GENERAL TECHNICAL INFORMATION

ARGENE® Real-Time Detection and Quantification

PRODUCT NAME	GENE TARGET	SPECIMENS CLAIMED	RANGE OF QUANTIFICATION	NUMBER OF TESTS
ADENOVIRUS R-GENE®	Hexon	Whole blood, Plasma, Stool, BAL	- BAL and Plasma: From 500 to 1E+08 copies/mL - Whole blood: From 1,500 to 1E+08 copies/mL - Stool: From 1,500 to 1E+09 copies/g	90 tests
BK Virus R-GENE®	StAg	Whole blood, Plasma, Urine	- Plasma: From 218 to 1E+06 copies/mL - Whole blood: From 439 to 1E+06 copies/mL - Urine: From 315 to 1.2E+09 copies/mL	90 tests
CMV R-GENE®	UL83	Whole blood, Plasma, CSF, BAL, Urine, Amniotic fluid, Saliva swab	From 500 to 7.2E+07 copies/mL	90 tests
EBV R-GENE®	BXFL1	Whole blood, Plasma, CSF, BAL	From 500 to 1E+07 copies/mL	90 tests
HHV6 R-GENE®	U57	Whole blood, Plasma, CSF, BAL	From 500 to 9E+07 copies/mL	90 tests
HSV1&2 VZV R-GENE®	US7(HSV1), UL27(HSV2), gp19(VZV)	Quantitative: Whole blood, Plasma, CSF BAL (only for HSV1&2) Qualitative: Mucocutaneous swab (HSV1&2, VZV), Throat swab (only HSV1&2), Anogenital swab (only HSV1&2)	- Whole blood, Plasma (HSV1, HSV2 and VZV): from 500 to 1.E+08 copies/mL - BAL: from 500 to 1.E+08 copies/mL - Cerebrospinal fluid: • HSV1: From 250 to 1E+08 copies/mL • HSV2: From 100 to 1E+08 copies/mL • VZV: From 500 to 1E+08 copies/mL	120 tests*
Parvovirus B19 R-GENE®	NS1	Whole blood, Plasma, Bone marrow	From 500 to 1E+10 copies/mL	90 tests

*60 tests HSV1&2 + 60 tests VZV

ARGENE® Real-Time Detection

PRODUCT NAME	GENE TARGET	SPECIMENS CLAIMED	NUMBER OF TESTS
HSV1 HSV2 R-GENE®	US7(HSV1), UL27(HSV2)	Whole blood, Plasma, CSF, BAL, Throat swab, Anogenital swab, Mucocutaneous swab	60 tests
VZV R-GENE®	Gp19	Whole blood, Plasma, CSF, Mucocutaneous swab	60 tests

A GRAFT IS PRECIOUS
GIVE IT ITS CHANCE WITH TTV R-GENE®

The only IVDR assay used in TTV GUIDE TX project, funded by European Union's horizon 2020 (grant agreement 896932)

Monitoring the immune system of transplant patients is difficult.
Our innovative biomarker TTV R-GENE® may be a solution to this problem.

TTV R-GENE® is a real-time PCR assay (Ref. 423414) intended for the detection and quantification of Torque Teno Virus (TTV) genome. The results obtained with TTV R-GENE® allow the monitoring of TTV viral load in transplanted patient samples.

TTV-based personalization and optimization of immunosuppressant might enable clinicians to reduce infections and rejection in solid organ transplant recipients.

→ Visit our TTV R-GENE® webpage to get more information

bioMérieux S.A. • 69280 Marcy l'Etoile • France • Tel.: + 33 (0)4 78 87 20 00 • Fax: +33 (0)4 78 87 20 90
www.biomerieux.com

ARGENE®
Real time PCR assays - Transplant Range

THE POWER OF TRUE EXPERIENCE

BK Virus
ADV
CMV
VZV
HSV2
HSV1
EBV
Parvovirus B19
HHV6

PIONEERING DIAGNOSTICS

ARGENE®
CE-IVDR REAL-TIME PCR ASSAYS

FOR VIRAL INFECTIONS MANAGEMENT IN TRANSPLANT PATIENTS

Viral infections / reactivations remain a major complication for transplant patients.

Real-Time PCR assays permit rapid and specific detection of various viral infections prior to viral diseases. This is of vital importance in the management of the transplant patients, to prevent rejection and to allow patient survival.

DETECT ACTIVE VIRAL INFECTIONS

Use of quantitative Real-Time PCR assays to monitor patients, at predefined intervals after transplantation, allows to detect active infections (primary infections and/or reactivations) before symptoms arise (disease), and to initiate adapted therapy (anti-viral therapy and / or adjustment of immunosuppressive therapy). A quantitative follow-up showing a significant increase of the viral load could be a very early predictive indicator of an active viral infection. During treatment, the viral load measurement and its kinetics indicate the effectiveness of the treatment.

Monitoring by quantitative assays is usually done in whole blood or plasma.

DETECT VIRAL DISEASES

When transplant patients present symptoms that could be associated to viral infections, qualitative or quantitative Real-Time PCR assays allow to identify virus and to initiate adapted therapy.

In this case, qualitative or quantitative assays are usually done on specimens representative of the localisation of symptoms: urine, stool, CSF, muco-cutaneous swabs, BAL.

GET BENEFITS OF ARGENE® SIMPLICITY

- Complete kits
- Ready-to-use reagents
- Same pipetting procedure

EXPERIENCE A SEAMLESS INTEGRATION

- Multi-specimens validated
- Multi-extraction platforms validated
- Multi-amplification platforms validated

EMPOWER YOUR LAB EFFICIENCY

- Common internal control
- Harmonized extraction and amplification protocols
- Multiple target detection from one extracted sample

GENERAL TECHNICAL INFORMATION	
Regulatory Status	For *In Vitro* Diagnostic use (IVDR, CE marked under EU regulation 2017/746)
Technology	5' nuclease technology
Procedure	Same protocol for all viruses
Controls included	Extraction / Inhibition Control, Negative Control, Positive Control, Quantification Standards and Sensitivity Control
Storage conditions	-15 C°/-31C°
Detection	Real-time detection (quantitative and/or qualitative)
Result within	≈ 90 min*
Report units	Number of viral copies/mL – Possibility to convert into IU/mL depending on international standards availability

*Extraction step excluded

VALIDATED PLATFORMS	
Extraction	**Amplification**
• **EMAG®** (all specimens claimed) • **NUCLISENS® easyMAG®** (all specimens claimed) • **MagNA Pure 96** (whole blood & plasma) • **QIAsymphony® SP** (whole blood & plasma)	• **ABI 7500 Fast / ABI 7500 Fast Dx** (run in Fast mode) • **QuantStudio™ 5 / QuantStudio™ 5 Dx** • **LightCycler® 480** (Instrument II) • **Rotor-Gene® Q** • **CFX96** • **CFX Opus 96**

ORDERING INFORMATION		
Product name	**Features**	**Reference**
ADENOVIRUS R-GENE®	Real-time detection and quantification kit	69-010B
BK Virus R-GENE®	Real-time detection and quantification kit	69-013B
CMV R-GENE®	Real-time detection and quantification kit	69-003B
EBV R-GENE®	Real-time detection and quantification kit	69-002B
HHV6 R-GENE®	Real-time detection and quantification kit	69-006B
HSV1&2 VZV R-GENE®	Real-time detection and quantification kit	69-014B
Parvovirus B19 R-GENE®	Real-time detection and quantification kit	69-019B
HSV1 HSV2 R-GENE®	Real-time detection kit	71-021
VZV R-GENE®	Real-time detection kit	71-022

ONE

- ELUATE, **whatever the test,** thanks to our harmonized Internal Control
- EXTRACTION RUN, **whatever the sample type,** thanks to our harmonized extraction workflow
- AMPLIFICATION RUN, **whatever the test,** thanks to our harmonized amplification PCR program