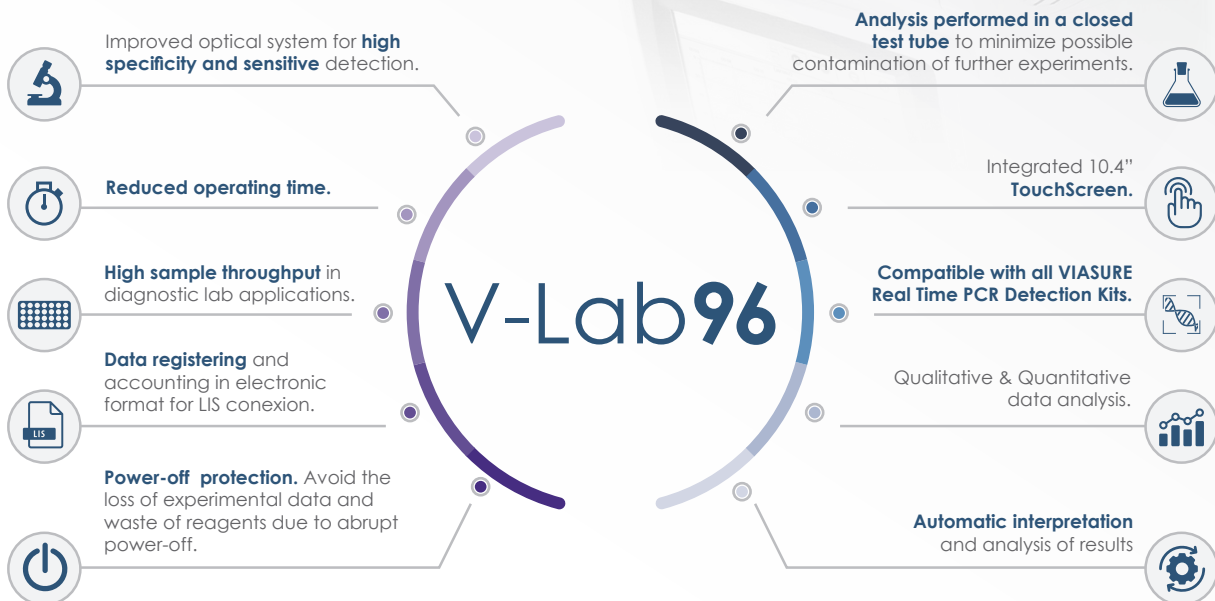
VIASURE V-Lab96 allows users to analyze 96 samples simultaneously for qualitative and quantitative Real Time PCR.



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**



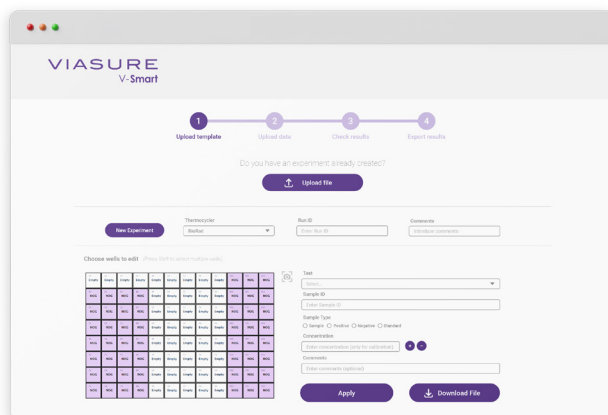
**Big range of RT-PCR Thermocyclers**



**LIS connection & Report**



**Machine-learning based**

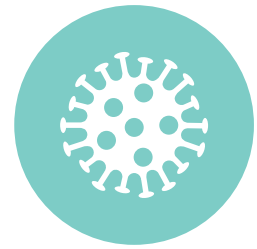


### Supported qPCR systems

- 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:

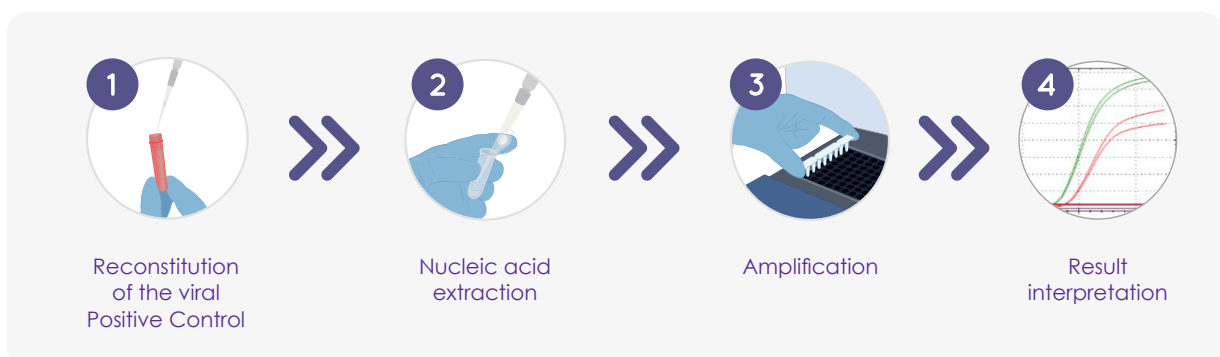
Reference	Description
VS-VP1NCO	VIASURE Viral <b>SARS-CoV-2</b> Positive Control Kit
VS-VP1SUK	VIASURE Viral <b>SARS-CoV-2 Alpha (B.1.1.7)</b> Positive Control Kit
VS-VP1SSA	VIASURE Viral <b>SARS-CoV-2 Beta (B.1.351)</b> Positive Control Kit
VS-VP1SBR	VIASURE Viral <b>SARS-CoV-2 Gamma (P.1)</b> Positive Control Kit
VS-VP1SWT	VIASURE Viral <b>SARS-CoV-2 Total</b> Positive Control Kit
VS-VP1ABR	VIASURE Viral <b>ABR</b> Positive Control Kit
VS-VP1YIA	VIASURE Viral <b>Influenza A (H1N1)</b> Positive Control Kit
VS-VP1YIB	VIASURE Viral <b>Influenza B</b> Positive Control Kit
VS-VP1DEB	VIASURE Viral <b>Dengue 2</b> Positive Control Kit
VS-VP1CHI	VIASURE Viral <b>Chikungunya</b> 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:



## **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.**

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50840, San Mateo de Gállego, Zaragoza (Spain)

Tel. (+34) 976 520 354

Fax (+34) 976 106 268

[viasure@certest.es](mailto:viasure@certest.es)

[www.certest.es](http://www.certest.es)



VIASURE/GEN-0522EN

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