VIRAL INFECTIONS IN IMMUNOCOMPROMISED PATIENTS

HHV7

BK virus

CMV

HHV6

AdV

HSV1

EBV

HHV8

VZV

Parvovirus B19

HSV2

ARGENE

R-gene® Real-Time PCR kits

Detect and Quantify all the major viruses involved in infections of the immunocompromised in one single run

BIOMÉRIEUX

PIONEERING DIAGNOSTICS

ARGENE

Management strategies for viral infections in immuno

FEATURES

Ideally suited for preventive and/or preemptive strategies as well as efficient follow-up of treatments, R-gene® solution offers the unique possibility to efficiently detect and monitor the viral load of CMV, EBV, HHV6, Adenovirus, BK Virus, HSV1, HSV2, VZV, Parvovirus B19…

Confirming active infections

Viral infections remain a major complication for immunocompromised patients.

Real-Time PCR-based assays permit rapid and specific detection of various viral infections prior to clinical symptoms.

This is of vital importance in the management of the infection, to prevent rejection and to allow patient survival.

Before treatment

For the very low positive results, a quantitative follow-up showing a significant increase of the viral load could be a very early predictive indicator of viral infection.

During treatment

Viral load measurement during treatment and its kinetics indicate the effectiveness of the treatment.

After treatment

Viral load measurement can be used after cessation of therapy to monitor for relapse.

*Not for donor screening

R-gene® ADVANTAGES

SCREENING*

Common extraction and amplification program for the entire R-gene® range of products allows a simultaneous sample analysis for the following viruses: CMV, EBV, HHV6, Adenovirus, BK Virus, HSV1, HSV2, VZV, HHV7, HHV8, Parvovirus B19…

STANDARDIZATION

R-gene® assays are widely used in many international laboratories.

The robustness of R-gene® assays facilitates an intra and inter-laboratory standardization and enables the determination of significant viral load thresholds.

QUANTIFICATION

R-gene® solution provides a complete range of quantification assays for: CMV, EBV, HHV6, Adenovirus, BK Virus, HSV1, HSV2, VZV, Parvovirus B19…

It allows an accurate quantification over a wide linear range clinically specific to each virus.

TIME SAVING & COST-EFFECTIVENESS

Harmonized test profiles enable the detection and the quantification of various viruses for one sample or the analysis of various samples for one virus at the same time.

ocompromised patients: R-gene® solutions

All our kits use 5' nuclease TAQMAN® technology and contain:

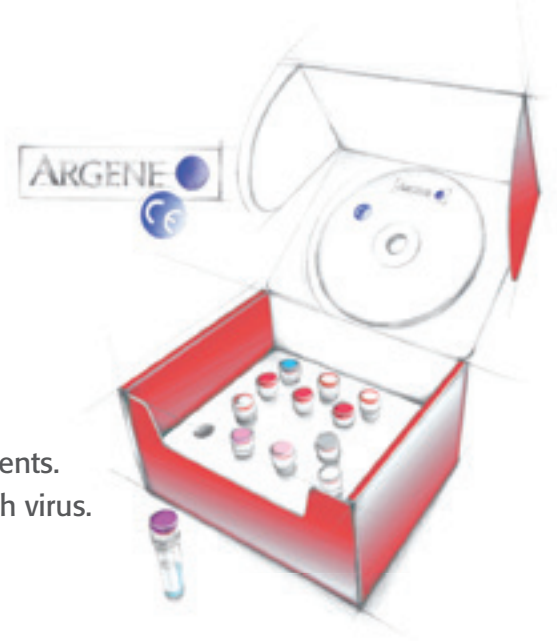
- Specific & ready-to-use amplification premix
- 4 Quantification Standards (QS)
- One extraction/inhibition control (IC)
- Sensitivity Control
- Negative control (molecular grade water)

Designation	CMV R-gene®	CMV HHV 6, 7, 8 R-gene®	EBV R-gene®	HSV1 HSV2 VZV R-gene®	Adenovirus R-gene®	BK virus R-gene®	Parvovirus B19 R-gene®
Technology	5'nuclease TAQMAN® Technology						
Protocol	Same protocol for all viruses						
Detected Pathogens	CMV	CMV, HHV6, HHV7 HHV8	EBV	HSV1, HSV2, VZV	Adenoviruses	BK virus	Parvovirus B19
Specimen*	Whole blood, plasma, serum, CSF*, amniotic fluid, biopsy, urine, BAL*, tissue, cell culture, gynaecological smears, cutaneous and mucous smears, ears nose throats (ENT), ophtalmologic samples, stools, bone marrow, medullary plasma						
Controls included	Positive Control, Negative Control, Internal Control and Sensitivity Control						
Range of linearity	Wide range of linearity in agreement with clinical specificities of each virus						
Reporting units	Number of viral copies/ml of samples. Possibility to convert into IU/ml when applicable						
Result Within	1h30 after extraction						
Validated Equipments*	Extraction: NucliSENS® easyMAG® (bioMérieux) MagNA Pure Compact (Roche Diagnostics) MagNA Pure LC system (Roche Diagnostics) MagNA Pure 96 system (Roche Diagnostics) QIAsymphony SP (Qiagen) EZ1 Advanced XL (Qiagen) QIAamp DNA blood mini kit (Qiagen) QIAamp MinElute virus spin kit (Qiagen) QIAcube (Qiagen) m2000sp (Abbott) Versant kPCR Molecular System SP (Siemens) BioRobot EZ1 Workstation (Qiagen) BioRobot M48				Amplification: ABI 7500, 7500 Fast, 7500 Fast DX, ViiA7, StepOne (Applied Biiosystems) LightCycler 480, LightCycler 2 (Roche Diagnostics) Rotor-Gene (Qiagen) Dx Real-Time System and CFX96 (Bio-Rad) Stratagene/Agilent/Versant kPCR AD SmartCycler (Cepheid)		
Status	For *in vitro* diagnostic use, CE marking in Europe - Please inquire						

* Depends on the assay, please inquire.
** CSF : Cerebrospinal Fluid
*** BAL : Bronchoalveolar Fluid

Flexibility

- Qualified with the major Real-Time PCR platforms.
- Validated for use on multiple automatic extraction systems.
- Validated on various types of samples.
- Designed for low, medium and high throughput.
- Common extraction program for the entire range.



Performance

- Robust.
- Optimal reproducibility, also for the low viral load measurements.
- Wide dynamic range, in agreement with the specificity of each virus.
- High sensitivity.
- Fast results.

Reliability

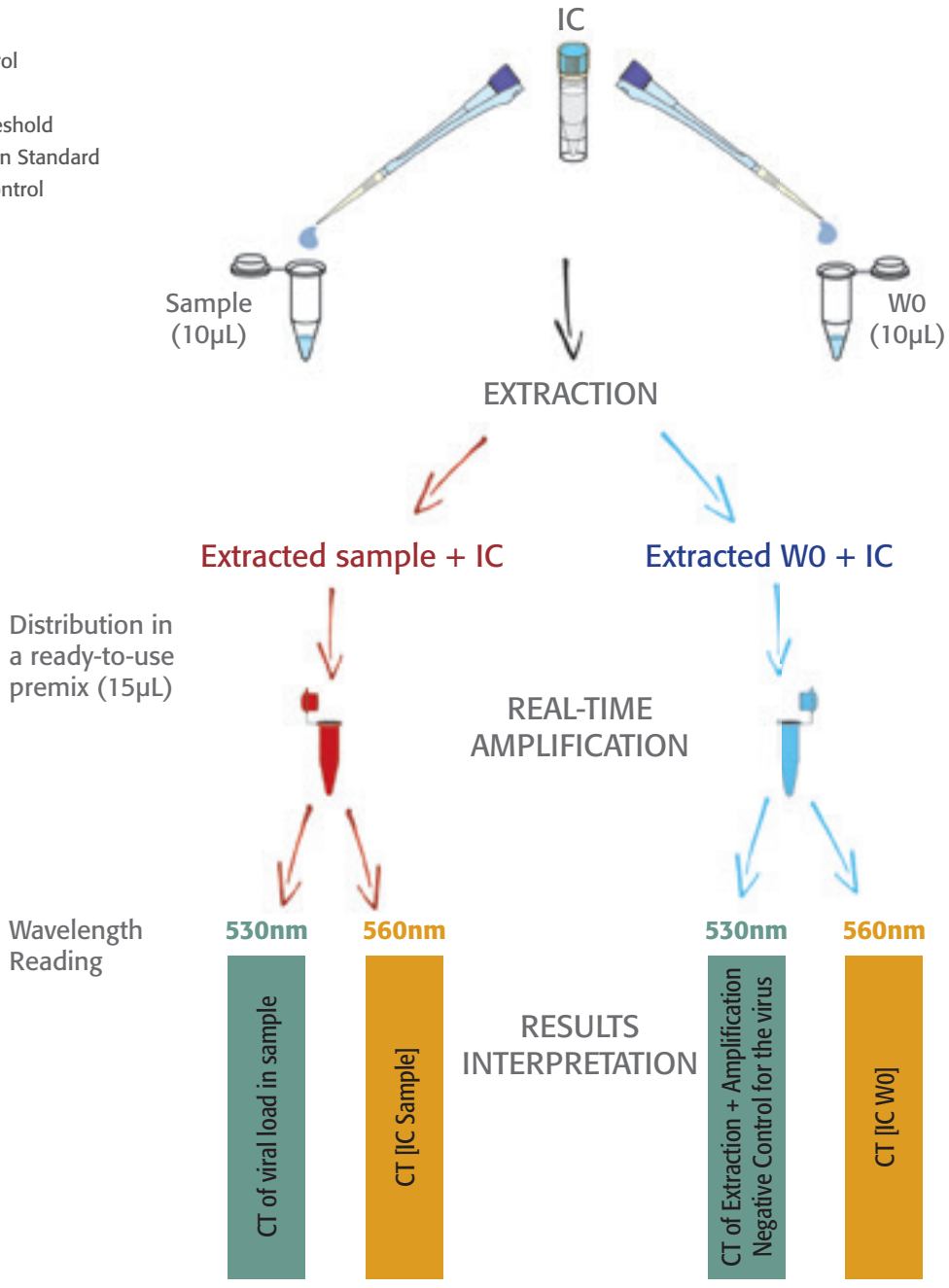
- CE marked.
- Standardized assays with all controls included from extraction to amplification.
- Checking of the efficiency of the extraction.
- TAQMAN® 5' nuclease assay technology.
- Reaction in closed tube.

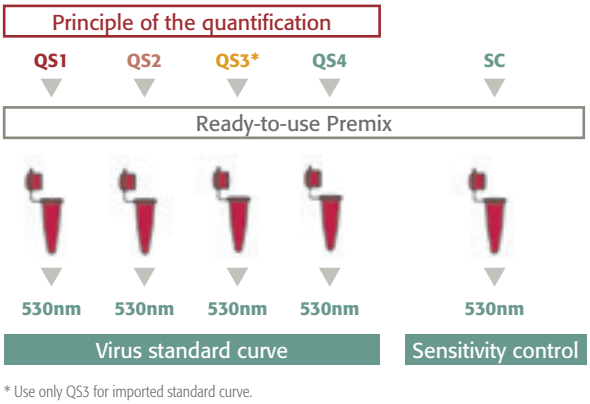
Usefulness

- Ready-to-use reagents, suitable for automation.
- Uniform protocol for all major extraction and Real-Time PCR platforms.
- Harmonized test profiles for multi-target analysis.
- Detection of viral target and extraction/inhibition control in one tube.
- Long expiry date.

Principle of R-gene® real-time PCR kits

GLOSSARY
IC = Internal Control
W0 = Water
CT = Crossing Threshold
QS = Quantification Standard
SC = Sensitivity Control



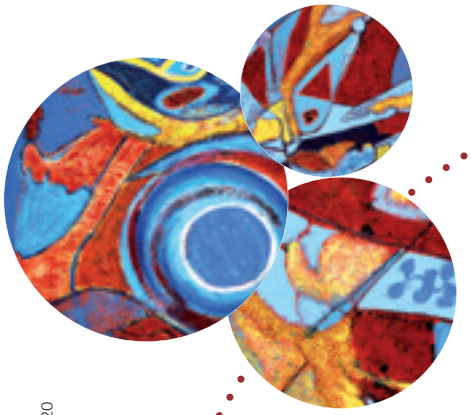


* Use only QS3 for imported standard curve.

SAMPLE INTERPRETATION

CT [IC Sample] ≤ CT [IC WO] + 3

The sample is correctly extracted and does not contain inhibitory agents of amplification.



PRODUCT NAME	NUMBER OF TESTS	REF
CMV R-gene® Real-Time Detection and Quantification kit	90 tests	69-003B
CMV HHV6,7,8 R-gene® Real-Time Detection and Quantification kit	140 tests	69-100B
EBV R-gene® Real-Time Detection and Quantification kit	90 tests	69-002B
ADENOVIRUS R-gene® Real-Time Detection and Quantification kit	90 tests	69-010B
HSV1 HSV2 VZV R-gene® Real-Time Detection and Quantification kit	180 tests	69-004B
BK Virus R-gene® Real-Time Detection and Quantification kit	90 tests	69-013B
Parvovirus B19 R-gene® Real-Time Detection and Quantification kit	90 tests	69-019B

bioMérieux also offers a complete ARGENE® range of immunology products.
For any additional information please don't hesitate to contact our sales team !

bioMérieux manufactures its reagents in compliance with cGMP and ISO 13485 for optimal product quality and consistent results. bioMérieux has entered into a license agreement covering real-time PCR technology with F.Hoffmann-La Roche Ltd and Roche Molecular Systems, Inc. Therefore the purchase of these products grants the purchaser rights under certain Roche patents to use them solely for human in vitro diagnostic testing services.
No general patent or other license of any kind other than this specific right of use from purchase is granted hereby by bioMérieux.
For *in vitro* diagnostic use, CE marking in Europe - Please inquire.

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