VIASURE

Molecular Diagnostic
workflow for your lab

certest

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

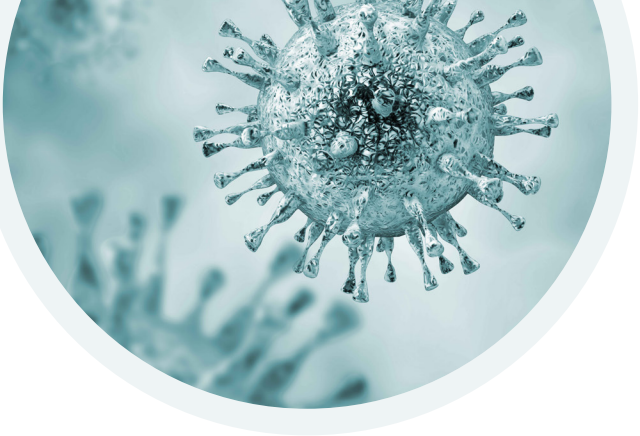
Shipping and storage at **room temperature.** Shelf-life: **24 months**

Validated according to **ISO 13485** and **CE-IVD** marked

Unique thermal protocol: multiple parameters simultaneously in a single PCR

Molecular Diagnostics

- Gastrointestinal infections
- Respiratory infections
- Antimicrobial resistance
- Tropical & Vector-Borne transmission diseases
- Sexual Health
- Immuno-supressed and Meningitis
- Non infectious diseases



VIASURE

Your tailored solution!

Sample

p. 4

DNA/RNA extraction reagents

Extraction kits

V-Quick32
V-Flex

p. 6

Automation. Extraction and PCR set-up.

p. 8

Reagents for amplification.

Real Time PCR Detection kits

V-Lab96

p. 17

PCR Platform.

p. 18

Automatic interpretation.

V-Smart

Result

p. 19

Check your full process.

Viral particles

VIASURE Universal Pathogens Extraction Kit for VIASURE V-Quick32

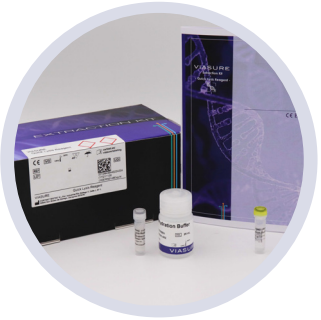
Quick

IVDR CERTIFIED

- **Ready to use reagents** with preloaded plates.
- **Compatible** with a wide range of sample types.
- Stable at **Room Temperature.**
- Purification of viral, bacterial, parasitic and fungal **DNA and RNA.**
- **Magnetic beads** technology.
- **27 minutes** Universal extraction.

Reference	Description
VS-EAU0196VQ	VIASURE Universal Pathogens Extraction Kit for VIASURE V-Quick32, 96 prep

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.

IVDR CERTIFIED

- **Ready to use.**
- **Quick** sample processing **10 minutes.**
- **Compatible** with:
  - **Nasopharyngeal** and **oropharyngeal** swabs
  - **Saliva**
- **No freezing** during transport and storage.
- **High Specificity and Sensitivity.** Detection up to 5 copies/qPCR reaction.

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

VIASURE Extraction Kits

Automate

Simultaneous processing of **different types of biological samples.**

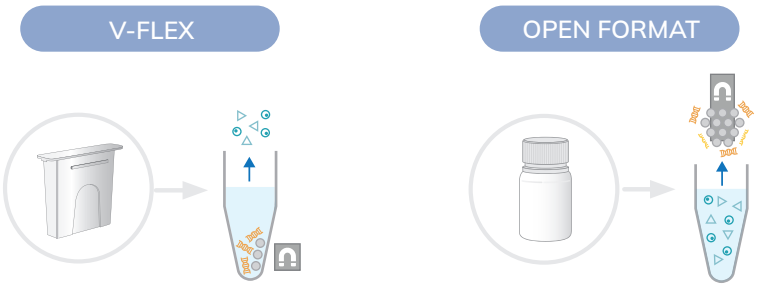
Magnetic beads technology

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



VIASURE DNA/RNA Pathogen Extraction Kit

IVDR CERTIFIED

Swabs, saliva, sputum, faeces, and urine.

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

VIASURE Blood Pathogens Extraction Kit

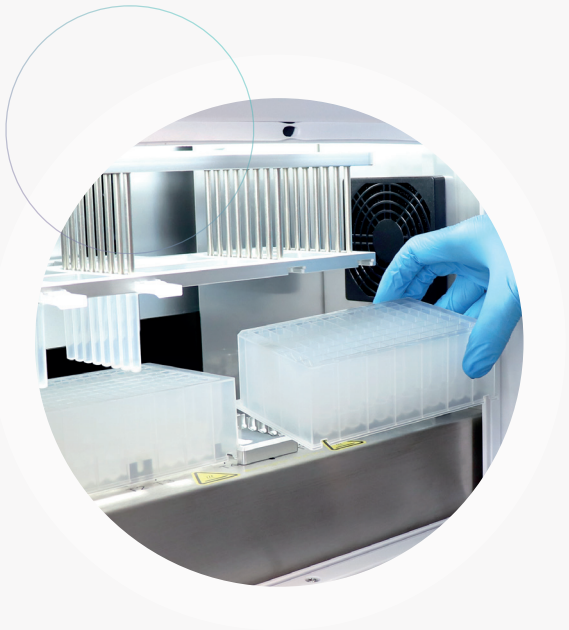
IVDR CERTIFIED

Optimised for whole blood, serum, plasma, blood hemocultures, cerebrospinal fluid, fresh urine and STI swabs.

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

V-Quick32

Automatic nucleic acid extraction instrument



Integrated touchscreen
User friendly software

DNA/RNA **Universal Extraction Protocol**

Fast extraction protocol:
Only 27 minutes

Highly efficient:
Based on magnetic Beads technology

Flexible Capacity:
From 1 to 32 samples

IVDR CERTIFIED

V-Flex

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

Flexible configurations for different needs.

- **Fully automated extraction** (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** in 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**.

IVDR CERTIFIED

VIASURE Real Time PCR Detection Kits

Gastrointestinal infections

Multiplex

Type	Reference	Description	Tests
Virus	NOR	Norovirus GI + GII	48/96
Bacteria	AEY	Aeromonas + Yersinia enterocolitica	48/96
	CDA	Clostridium difficile toxins A+B	48/96
	CLA	H. pylori + Clarithromycin resistance	48/96
	CLJ	Campylobacter coli, C. lari & C. jejuni	48/96
	ECT	E. coli typing (2 wells): (E. coli ETEC + EIEC) + (E. coli EHEC, EPEC & EIEC)	24/48
	EEE	E. coli EHEC, EPEC & EIEC	48/96
	ESE	E. coli ETEC + EIEC	48/96
	SCS	Salmonella, Campylobacter & Shigella/EIEC	48/96
	SCY	Salmonella, Campylobacter & Yersinia enterocolitica	48/96
Parasites	BLD	Blastocystis hominis + Dientamoeba fragilis	48/96
	KGE	Cryptosporidium, Giardia & E. histolytica	48/96

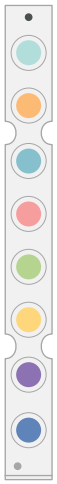
Monoplex

Type	Reference	Description	Tests
Virus	ADV	Adenovirus	48/96
	ATV	Astrovirus	48/96
	NOG	Norovirus GI	48/96
	NOP	Norovirus GII	48/96
	RTV	Rotavirus	48/96
	SAV	Sapovirus	48/96
Bacteria	CAM	Campylobacter	48/96
	CDS	Clostridium difficile	48/96
	CIA	Clostridium difficile toxins A/B	48/96
	CTB	Clostridium difficile toxB	48/96
	PYR	Helicobacter pylori	48/96
	SAM	Salmonella	48/96
	SHY	Shigella/EIEC (Enteroinvasive Escherichia coli)	48/96
	YER	Yersinia enterocolitica	48/96
Parasites	DIE	Dientamoeba fragilis	48/96
	ETD	Entamoeba dispar	48/96
	ETH	Entamoeba histolytica	48/96
	GIA	Giardia lamblia	48/96
	KRY	Cryptosporidium	48/96

One Thermal Protocol. More Targets. Less Time!

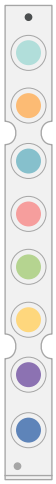
Panels

GP01 | 12 tests



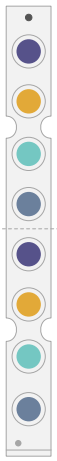
- Salmonella, Y. enterocolitica y Campylobacter
- Shigella/EIEC
- Giardia lamblia, E. histolytica y Cryptosporidium
- Norovirus GII, Norovirus GI
- Rotavirus
- Adenovirus
- Astrovirus
- Sapovirus

GP02 | 12 tests



- Salmonella, Campylobacter & Shigella/EIEC
- Aeromonas spp. + Yersinia enterocolitica
- E. coli EHEC, EPEC & EIEC
- E. coli ETEC + EIEC
- Clostridium difficile
- Clostridium difficile toxB
- Cryptosporidium, Giardia & E. histolytica
- Blastocystis hominis + Dientamoeba fragilis

GP03 | 24 tests



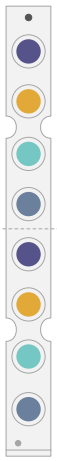
Patient #1

- Salmonella, Campylobacter & Shigella/EIEC
- Aeromonas spp. + Yersinia enterocolitica
- E. coli EHEC, EPEC & EIEC
- E. coli ETEC + EIEC

Patient #2

- Salmonella, Campylobacter & Shigella/EIEC
- Aeromonas spp. + Yersinia enterocolitica
- E. coli EHEC, EPEC & EIEC
- E. coli ETEC + EIEC

GP04 | 24 tests



Patient #1

- Clostridium difficile toxins A + B
- Salmonella, Campylobacter & Y. enterocolitica
- Campylobacter coli, C. lari & C. jejuni
- E. coli EHEC, EPEC & EIEC

Patient #2

- Clostridium difficile toxins A + B
- Salmonella, Campylobacter & Y. enterocolitica
- Campylobacter coli, C. lari & C. jejuni
- E. coli EHEC, EPEC & EIEC

Respiratory infections

Multiplex

Type	Reference	Description	Tests
Virus	ABC	Flu A, Flu B & SARS-CoV-2	48/96
	ABR	Flu A, Flu B & RSV	48/96
	AMB	Adenovirus, Metapneumovirus & Bocavirus	48/96
	CFR	SARS-CoV-2, Flu & RSV	48/96
	COR	Coronavirus (229E, NL63, 0C43 & HKU1)	48/96
	ERNCO2	Quick SARS-CoV-2 (Resp. Viruses Quick Lysis + SARS-CoV-2)	48
	HXN	Flu Typing II (H1N1, H5N1, H3N2 & H7N9)	48/96
	H13	Flu Typing I (H1N1 + H3N2)	48/96
	IAB	Flu A + Flu B	48/96
	MER	MERS Coronavirus (2 wells)	24/48
	NCO2	SARS-CoV-2 (ORF1ab & N genes)	48/96
	NCO3	SARS-CoV-2 (N1 + N2)	48/96
	NCO4	SARS-CoV-2 Triplex (ORF1ab, E & N genes)	48/96
	PIZ	Parainfluenza (2 wells): (1, 3 & 2, 4)	24/48
	RHE	Rhinovirus + Enterovirus	48/96
	RPA	Respiratory Viral Panel I (2 wells): (Flu A, Flu B & RSV) + (H1N1, H5N1, H3N2 & H7N9)	24/48
	RSV	RSV A + B	48/96
	SUK2	SARS-CoV-2 del 69/70, ORF1ab & N genes	48/96
	VAI	SARS-CoV-2 Variant II (P681R, L452R, E484Q)	48/96
	VAO	SARS-CoV-2 Variant III (Q954H, A2710T)	48/96
	VAR	SARS-CoV-2 Variant I (E484K, K417N, K417T, N501Y)	48/96
Bacteria	BDT	Bordetella (B. pertussis, B. parapertussis & B. holmesii)	48/96
	CML	C. pneumoniae, M. pneumoniae & L. pneumophila	48/96
	HSM	H. influenzae, S. pneumoniae & M. catarrhalis	48/96
	MTD	M. tuberculosis complex + Non-tuberculosis mycobacteria	48/96
Fungi	ASP	Aspergillus differentiation (A. fumigatus, A. flavus, A. terreus)	48/96

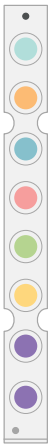
Monoplex

Type	Reference	Description	Tests
Virus	BVS	Bocavirus	48/96
	HNV	Influenza A(H1N1)pdm09	48/96
	MPV	Human metapneumovirus	48/96
	RSA	RSV A	48/96
	RSB	RSV B	48/96
	YIA	Influenza A	48/96
	YIB	Influenza B	48/96
Bacteria	GAS	Group A Streptococcus	48/96
	LGN	Legionella pneumophila	48/96
	MTC	M. Tuberculosis complex	48/96
Fungi	JIR	Pneumocystis jirovecii (q)	48/96

(q) Quantitative

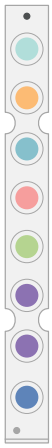
Panels

RP01 | 12 tests



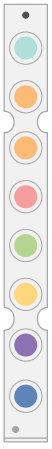
- Flu A, Flu B & RSV
- Rhinovirus + Enterovirus
- Adenovirus, Metapneumovirus & Bocavirus
- MERS Coronavirus
- MERS Coronavirus
- Coronavirus (229E, NL63, OC43 & HKU1)
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)

RP02 | 12 tests



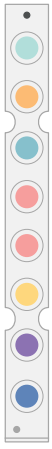
- Flu A + Flu B
- RSV A + B
- Flu Typing II (H1N1, H5N1, H3N2 & H7N9)
- Adenovirus, Metapneumovirus & Bocavirus
- Coronavirus (229E, NL63, OC43 & HKU1)
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)
- C. pneumoniae, M. pneumoniae & L. pneumophila

RP03 | 12 tests



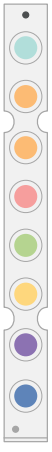
- Flu A, Flu B & RSV
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)
- Adenovirus, Metapneumovirus & Bocavirus
- Rhinovirus + Enterovirus
- Coronavirus (229E, NL63, OC43 & HKU1)
- C. pneumoniae, M. pneumoniae & L. pneumophila
- H. influenzae, S. pneumoniae & M. catarrhalis

RP04 | 12 tests



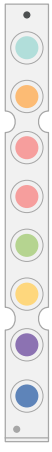
- Flu A + Flu B
- Influenza H1N1
- RSV A + B
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)
- Adenovirus, Metapneumovirus & Bocavirus
- Rhinovirus + Enterovirus
- Coronavirus (229E, NL63, OC43 & HKU1)

RP05 | 12 tests



- Flu A, Flu B & RSV
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)
- Adenovirus, Metapneumovirus & Bocavirus
- Rhinovirus + Enterovirus
- Coronavirus (229E, NL63, OC43 & HKU1)
- Legionella pneumophila
- H. influenzae, S. pneumoniae & M. catarrhalis

RP06 | 12 tests



- Flu A, Flu B & RSV
- Flu Typing I (H1N1 & H3N2)
- Parainfluenza (1, 3 & 2, 4)
- Parainfluenza (1, 3 & 2, 4)
- Adenovirus, Metapneumovirus & Bocavirus
- Rhinovirus + Enterovirus
- Coronavirus (229E, NL63, OC43 & HKU1)
- SARS-CoV-2 (ORF1ab & N genes)

Tropical & Vector-Borne transmission diseases

Multiplex

Reference	Description	Tests
BAC	Borrelia, Anaplasma & C. burnetii	48/96
DES	Dengue Serotyping (2 wells): (Dengue 1, 4 & 2, 3)	24/48
MAD	Malaria differentiation (2 wells): (P. malariae, P. knowlesi & P. ovale) + (P. falciparum + P. vivax)	24/48
TBD	Tick Borne Diseases (3 wells): (Borrelia, Anaplasma & C. burnetii) + (Rickettsia, Babesia & Ehrlichia) + (TBEV)	24/48
ZDC	Zika, Dengue & Chikungunya Virus	48/96

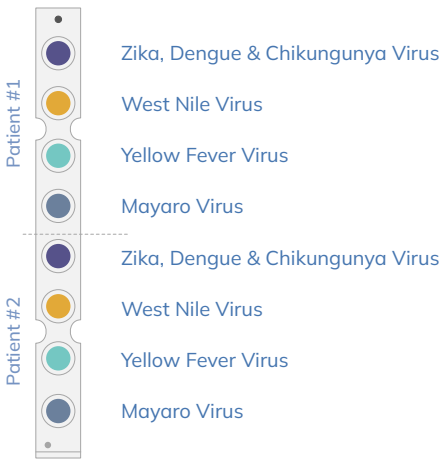
Monoplex

Type	Reference	Description	Tests
Virus	**CCV**	Crimean-Congo Hemorrhagic Fever Virus	48/96
	CHI	Chikungunya Virus	48/96
	DEN	Dengue Virus	48/96
	FEV	Yellow Fever Virus	48/96
	JEV	Japanese Encephalitis Virus	48/96
	MPX	Monkeypox Virus	48/96
	MYV	Mayaro Virus	48/96
	WNV	West Nile Virus	48/96
	ZIK	Zika Virus	48/96
Parasites	**CHA**	Trypanosoma cruzi (Chagas)	48/96
	LEI	Leishmania	48/96
	MAL	Malaria (q)	48/96
	TGO	Toxoplasma gondii (1)	48/96

Panel

TP01

24 tests



(1) Research Use Only

Sexual health

Multiplex

Reference	Description	Tests
CGT	C. albicans, G. vaginalis & T. vaginalis	48/96
CTN	N. gonorrhoeae + C. trachomatis	48/96
HHT	Herpes virus 1, Herpes virus 2 & Treponema pallidum	48/96
HPV	Human Papilloma Virus 16 + 18	48/96
HRP	High Risk Papilloma (2 wells): (16), (18) & (35/58/66) + (33/45/51), (52/59/68) & (31/39/56)	48/96
MGR	Macrolide resistance-associated mutations (23S rRNA)	48/96
NCR	Neisseria gonorrhoeae ciprofloxacin resistant	48/96
NMT	Neisseria gonorrhoeae, Chlamydia trachomatis & Mycoplasma genitalium (1) NEW	48/96
STD	Sexually transmitted diseases (2 wells): (N. gonorrhoeae, C. trachomatis & M. genitalium) + (T. vaginalis, U. urealyticum, U. parvum & M. hominis)	24/48

Monoplex

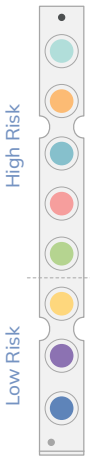
Type	Reference	Description	Tests
Bacteria	**AVA**	Atopobium vaginae (1)	48/96
	GBS	Streptococcus B	48/96
	LGV	C. trachomatis (LGV)	48/96
	TPA	Treponema pallidum	48/96

Panels

SP01 | 24 tests

- 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
- 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

SP02 (1) NEW | 12 tests



- 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)

(1) Research Use Only

Immunosupressed and Meningitis

Multiplex

Type	Reference	Description	Tests
Virus	BJV	BK + JC Virus	48/96
	HHZ	Herpes Virus 1, Herpes Virus 2 & Varicela Zoster Virus	48/96
	HHV	Human Herpes Virus 6, 7 & 8	48/96
	MEP	Mumps, Enterovirus & Parechovirus	48/96
	NEU	Adenovirus, CMV, EBV & Parvovirus B19 (1)	48/96
Bacteria	HNS	H. influenzae, N. meningitidis & S. pneumoniae	48/96
	SLE	S. agalactiae, L. monocytogenes & E. coli	48/96

Monoplex

Type	Reference	Description	Tests
Virus	BKQ	BK Virus (q)	48/96
	CMV	Cytomegalovirus (q)	48/96
	EBV	Epstein-Barr Virus (1) (q)	48/96
	HBV	Hepatitis B Virus (1) (q)	48/96

Panel

MP01 (1)

24 tests

Non infectious diseases

Multiplex

Reference	Description	Tests
CEL	HLA celiac (2 wells): (DQA1*05, DQB1*03:02, DQB1*02) & (DQA1*02, DQA1*03 & no DQB1*02)	24/48
RNP	Control RNase P (1)	48/96

(q) Quantitative *(1) Research Use Only*

Antimicrobial resistance and sepsis

Multiplex

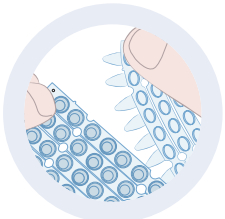
Reference	Description	Tests
MSA	Methicillin-resistant Staphylococcus aureus (2 wells): (MRSA, MSSA and/or MRCoNS)	24/48
VAN	Vancomycin resistance	48/96
CPE	Carbapenemase-producing Enterobacteriaceae (2 wells): (NDM + VIM) + (OXA, KPC & IMP)	24/48
BLC	CTX, TEM, SHV & mcr	48/96
PKP	P. aeruginosa, K. pneumoniae & P. mirabilis	48/96
EAC	Enterobacter, A. baumannii & E. coli	48/96
EFF	Enterococcus faecalis + Enterococcus faecium	48/96
CLA	H. pylori + Clarithromycin resistance	48/96
NCR	Neisseria gonorrhoeae ciprofloxacin resistant	48/96
MGR	Macrolide resistance-associated mutations (23S rRNA)	48/96

Monoplex

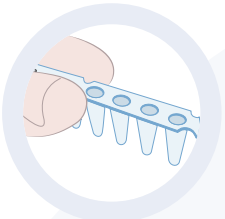
Reference	Description	Tests
CAU	Candida auris (1) NEW	48/96

Genetic diseases

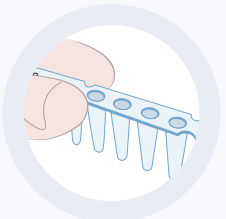
Available formats



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

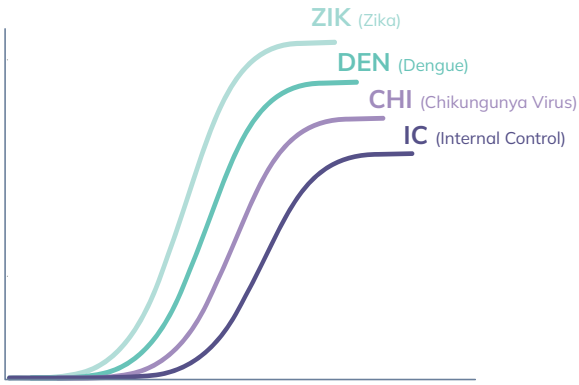
How does *Multiplex testing* work?

Detection and differentiation of **multiple pathogens from a single sample,** optimizing time and resources in diagnosis.

One sample

Multiple targets in the same PCR tube

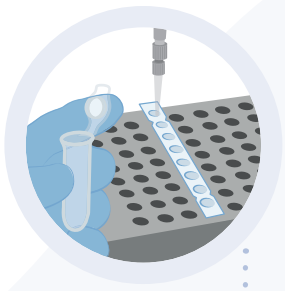
ZDC



PCR Work flow

01

Add 15 µl of rehydration buffer into each well.

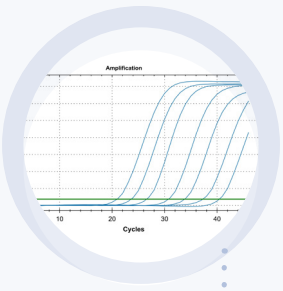


02

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

03

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



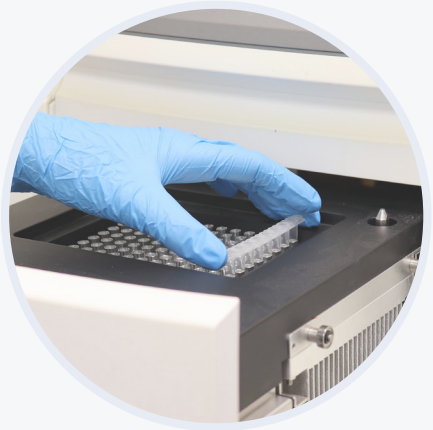
04

Analysis of results..

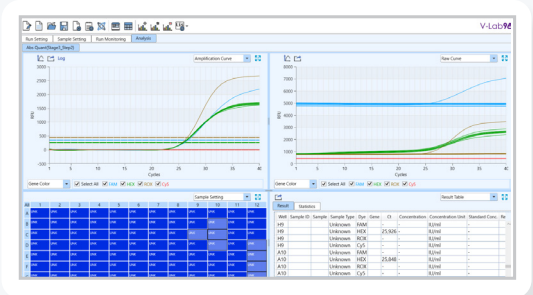
V-Lab96

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



VIASURE V-Lab96 software screen.

V-Smart

Automatic interpretation

VIASURE V-Smart allows the analysis 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

Artificial Intelligence
based. **Automatic results**
PCR interpretation

LIS connection & Report

Big Range of compatible thermocyclers

IVDR CERTIFIED

PCR platforms compatibility

- Agilent Technologies
- Applied Biosystems
- Bio-Rad
- DNA-Technology
- Qiagen-Rotorgene
- Bioer-QuantGene 9600
- Tianlong-Gentier 96E
- Roche
- V-Lab96

EXTERNAL POSITIVE CONTROLS

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.**

Find us on
@certestbiotec

VIASURE
by certest

Certest Biotec, S.L.
Pol. Industrial Río Gállego II · Calle J, N°1
50840, San Mateo de Gállego, Zaragoza (Spain)
Tel. (+34) 976 520 354
salesmdx@certest.es · **www.certest.es**

VIASURE/GEN-1224EN