Products for infectious disease

ARGENE

BIOMÉRIEUX

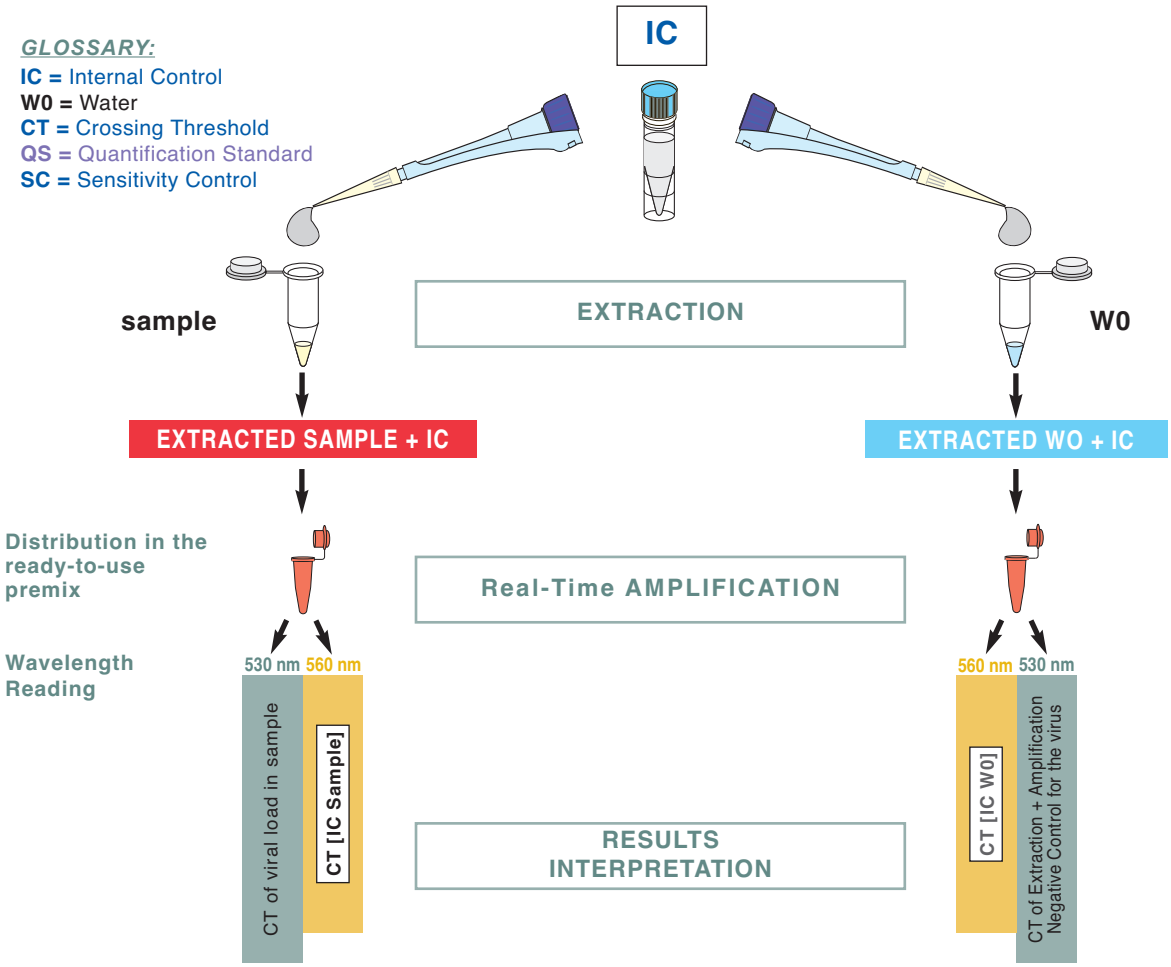
Table of contents

Real-time PCR R-gene™ kits

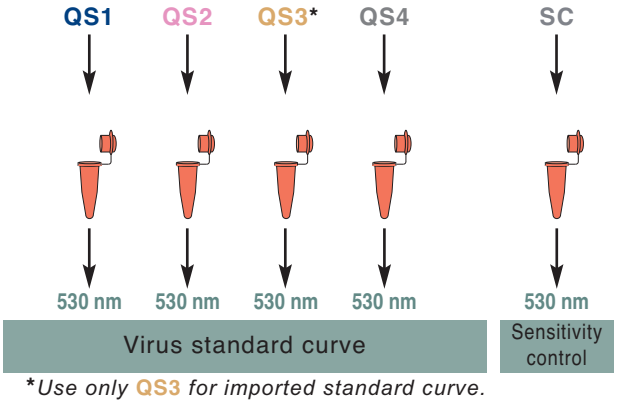
Argene manufactures its reagents in compliance with cGMP and ISO 13485 for optimal product quality and consistent results. Argene has entered into a broad license agreement with F. Hoffman-La Roche Ltd and Roche Molecular Systems, Inc, covering real-time PCR Technology for the detection of human pathogens. Therefore the purchase of these products grants the purchaser rights under certain Roche patents (among others under the so-called 5' Nuclease Detection patents and Chemically-Modified Hot Start Enzymes 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 Argene.

For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

Principle of real-time PCR R-gene™ kits



Principle of the quantification using QS



Use only QS3 for imported standard curve.

Sample interpretation

CT [ICsample] ≤ CT [IC W0] + 3

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

CMV HHV6,7,8 R-gene™ 69-100

CMV HHV6,7,8 R-gene™ - Quantification Assay

Related publications

USE FOR Real-time PCR for CMV and HHV-6 quantification, HHV-7 and HHV-8 detection.

• CMV HHV6,7,8 R-gene™ - Quantification COMPLETE kit	140 tests	69-100
• CMV HHV6,7,8 R-gene™ - Quantification kit	140 tests	69-100B

Herpesviruses are DNA viruses. CMV, HHV-6, HHV-7 and HHV-8 are characterized by high seroprevalency (range between 50% to 100%, depending on the geographical site) and are responsible for a wide range of pathologies. The primary infection commonly occurs during young childhood. The viral dissemination in blood may lead to benign and rare clinical signs. CMV, HHV-6, HHV-7 and HHV-8 establish a lifelong dormant infection. Often the virus may reactivate in case of an immunosuppression. The severity of infection depends on the immune status of the host (e.g. AIDS patients and organ transplant patients are commonly known as fragile hosts).

CMV is associated with neurological diseases, pneumopathy and in extreme cases with high mortality in immunocompromised patients. HHV-6 is also very likely to be involved in opportunistic infections in immunocompromised patients. HHV-7 acts the same way as HHV-6. HHV-6 and HHV-7 most likely increases the secondary CMV infections by a process of cross reactivation. When primary infection occurs, HHV-6 is also suspected to be responsible for mononucleosic syndroma, lymphadenopathy and hepatitis. HHV-8 is associated with lymphoproliferative diseases such as Kaposi sarcoma, Castleman disease and some lymphomas.

The **CMV HHV6,7,8 R-gene™** kit is designed to measure the viral load of CMV, HHV-6 and the detection of HHV-7 and HHV-8 by real-time PCR after viral DNA extraction. Combined with **HHV8 QS r-gene™** (**ref.: 68-008**), CMV HHV6,7,8 R-gene™ kit enables HHV-8 quantification. User-friendly and complete, the **CMV HHV6,7,8 R-gene™** kit is suitable for any laboratory. Several types of specimen and DNA purification systems (automatic and manual) have been validated with the kit. Extracted DNA is then amplified and detected by real-time PCR on the common available platforms. Thanks to a general amplification program within the **R-gene™** range of products, the sample analysis can be simultaneously run for the other viruses: CMV with **CMV R-gene™** kit (**ref.: 69-003**), HSV-1, HSV-2 and VZV with **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**), EBV with **EBV R-gene™** (**ref.: 69-002**), BKV with **BK Virus R-gene™** kit (**ref.: 69-013**) and Adenovirus with **ADENOVIRUS R-gene™** kit (**ref.: 69-010**). Results are validated with different controls, including an extraction control, all provided with the kit.

Results are useful for the diagnosis of primary infection and virus reactivation as well as for the management of patient therapy.

CMV HHV6,7,8 R-gene™

Detection and Quantification Complete Kit

PRODUCT INFORMATION

69-100

Principle of the Test	Genomic Detection and Quantification of CMV and HHV-6. Genomic Identification of HHV-7 and HHV-8.
Technology	Real-Time PCR. 5' Nuclease Technology TaqMan®.
Gene Target	CMV: Gene Coding for ppUL83 Protein. HHV-6: U57 Gene; HHV-7: U42 Gene; HHV-8: ORF26 Gene.
Specimen	Whole Blood, Plasma, CSF, Amniotic Fluid, Samples Coming from Guthrie Test, Serum, Urine, BAL, Biopsies.
Limit of Detection	CMV: 1 Copy/PCR. CMV: 50 Copies/mL. HHV-6: < 3 Copies/PCR. HHV-6: < 156 Copies/mL. HHV-8: 1 Copy/PCR. HHV-8: < 40 Copies/mL.
Dynamic Range of Quantification	Up to 10^7 Copies/mL.
Controls Included	Inhibition and Extraction Control, Sensitivity Control, Negative Control.
Result Within	1 H. 15 Extraction Step not Included.
Reporting Units	Number of Viral Copies/mL of Sample.
Number of Tests	140 Tests.
Kit Storage	-18°C/-22°C for Ref.: 69-100B (Quantification Kit). +2°C/+8°C for Ref.: 67-000 (DNA Extraction Kit, Available with the Complete Kit).
Necessary Equipment	Extraction: - **NucliSens® easyMAG™ (Biomérieux)**. - QIAamp DNA Blood Mini kit (Qiagen). - QIAcube, QIAsymphony SP (Qiagen). - MagNA Pure Compact® (Roche Diagnostics). - MagNA Pure LC System® (Roche Diagnostics). - m2000sp™ (Abbott). - Versant kPCR Molecular System SP (Siemens). - EZ1 Advanced and EZ1 Advanced XL (Qiagen). Amplification: - Applied Biosystems™. - LightCycler®. - Rotor-Gene™. - DNA Engine Opticon®, I-cycler, DX Real-Time System (Bio-Rad). - Stratagene®. - Versant kPCR Molecular System AD (Siemens).
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

CMV R-gene™ 69-003

CMV R-gene™ - Quantification Assay

Related publications

USE FOR CMV genome quantification by real-time PCR.

• CMV R-gene™ - Quantification COMPLETE kit	90 tests	69-003
• CMV R-gene™ - Quantification kit	90 tests	69-003B

The human cytomegalovirus (HCMV) is a double stranded enveloped DNA virus of the *Herpesviridae* family. The poorer the socio-economic conditions, the higher the prevalence (50 to 100%). After the primary infection, HCMV remains in its latent state in the host and may be the cause of recurrent secondary infections, during chronic or transient immunosuppression, by reactivation of the endogenous genome or by reinfection with a new strain. The consequences of the HCMV infection mainly depend on the cell immunity of the subject involved. Most often asymptomatic in healthy subjects, it may lead to serious damages in immunosuppressed patients and in the foetus or newborn child after *in utero* transmission. The infection with HCMV after organ or bone marrow allograft: HCMV is the main infectious agent after bone marrow allograft and organ transplant. Infection with HCMV is observed, on the average, in two-thirds of all recipients, regardless of the type of transplant. It occurs in the absence of prophylactic treatment between the 1st and 4th month after the graft. It is symptomatic in two-thirds of cases of primary infection, in 40% of cases of reinfection and less than 20% of the reactivations. Prolonged fever may be the only clinical manifestation of the infection or comprise complications of thrombo-leukopenia, cytolitic hepatitis, gastric disorders or cystitis. Chorioretinitis is rare. Interstitial pneumonitis is a major complication of a marrow graft. It occurs in about 20% of all recipients and its evolution, without treatment, is dangerous (90% mortality). In addition, infection with HCMV is a factor that triggers or accelerates the rejection or GVH (reaction of the graft against the host). In addition, it aggravates the immunosuppression and favours superinfections. Infection with HCMV during AIDS: the incidence of infections with HCMV has decreased by 80% since the beginning of highly active anti-retroviral treatments that provide at least partial immune restoration. Clinical manifestations occur at a major stage of immunosuppression, characterised by an average number of CD4+ T lymphocytes under 50/mm^3. Retinitis, observed before the era of the tri-therapies, in about 15 to 35% of the patients, remains the most common clinical manifestation. Peptic ulcers are the second leading clinical manifestations. Multiple types of neurological damage have been described although the incidence has not been established. Pneumopathy is exceptional. The **CMV R-gene™** kit is designed to measure the viral load of CMV by real-time PCR after viral DNA extraction. User friendly and complete, the **CMV R-gene™** kit is suitable for any laboratory. Several types of specimen and DNA purification systems (automatic and manual) have been validated with the kit. Extracted DNA is then amplified and detected by real-time PCR on the common available platforms. Thanks to a general amplification program within the **R-gene™** range of products, the sample analysis can be simultaneously run for the other viruses: EBV with **EBV R-gene™** kit (**ref.: 69-002**), HSV-1, HSV-2 and VZV with **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**), CMV, HHV-6, HHV-7 and HHV-8 with **CMV HHV6,7,8 R-gene™** kit (**ref.: 69-100**), BKV with **BK Virus R-gene™** kit (**ref.: 69-013**) and Adenovirus with **ADENOVIRUS R-gene™** kit (**ref.: 69-010**). Results are validated with different controls, including an extraction control, all provided with the kit. Results are useful for the diagnosis of primary infections and virus reactivation as well as for the management of patient therapy.

CMV R-GENE™

DETECTION AND QUANTIFICATION COMPLETE KIT

PRODUCT INFORMATION

69-003

PRINCIPLE OF THE TEST	GENOMIC DETECTION AND QUANTIFICATION OF CMV.
TECHNOLOGY	REAL-TIME PCR. 5' NUCLEASE TECHNOLOGY TAQMAN®.
GENE TARGET	CMV: GENE CODING FOR PPUL83 PROTEIN.
SPECIMEN	WHOLE BLOOD, PLASMA, CSF, AMNIOTIC FLUID, SAMPLES COMING FROM GUTHRIE TEST, SERUM, URINE, BAL, BIOPSIES.
LIMIT OF DETECTION	CMV: 1 COPY/PCR. CMV: 50 COPIES/mL.
DYNAMIC RANGE OF QUANTIFICATION	UP TO 10^7 COPIES/mL.
CONTROLS INCLUDED	INHIBITION AND EXTRACTION CONTROL, SENSITIVITY CONTROL, NEGATIVE CONTROL.
RESULT WITHIN	1 H. 15 EXTRACTION STEP NOT INCLUDED.
REPORTING UNITS	NUMBER OF VIRAL COPIES/mL OF SAMPLE.
NUMBER OF TESTS	90 TESTS.
KIT STORAGE	-18°C/-22°C FOR REF.: 69-003B (QUANTIFICATION KIT). +2°C/+8°C FOR REF.: 67-000 (DNA EXTRACTION KIT, AVAILABLE WITH THE COMPLETE KIT).
NECESSARY EQUIPMENT	EXTRACTION: **- NUCLISENS® EASYMAG™ (BIOMÉRIEUX).** - QIAAMP DNA BLOOD MINI KIT (QIAGEN). - QIACUBE, QIASYMPHONY SP (QIAGEN). - MAGNA PURE COMPACT® (ROCHE DIAGNOSTICS). - MAGNA PURE LC SYSTEM® (ROCHE DIAGNOSTICS). - M2000SP™ (ABBOTT). - VERSANT KPCR MOLECULAR SYSTEM SP (SIEMENS). - EZ1 ADVANCED AND EZ1 ADVANCED XL (QIAGEN). AMPLIFICATION: - APPLIED BIOSYSTEMS™. - LIGHTCYCLER®. - ROTOR-GENE™. - DNA ENGINE OPTICON®, I-CYCLER, DX REAL-TIME SYSTEM (BIO-RAD). - STRATAGENE®. - VERSANT KPCR MOLECULAR SYSTEM AD (SIEMENS).
STATUS	FOR *IN VITRO* DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE. USA: FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

ADENOVIRUS R-gene™ 69-010

ADENOVIRUS R-gene™ - Quantification Assay

Related publications

USE FOR ADENOVIRUS genome quantification by real-time PCR.

• ADENOVIRUS R-gene™ - Quantification COMPLETE kit	90 tests	69-010
• ADENOVIRUS R-gene™ - Quantification kit	90 tests	69-010B

Adenovirus infections are common, have a worldwide distribution and occur throughout the year. Over the last few years, adenoviruses have been increasingly recognized as significant viral pathogens with high morbidity and mortality among immunocompromised patients. Clinical manifestations in immunocompromised patients include pneumonia, hepatitis, hemorrhagic cystitis, colitis, pancreatitis, meningoencephalitis and disseminated disease. These clinical manifestations are depending on the underlying disease, affected organ system, patient age, and serotype of the virus. In case of a suspected infection by adenovirus, blood specimens should be tested by PCR, since the detection of adenovirus DNA from blood samples is usually significative for a disseminating disease. Surveillance in blood samples is currently a common practice among hematopoietic stem cell transplant (HSCT) recipients, especially in the pediatric population. The virus can be detected in blood 2-3 weeks before developing clinical symptoms, which offers the opportunity for intervention. Follow-up and prognosis can be validated more reliable with quantitative PCR methods. Increased viral load measurements are associated with increased risk of death. Amplification and detection of the viral genome by real-time PCR is highly-sensitive, and is particularly applicable in case of a non-infectious virus. In this case the viral load is too low to be detected by cell culture and results are needed rapidly. It is recommended to analyse the viral kinetics for each patient. The **ADENOVIRUS R-gene™** kit is designed to measure the viral load of Adenoviruses by real-time PCR after viral DNA extraction. **ADENOVIRUS R-gene™** is a user-friendly and complete kit and therefore ideal for routine diagnostics. Many types of specimen and numerous DNA purification systems (automatic and manual) have been validated with the kit. Extracted DNA is then amplified and detected by real-time PCR on the common available platforms.

Thanks to a general amplification program with the entire range of **R-gene™** products, the sample analysis can be simultaneously analyzed with the following other parameters: HSV1, HSV2, VZV with **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004B**), CMV with **CMV R-gene™** kit (**ref.: 69-003B**), CMV, HHV-6, HHV-7 and HHV-8 with **CMV HHV6,7,8 R-gene™** kit (**ref.: 69-100B**), and EBV with **EBV R-gene™** (**ref.: 69-002B**).

Results are validated with various controls, including an extraction control, which are all provided with the kit. Results are valid for the diagnosis of early disseminated adenovirus infections as well as for the management of patient therapy.

ADENOVIRUS R-GENE™ — PRODUCT INFORMATION

DETECTION AND QUANTIFICATION COMPLETE KIT — 69-010

PRINCIPLE OF THE TEST	GENOMIC DETECTION AND QUANTIFICATION OF ADENOVIRUSES.
TECHNOLOGY	REAL-TIME PCR. 5' NUCLEASE TECHNOLOGY TAQMAN®.
GENE TARGET	HEXON GENE.
SPECIMEN	PLASMA, WHOLE BLOOD, STOOL, BAL, URINE, NASOPHARYNGEAL SPECIMEN, BIOPSIES, CSF.
LIMIT OF DETECTION	WHOLE BLOOD = 8 COPIES/PCR. WHOLE BLOOD = 200 COPIES/mL. NASAL SECRETION = 10 COPIES/PCR. NASAL SECRETION = 261 COPIES/mL.
DYNAMIC RANGE OF QUANTIFICATION	UP TO $5x10^6$ COPIES/mL.
CONTROLS INCLUDED	INHIBITION AND EXTRACTION CONTROL, SENSITIVITY CONTROL, NEGATIVE CONTROL.
RESULT WITHIN	1 H. 15 EXTRACTION STEP NOT INCLUDED.
REPORTING UNITS	NUMBER OF VIRAL COPIES/mL OF SAMPLE.
NUMBER OF TESTS	90 TESTS.
KIT STORAGE	-18°C/-22°C FOR REF.: 69-010B (QUANTIFICATION KIT). +2°C/+8°C FOR REF.: 67-000 (DNA EXTRACTION KIT, AVAILABLE WITH THE COMPLETE KIT).
NECESSARY EQUIPMENT	EXTRACTION: **- NUCLISENS® EASYMAG™ (BIOMÉRIEUX).** - QIAAMP DNA BLOOD MINI KIT (QIAGEN). - QIAAMP DNA STOOL MINI KIT (QIAGEN). - QIACUBE, QIASYMPHONY SP (QIAGEN). - MAGNA PURE COMPACT® (ROCHE DIAGNOSTICS). - MAGNA PURE LC SYSTEM® (ROCHE DIAGNOSTICS). - BIOROBOT M48 (QIAGEN). - M2000SP™ (ABBOTT). - VERSANT KPCR MOLECULAR SYSTEM SP (SIEMENS). - EZ1 ADVANCED AND EZ1 ADVANCED XL (QIAGEN). AMPLIFICATION: - APPLIED BIOSYSTEMS™. - LIGHTCYCLER®. - ROTOR-GENE™. - SMARTCYCLER®. - STRATAGENE®. - VERSANT KPCR MOLECULAR SYSTEM AD (SIEMENS). - DX REAL-TIME SYSTEM (BIO-RAD).
STATUS	FOR *IN VITRO* DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE. USA: NOT AVAILABLE.

EBV R-gene™ 69-002 CE

EBV R-gene™ - Quantification Assay

Related publications

USE FOR EBV genome quantification by real-time PCR.

• EBV R-gene™ - Quantification COMPLETE kit	90 tests	69-002
• EBV R-gene™ - Quantification kit	90 tests	69-002B

Epstein-Barr (EBV) virus is an ubiquitous herpesvirus which infects the major part of human population (seroprevalence is 95%). After a prime infection (transmission by saliva), EBV remains latent in B cells. Periodically, EBV can reactivate in healthy individuals. This reactivation occurs with a replication of EBV in the oropharynx and does not have any clinical signs.

EBV is a causative agent of infectious mononucleosis. EBV is also involved in the pathogenesis of several cancers such as Burkitt's lymphoma, Hodgkin's lymphoma, and nasopharyngeal carcinoma. In immunosuppressed individuals, EBV may lead to lymphoproliferation of B cells. Indeed, the main characteristic of EBV is to make the B lymphocytes multiply and to subsequently produce a malignant lymphoma. In this context, the measure of the EBV viral load is very significant.

The **EBV R-gene™** kit is designed to measure the viral load of EBV by real-time PCR after viral DNA extraction. User friendly and complete, the **EBV R-gene™** kit is suitable for any laboratory.

Several types of specimen and DNA purification systems (automatic and manual) have been validated with the kit. Extracted DNA is then amplified and detected by real-time PCR on the common available platforms.

Thanks to a general amplification program within the **R-gene™** range of products, the sample analysis can be simultaneously run for the other viruses: CMV with **CMV R-gene™** kit (**ref.: 69-003**), HSV-1, HSV-2 and VZV with **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**), CMV, HHV-6, HHV-7 and HHV-8 with **CMV HHV6,7,8 R-gene™** kit (**ref.: 69-100**), BKV with **BK Virus R-gene™** kit (**ref.: 69-013**) and ADENOVIRUS with **Adenovirus R-gene™** kit (**ref.: 69-010**).

Results are validated with different controls, including an extraction control, all provided with the kit. Results are useful for the diagnosis of primary infections and virus reactivation as well as for the management of patient therapy.

EBV R-GENE™ — PRODUCT INFORMATION

DETECTION AND QUANTIFICATION COMPLETE KIT — 69-002

PRINCIPLE OF THE TEST	GENOMIC DETECTION AND QUANTIFICATION OF EBV.
TECHNOLOGY	REAL-TIME PCR. 5' NUCLEASE TECHNOLOGY TAQMAN®.
GENE TARGET	BXLF1 GENE CODING FOR THYMIDINE KINASE.
SPECIMEN	WHOLE BLOOD, CSF, PLASMA, BAL, BIOPSIES, TISSUE, CELL CULTURE.
LIMIT OF DETECTION	4 COPIES/PCR.
DYNAMIC RANGE OF QUANTIFICATION	UP TO 5 000 000 COPIES/mL.
CONTROLS INCLUDED	INHIBITION AND EXTRACTION CONTROL, SENSITIVITY CONTROL, NEGATIVE CONTROL.
RESULT WITHIN	1 H. 15 EXTRACTION STEP NOT INCLUDED.
REPORTING UNITS	NUMBER OF VIRAL COPIES/mL OF SAMPLE.
NUMBER OF TESTS	90 TESTS.
KIT STORAGE	-18°C/-22°C FOR REF.: 69-002B (QUANTIFICATION KIT). +2°C/+8°C FOR REF.: 67-000 (DNA EXTRACTION KIT, AVAILABLE WITH THE COMPLETE KIT).
NECESSARY EQUIPMENT	EXTRACTION: **- NUCLISENS® EASYMAG™ (BIOMÉRIEUX).** - QIAAMP DNA BLOOD MINI KIT (QIAGEN). - QIAAMP MINELUTE VIRUS SPIN KIT (QIAGEN). - QIACUBE, QIASYMPHONY SP (QIAGEN). - MAGNA PURE COMPACT® (ROCHE DIAGNOSTICS). - MAGNA PURE LC SYSTEM® (ROCHE DIAGNOSTICS). - EZ1 ADVANCED AND EZ1 ADVANCED XL (QIAGEN). - M2000SP™ (ABBOTT). - VERSANT KPCR MOLECULAR SYSTEM SP (SIEMENS). - HIGH PURE VIRAL NUCLEIC ACID KIT (ROCHE DIAGNOSTICS). AMPLIFICATION: - APPLIED BIOSYSTEMS™. - LIGHTCYCLER®. - SMARTCYCLER®. - ROTOR-GENE™. - STRATAGENE®. - VERSANT KPCR MOLECULAR SYSTEM AD (SIEMENS). - I-CYCLER, DX REAL-TIME SYSTEM (BIO-RAD).
STATUS	FOR *IN VITRO* DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE. USA: FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

HSV1 HSV2 VZV R-gene™ 69-004

HSV1 HSV2 VZV R-gene™ - Quantification Assay

Related publications

USE FOR HSV-1, HSV-2 and VZV genome quantification by real-time PCR.

- HSV1 HSV2 VZV R-gene™ - Quantification COMPLETE kit — 180 tests — 69-004
- HSV1 HSV2 VZV R-gene™ - Quantification kit — 180 tests — 69-004B

The *Herpesviridae* are a family of DNA viruses which are responsible for a wide spectrum of infections in humans. The primary infection is generally limited to the mucous membranes and the skin. After the primary infection, the virus persists in its host in a latent state and, assisted by chronic or transient immunosuppression, can be reactivated to give recurrent infections.
There are eight human *Herpesviridae*, of which Herpes Simplex Virus types 1 (HSV-1) and 2 (HSV-2) and Varicella Zoster Virus (VZV) are the most common in immunocompetent patients. Usually benign, the infections linked with these viruses can nevertheless develop severe clinical forms such as encephalitis, meningitis, retinitis and neonatal infections. These severe and often atypical infections do not allow the implicated virus to be identified.
For many years various antivirals have proven their worth in efficiently treating these pathologies if prescribed early and at appropriate doses. In severe infections, it is therefore essential to obtain an early and rapid diagnosis of the infection. Among the severe forms of HSV-1, HSV-2 or VZV infections in adults, HSV-1-induced encephalitis - of which there are 1/250,000 to 1/1,000,000 cases per year - can still be fatal if untreated. Encephalitis caused by HSV-2 or VZV usually has a more favourable prognosis. Neonatal encephalitis in new-born babies can be traced to both HSV-1 and HSV-2 viruses, but it is HSV-2 virus which is responsible for the most serious neurological disorders. VZV virus had been associated with encephalitis in immunocompromised subjects for a long time, thanks to viral genome detection techniques, it has been revealed increasingly in meningo-encephalitis type infections in immunocompetent subjects. Although conventional immunological culture and detection techniques are suitable for diagnosing the benign skin infections for which these viruses are responsible, they are unsuitable for severe infections of the central nervous system (CNS) and congenital infections. The time to obtain a result and the sensitivity of these immunological techniques are inadequate.
The **HSV1 HSV2 VZV R-gene™** kit is designed to measure the viral load of HSV-1, HSV-2 and VZV by real-time PCR after viral DNA extraction. User friendly and complete, the **HSV1 HSV2 VZV R-gene™** kit is suitable for any laboratory. Various types of samples, automatic and manual extraction systems have been validated including a combined DNA/RNA extraction kit. For this reason, it is possible to perform simultaneously a DNA analysis with HSV1 HSV2 VZV R-gene™ and RNA analysis with Enterovirus R-gene™ (**ref.: 69-005**) on the same extracted sample. Extracted DNA is then amplified and detected by real-time PCR on the common available platforms.
Thanks to a general amplification program within the **R-gene™** range of products, the sample analysis can be simultaneously run for the other viruses: CMV with **CMV R-gene™** kit (**ref.: 69-003**), CMV, HHV-6, HHV-7 and HHV-8 with **CMV HHV6,7,8 R-gene™** kit (**ref.: 69-100**), EBV with **EBV R-gene™** kit (ref.: **69-002**), BKV with **BK Virus R-gene™** kit (**ref.: 69-013**) and Adenovirus with **ADENOVIRUS R-gene™** kit (**ref: 69-010**).
Results are validated with different controls, including an extraction control, all provided in the kit. Results are useful for the diagnosis of primary infections and virus reactivation as well as for the management of patient therapy.

HSV1 HSV2 VZV R-gene™

PRODUCT INFORMATION

Detection and Quantification Complete Kit

69-004

Principle of the Test	Genomic Detection and Quantification of HSV-1, HSV-2, VZV.
Technology	Real-Time PCR. 5' Nuclease Technology TaqMan®.
Gene Target	HSV-1: US7 Gene. HSV-2: US2 Gene. VZV: gp19 (orf17) gene.
Specimen	CSF, Gynaecological Smears, Cutaneous and Mucous Smears, Ears Nose Throat (ENT) and Ophthalmologic Samples, Broncho-Alveolar Liquid (BAL), Plasma, Cell Culture.
Limit of Detection	HSV-1: 2 Copies/PCR. HSV-2: 2 Copies/PCR. VZV: 2 Copies/PCR.
Dynamic Range of Quantification	HSV-1: Up to 500 000 Copies/mL. HSV-2: Up to 500 000 Copies/mL. VZV: Up to 500 000 Copies/mL.
Controls Included	Inhibition and Extraction Control, Sensitivity Control, Negative Control.
Result Within	1 h. 15 Extraction Step not Included.
Reporting Units	Number of Viral Copies/mL of Sample.
Number of Tests	180 Tests.
Kit Storage	-18°C/-22°C for Ref.: 69-004B (Quantification Kit). +2°C/+8°C for Ref.: 67-000 (DNA Extraction Kit, Available with the Complete Kit).
Necessary Equipment	Extraction: - **NucliSens® easyMAG™ (Biomérieux).** - QIAamp DNA Blood Mini kit (Qiagen). - QIAamp MinElute Virus Spin kit (Qiagen). - QIAcube, QIAsymphony SP (Qiagen). - MagNA Pure Compact® (Roche Diagnostics). - MagNA Pure LC System® (Roche Diagnostics). - Versant kPCR Molecular System SP (Siemens). - EZ1 Advanced and EZ1 Advanced XL (Qiagen). Amplification: - Applied Biosystems™; LightCycler®; SmartCycler®; Rotor-Gene™; Stratagene®; Versant kPCR Molecular System AD (Siemens); DX Real-Time System (Bio-Rad).
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

HSV1 r-gene™ 71-015

HSV1 r-gene™

USE FOR Real-time PCR amplification and detection of HSV-1.

• HSV1 r-gene™	60 reactions	2 x 450 µL	71-015

The **HSV1 r-gene™** is an amplification premix which, in association with the **HSV1 HSV2 VZV R-gene™** kit (Argene, **ref.: 69-004**), enables quantification of the HSV-1 genome using real-time PCR methods.

The **HSV1 r-gene™** kit thus rounds off the tests offered by the **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**) for laboratories with a higher demand for HSV-1 analysis than HSV-2 and VZV.

HSV2 r-gene™ 71-016

HSV2 r-gene™

USE FOR Real-time PCR amplification and detection of HSV-2.

• HSV2 r-gene™	60 reactions	2 x 450 µL	71-016

The **HSV2 r-gene™** is an amplification premix which, in association with the **HSV1 HSV2 VZV R-gene™** kit (Argene, **ref.: 69-004**), enables quantification of the HSV-2 genome using real-time PCR methods.

The **HSV2 r-gene™** kit thus rounds off the tests offered by the **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**) for laboratories with a higher demand for HSV-2 analysis than HSV-1 and VZV.

VZV r-gene™ 71-017

VZV r-gene™

USE FOR Real-time PCR amplification and detection of VZV.

• VZV r-gene™	60 reactions	2 x 450 µL	71-017

The **VZV r-gene™** is an amplification premix which, in association with the **HSV1 HSV2 VZV R-gene™** kit (Argene, **ref.: 69-004**), enables quantification of the VZV genome using real-time PCR methods.

The **VZV r-gene™** kit thus rounds off the tests offered by the **HSV1 HSV2 VZV R-gene™** kit (**ref.: 69-004**) for laboratories with a higher demand for VZV analysis than HSV-1 and HSV-2.

For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

BK Virus R-gene™ 69-013

BK Virus R-gene™ - Quantification Assay

Related publications

USE FOR BKV genome quantification by real-time PCR.

• BK Virus R-gene™ - Quantification COMPLETE kit	90 tests	69-013
• BK Virus R-gene™ - Quantification kit	90 tests	69-013B

BK virus, a polyomavirus belonging to the family of papovaviridae, particularly infects the human population (seroprevalence 60 to 100%). Primary infection is asymptomatic and migrates through the respiratory tract during early childhood. Hereafter, the virus migrates to the primary sites of latency, such as the kidney and the urothelium. In general, the prevalence of BK virus in urine lies between 0.3% and 6%, but this prevalence increases with the level of immunosuppression.

The reactivation of symptoms is associated with urinary tract infections and manifests itself as hemorrhagic cystitis (in bone marrow transplant patients), urethral stenosis, tubulo-interstitial nephropathy and interstitial nephritis (in kidney transplant patients). Interstitial nephritis is an opportunistic and emerging renal tropism infection and is the major cause of organ rejection. In this stage the virus can then be detected in both blood and urine samples. A virological diagnosis is obtained by the search for the specific virus. Serological diagnosis only has a limited application due to the high seroprevalence of polyomavirus antibodies. Electronic microscopy and urine cytology remain the major techniques to put in place.

Quantitative real-time PCR with the **BK Virus R-gene™** kit is a fast and sensitive method for the detection and quantification of BK virus. Viral load measurement and follow-up in renal transplant patients with BKV associated nephropathy enables to adapt the treatment (only immunosuppressive treatment or in combination with antiviral drugs).

The **BK Virus R-gene™** kit enables the quantification of BK virus in real-time PCR after viral DNA extraction. **BK Virus R-gene™** is a user-friendly and complete kit and therefore ideal for routine diagnostics. The kit has been clinically validated on many types of specimen in combination with numerous DNA purification systems (automatic and manual) and amplification platforms.

Thanks to a general amplification program for the entire range of **R-gene™** kits, the sample analysis can be simultaneously run for all other DNA viruses: **JC Virus r-gene™ Primers/Probe** (**ref.: 71-004**), Adenovirus with **Adenovirus R-gene™** kit (**ref.: 69-010B**), CMV with **CMV R-gene™** kit (**ref.: 69-003B**), CMV, HHV-6, HHV-7 and HHV-8 with **CMV HHV6,7,8 R-gene™** kit (**ref.: 69-100B**), EBV with **EBV R-gene™** kit (**ref.: 69-002B**), HSV-1, HSV-2, and VZV with **HSV1 HSV2 VZV R-gene** kit (**ref.: 69-004B**).

Results are validated with all the necessary controls (including an internal extraction control) provided with the kit.

BK Virus R-gene™ — Quantification Complete Kit

PRODUCT INFORMATION

69-013

Principle of the Test	Genomic Detection and Quantification of BKV.
Technology	Real-Time PCR. 5' Nuclease Technology TaqMan®.
Gene Target	Small T Antigen (StAg).
Specimen	Whole Blood, Plasma, Urine Samples.
Limit of Detection	2.6 Copies/PCR. 65 Copies/mL.
Dynamic Range of Quantification	Up to 10^{11} Copies/mL.
Controls Included	Inhibition and Extraction Control, Sensitivity Control, Negative Control.
Result Within	1 H. 15 Extraction Step not Included.
Reporting Units	Number of Viral Copies/mL of Sample.
Number of Tests	90 Tests.
Kit Storage	-18°C/-22°C for Ref.: 69-013B (Quantification Kit). +2°C/+8°C for Ref.: 67-000 (DNA Extraction Kit, Available with the Complete Kit).
Necessary Equipment	Extraction: - **NucliSens® easyMAG™ (Biomérieux).** - QIAamp DNA Blood Mini kit (Qiagen). - QIAcube, QIAsymphony SP (Qiagen). - Versant kPCR Molecular System SP (Siemens). - MagNA Pure Compact® (Roche Diagnostics). - MagNA Pure LC System® (Roche Diagnostics). - EZ1 Advanced and EZ1 Advanced XL (Qiagen). Amplification: - Applied Biosystems™. - LightCycler® (Roche Diagnostics). - SmartCycler® (Cepheid). - Rotor-Gene™ (Corbett Research). - Stratagene® Mx3000P, Stratagene® Mx3005P. - Versant kPCR Molecular System AD (Siemens). - DX Real-Time System (Bio-Rad).
Status	For *in Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: Not Available.

JC Virus r-gene™ Primers/Probe 71-004

JC Virus r-gene™ Primers/Probe

USE FOR Real-time PCR amplification and detection of JC Virus.

• JC Virus r-gene™ Primers/Probe	60 reactions	2 x 450 µL	71-004

JC Virus r-gene™ Primers/Probe product is a premix designed to amplify JC virus using 5' nuclease real-time assay technology. The targeted sequence corresponds to a fragment of 197/198 bp located in the gene coding for the "Large T antigen".

BK Virus r-gene™ Primers/Probe 71-005

BK Virus r-gene™ Primers/Probe

USE FOR Real-time PCR amplification and detection of BK Virus.

• BK Virus r-gene™ Primers/Probe	60 reactions	2 x 450 µL	71-005

BK Virus r-gene™ Primers/Probe product is a premix designed to amplify BK Virus using 5' nuclease real-time assay technology. The targeted sequence corresponds to a fragment of 197/198 bp located in the gene coding for the "Large T antigen".

Adenovirus r-gene™ Primers/Probes 71-010

Adenovirus r-gene™ Primers/Probes

USE FOR 5' nuclease real-time PCR Adenovirus amplification and detection (7 species).

• Adenovirus r-gene™ Primers/Probes	60 reactions	2 x 450 µL	71-010

Adenovirus r-gene™ Primers/Probes product is a premix designed to amplify Adenovirus using 5' nuclease real-time assay technology. The targeted sequence corresponds to a fragment of 138 bp, located in the gene coding for the Hexon.

Parechovirus r-gene™ 71-020 CE

Parechovirus r-gene™

USE FOR Parechovirus genome detection by real-time PCR.

• Parechovirus r-gene™	60 tests	2 x 450 µL	71-020

Human Parechoviruses (HPeV) belong to the Picornaviridae family. Fourteen types of Human Parechoviruses have been identified. Human Parechoviruses are frequent pathogens (seroprevalence of 95% has been reported), usually causing asymptomatic infections. However, human parechovirus infections have also been described to be associated with serious respiratory illnesses, encephalitis and aseptic meningitis.

Parechovirus r-gene™ is designed for the real-time PCR detection of Parechoviruses on respiratory and cerebrospinal fluid samples by using the 5' nuclease technology.

The amplified fragment measures 265 base pairs and is located in the 5'UTR region of the Parechovirus genome. Reverse transcriptase is supplied along with an inhibition control and a positive control to validate the entire assay.

The **Parechovirus r-gene™** amplification protocol is similar to other **Argene** real-time PCR products. Therefore Parechovirus can be tested simultaneously with other viruses involved in central nervous system and/or respiratory infections.

Methods for DNA amplification using Polymerase Chain Reaction (PCR), RT-PCR process and 5' nuclease are covered by US patents issued to Hoffmann-La Roche. Neither anything in this publication nor purchase of these products from ARGENE should be construed as an authorization or implicit license to use these methods.

ENTEROVIRUS R-gene™ 69-005

ENTEROVIRUS R-gene™ - Real-time PCR Assay

Related publications

USE FOR Real-time PCR amplification and detection of Enteroviruses.

- ENTEROVIRUS R-gene™ - Real-time PCR COMPLETE kit — 90 tests — 69-005
- ENTEROVIRUS R-gene™ - Real-time PCR kit — 90 tests — 69-005B

Members of the Picornaviridae family, enteroviruses are single-strand RNA viruses, split into 4 families (Enterovirus A, B, C and D). More than 100 serotypes have been described, of which 68 are currently recognised in the 2005 international classification (*8th report of the International Committee on the Taxonomy of Viruses. 2005*).

In temperate climates, Enterovirus infections occur mostly seasonally (from May to October) and are particular common infections in children and adolescents. Enteroviruses are the leading cause of meningitis. The clinical criteria of meningitis caused by an Enterovirus infection can not be discriminated from those caused by other infectious agents (e.g. Mumps virus or Herpes Simplex virus). Enteroviruses are also associated with cardiac, respiratory, cutaneous mucosa or neonatal pathologies.

Polioviruses are responsible for acute anterior poliomyelitis. This disease is currently being eradicated worldwide.

The standard method for the diagnosis of Enteroviruses is isolation by cell culture followed, if necessary, by a sero-neutralisation typing. However, this traditional method sometimes lacks sensitivity for certain serotypes (Coxsackievirus A and enterovirus 68 to 71). Currently, the method of choice for the diagnosis of these neuro-meningitis infections is the molecular diagnosis on CSF samples. Much faster than conventional PCR methods, real-time PCR enables a rapid and sensitive identification of all the serotypes, allowing clinicians to cut off unnecessary treatment and useless clinical examinations.

The **ENTEROVIRUS R-gene™** kit enables the generic detection of Enteroviruses by amplification of the highly conserved 5' non-coding region, by means of real-time PCR amplification on CSF samples, stool samples, respiratory specimens or culture cells.

The kit has been clinically validated on several types of specimens with various RNA purification systems (automatic and manual) and the most common real-time PCR platforms.

Results are validated with different controls, including an extraction control, all provided with the kit. Results are useful for the rapid identification of all serotypes and the management of patient therapy.

ENTEROVIRUS R-GENE™

DETECTION COMPLETE KIT

PRODUCT INFORMATION
69-005

PRINCIPLE OF THE TEST	REAL-TIME PCR AMPLIFICATION AND DETECTION OF ENTEROVIRUSES.
TECHNOLOGY	REAL-TIME PCR. 5' NUCLEASE TECHNOLOGY TAQMAN®.
GENE TARGET	5' NON CODING REGION.
SPECIMEN	CSF, STOOL, RESPIRATORY SPECIMEN, CELL CULTURE.
LIMIT OF DETECTION	0.01 (COXA13) TO 10 (PV1) $TCID_{50}$/mL.
DYNAMIC RANGE OF QUANTIFICATION	N/A
CONTROLS INCLUDED	INHIBITION AND EXTRACTION CONTROL, POSITIVE CONTROL, NEGATIVE CONTROL.
RESULT WITHIN	2 H. EXTRACTION STEP NOT INCLUDED.
REPORTING UNITS	QUALITATIVE TEST.
NUMBER OF TESTS	90 TESTS.
KIT STORAGE	-18°C/-22°C FOR REF.: 69-005B (REAL-TIME PCR KIT). +2°C/+8°C FOR REF.: 67-020 (DNA/RNA EXTRACTION KIT, AVAILABLE WITH THE COMPLETE KIT).
NECESSARY EQUIPMENT	EXTRACTION: **- NUCLISENS® EASYMAG™ (BIOMÉRIEUX).** - QIAAMP RNA VIRUS MINI KIT (QIAGEN). - QIAAMP MINELUTE VIRUS SPIN KIT (QIAGEN). - QIACUBE (QIAGEN). - MAGNA PURE COMPACT® (ROCHE DIAGNOSTICS). - VERSANT KPCR MOLECULAR SYSTEM SP (SIEMENS). - EZ1 ADVANCED AND EZ1 ADVANCED XL (QIAGEN). AMPLIFICATION: - APPLIED BIOSYSTEMS™. - LIGHTCYCLER®. - ROTOR-GENE™. - STRATAGENE. - SMARTCYCLER®. - VERSANT KPCR MOLECULAR SYSTEM AD (SIEMENS). - DX REAL-TIME SYSTEM (BIO-RAD).
STATUS	FOR *IN VITRO* DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE.

BORDETELLA R-gene™ 69-011

BORDETELLA R-gene™ - Real-time PCR Assay

Related publications

USE FOR Real-time PCR amplification and detection of *Bordetella*.

• *BORDETELLA* R-gene™ - Real-time PCR COMPLETE kit	60 tests	69-011
• *BORDETELLA* R-gene™ - Real-time PCR kit	60 tests	69-011B

Whooping cough is caused by the bacterium *Bordetella pertussis*. The bacteria enter the body through the airways and attach to the mucosa of the upper respiratory tract (trachea and bronchi). The inflammatory and necrotic impairments that it causes are due to the pertussis toxin that is released.

Whooping cough is a highly contagious childhood respiratory disease. It mainly affects children under 5 years old and may be very serious in infants under 6 months, because they do not have any immunity against the illness (maternal antibodies against whooping cough do not cross the placenta). The disease can then lead to respiratory complications (apnea and bacterial surinfections). This disease may be fatal among newborn infants under 6 months. Whooping cough can affect people of any age. In well-vaccinated countries, mortality and morbidity have been reduced by 95%. However, a change in the transmission mode of the disease has been observed for some years in the absence of natural or vaccination boosting. It no longer occurs from child to child but from adult or adolescent to non-vaccinated infants.

Bordetella pertussis is generally diagnosed by cell culture. This technique is still the reference technique in all cases of non-vaccinated or incompletely vaccinated patients. Diagnosis by serology is also used but presents problems associated with the vaccination because it is not possible to differentiate between the vaccinal serological response and the response to an infection by the pathogen. Real-time PCR is an effective alternative for diagnosing *Bordetella* because it produces sensitive, specific and faster results than culture.

The ***BORDETELLA* R-gene™** kit enables the detection of *Bordetella* bacteria containing the IS481 sequence (traditionally found in *Bordetella pertussis*) using real-time PCR on respiratory samples (nasopharyngeal aspiration and expectoration).

Several types of purification systems (automatic and manual) have been validated with the kit. Extracted DNA is then amplified and detected by real-time PCR on the commonly available platforms.

Results are validated with different controls, including an extraction control, all provided in the kit.

BORDETELLA R-GENE™
DETECTION COMPLETE KIT

PRODUCT INFORMATION
69-011

PRINCIPLE OF THE TEST	REAL-TIME PCR AMPLIFICATION AND DETECTION OF *BORDETELLA*.
TECHNOLOGY	REAL-TIME PCR. 5' NUCLEASE TECHNOLOGY TAQMAN®.
GENE TARGET	IS481 REGION.
SPECIMEN	NASOPHARYNGEAL ASPIRATIONS AND EXPECTORATIONS.
LIMIT OF DETECTION	<10 BACTERIAL GENOME / ML.
DYNAMIC RANGE OF QUANTIFICATION	N/A
CONTROLS INCLUDED	INHIBITION AND EXTRACTION CONTROL, POSITIVE CONTROL, NEGATIVE CONTROL.
RESULT WITHIN	1 H. 15 EXTRACTION STEP NOT INCLUDED.
REPORTING UNITS	QUALITATIVE TEST.
NUMBER OF TESTS	60 TESTS.
KIT STORAGE	-18°C/-22°C FOR REF.: 69-011B (QUANTIFICATION KIT). +2°C/+8°C FOR REF.: 67-000 (DNA EXTRACTION KIT, AVAILABLE WITH THE COMPLETE KIT).
NECESSARY EQUIPMENT	EXTRACTION: **- NUCLISENS® EASYMAG™ (BIOMÉRIEUX).** - QIAAMP DNA BLOOD MINI KIT (QIAGEN). - QIAAMP DNA MINI KIT (QIAGEN). - QIACUBE (QIAGEN). - MAGNA PURE COMPACT® (ROCHE DIAGNOSTICS). - MAGNA PURE LC SYSTEM® (ROCHE DIAGNOSTICS). - HIGH PURE PCR TEMPLATE PREPARATION KIT (ROCHE DIAGNOSTICS). AMPLIFICATION: - APPLIED BIOSYSTEMS™. - LIGHTCYCLER®. - ROTOR-GENE™. - SMARTCYCLER®. - DX REAL-TIME SYSTEM (BIO-RAD).
STATUS	FOR *IN VITRO* DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE. USA: FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

Bordetella parapertussis r-gene™ 71-012

Bordetella parapertussis r-gene™

USE FOR 5' nuclease real-time PCR *Bordetella parapertussis* amplification and detection.

USE FOR *Bordetella parapertussis* extraction and amplification control.

• *Bordetella parapertussis* r-gene™	60 reactions	2 x 450 µL	71-012

***Bordetella parapertussis* r-gene™** is a ready-to-use premix optimized for the real-time amplification of IS1001 region of *Bordetella parapertussis*, using the 5' nuclease technology. An internal control checks, in the same tube, the efficiency of extraction step and the possible presence of inhibitory agents of amplification.

RSV A/B r-gene™ Primers/Probes 71-007

RSV A/B r-gene™ Primers/Probes

USE FOR 5' nuclease real-time RT-PCR RSV A and B amplification and detection.

• RSV A/B r-gene™ Primers/Probes	60 reactions	2 x 450 µL	71-007

RSV A/B r-gene™ Primers/Probes product is a premix designed to amplify RSV A and B using 5' nuclease real-time assay technology. The targeted sequence corresponds to a fragment of 185 bp, located in the gene coding for a nucleoprotein.

hMPV A/B r-gene™ Primers/Probes 71-008

hMPV A/B r-gene™ Primers/Probes

USE FOR 5' nuclease real-time RT-PCR hMPV A and B amplification and detection.

• hMPV A/B r-gene™ Primers/Probes	60 reactions	2 x 450 µL	71-008

hMPV A/B r-gene™ Primers/Probes product is a premix designed to amplify hMPV A and B using 5' nuclease real-time assay technology. The targeted sequence corresponds to a fragment of 135 bp, located in the gene coding for a matricial protein.

Bocavirus r-gene™ Primers/Probe 71-009

Bocavirus r-gene™ Primers/Probe

USE FOR 5' nuclease real-time PCR Bocavirus amplification and detection.

• Bocavirus r-gene™ Primers/Probe	60 reactions	2 x 450 µL	71-009

Bocavirus r-gene™ Primers/Probe product is a premix designed to amplify Bocavirus using 5' nuclease real-time assay technology. Targeted sequences correspond to a fragment of 77 bp, located in the gene coding for the non structural protein NS1.

Influenza A/B r-gene™ Primers/Probes 71-006

Influenza A/B r-gene™ Primers/Probes

USE FOR Amplification and detection of Influenza A and B viruses by real-time RT-PCR.

• Influenza A/B r-gene™ Primers/Probes	60 reactions	2 x 450 µL	71-006

Influenza A/B r-gene™ Primers/Probes product is a premix designed to amplify Influenza A and B viruses using 5' nuclease real-time assay technology. Targeted sequences correspond to fragments of 233 and 146 bp, located in the M gene coding for a matricial protein.

Influenza A(M) Group & H_1N_1 2009 r-gene™ 71-300

Influenza A(M) Group & H_1N_1 2009 r-gene™

USE FOR Typing of the novel 2009 Influenza A/H_1N_1 and detection of Influenza A group viruses by real-time RT-PCR.

• *Influenza* A(M) Group & H_1N_1 2009 r-gene™	60 tests	2 x 450 µL	71-300

***Influenza* A(M) Group & H_1N_1 2009 r-gene™** product is a premix designed to amplify Influenza A virus and Influenza A/H_1N_1 2009 virus using 5' nuclease real-time assay technology. Targeted sequence corresponds to a fragment of 233 bp, located in the M gene coding for a matricial protein.

Quanti FluA QS r-gene™ 68-006

Quanti FluA QS r-gene™

USE FOR Quantification of Influenza A group viruses and/or novel 2009 Influenza A/H_1N_1 in respiratory samples by real-time qPCR.

• Quanti FluA r-gene™	30 reactions	68-006

Quanti FluA QS r-gene™ is designed to quantify the genome of the following Influenza viruses:
- Swine-lineage Influenza A/H_1N_1 2009 virus using **Influenza A(M) Group & H_1N_1 r-gene™** premix (**ref.: 71-300**);
- Influenza A virus using **Influenza A/B r-gene™ Primers/Probes** premix (**ref.: 71-006**).

The use of **CELL Control r-gene™** (**ref.: 71-106**) in parallel with **Quanti FluA QS r-gene™** will allow to obtain relative quantification in copies of virus per cell.

CELL Control r-gene™ 71-106

CELL Control r-gene™

USE FOR Validation of the presence of cells in the sample by real-time PCR assays for DNA or RNA genomes.

USE FOR Quantification of cells in the sample.

• CELL Control r-gene™	100 reactions	2 x 750 µL	71-106

The **CELL Control r-gene™** is a ready to use premix designed to validate results obtained by real-time amplification checking the presence of cells in extracted samples. **CELL Control r-gene™** determines the number of cells in the sample by using the quantification standards supplied with the kit.

DICO Ampli r-gene™ 71-100

DICO Ampli r-gene™

Related publications

USE FOR DNA target inhibition control premix for real-time PCR.

• DICO Ampli r-gene™	100 reactions	2 x 750 µL	71-100

The **DICO Ampli r-gene™** is a ready-to-use premix designed to control the presence of amplification inhibitory agents in real-time PCR (5' nuclease).

DICO Extra r-gene™ 71-101

DICO Extra r-gene™

Related publications

USE FOR Extraction and inhibition control for real-time PCR assays on DNA genomes.

• DICO Extra r-gene™	100 reactions	71-101

DICO Extra r-gene™ checks the entire real-time process from extraction to amplification (5' nuclease). **DICO Extra r-gene™** controls the efficiency of the extraction procedure (lysis included) and the possible presence of inhibitory agents in the extracted product.
The internal control (IC2) provided with **DICO Extra r-gene™** is added to the sample prior to extraction. The extraction step is then performed as usual in standard conditions.
Extracted product must be distributed in the **DICO Extra r-gene™** premix (DP2) and in the amplification premix specific to the target DNA.
A reference control, PCR grade water (W0), processed as a sample through the extraction, is also provided with **DICO Extra r-gene™**.
The analysis of results obtained with the DP2 premix validates the extraction process as well as the presence of amplification inhibitory agents in the sample.

RICO Extra r-gene™ 71-105

RICO Extra r-gene™

USE FOR Extraction and inhibition control for real-time PCR assays on RNA genomes.

• RICO Extra r-gene™	100 reactions	71-105

RICO Extra r-gene™ checks the entire real-time process from extraction to amplification (5' nuclease). **RICO Extra r-gene™** controls the efficiency of the extraction procedure (lysis included) and the possible presence of inhibitory agents in the extracted product.
The Internal Control (IC1) provided with **RICO Extra r-gene™** is added to the sample prior to extraction. The extraction step is then performed as usual in standard conditions.
Extracted product must be distributed in the **RICO Extra r-gene™** premix (RP1) and in the amplification premix specific to the target RNA.
A reference control, PCR grade water (W0), processed as a sample through the extraction, is also provided with **RICO Extra r-gene™**.
The analysis of results obtained with the RP1 premix validates the extraction process as well as the presence of amplification inhibitory agents in the sample.

COLOUR Compensation r-gene™ 71-103

COLOUR Compensation r-gene™

USE FOR Creation of colour compensation file (530-560 nm on LightCycler© 2.0).

• COLOUR Compensation r-gene™	2 calibration runs	3 x 60 µL	71-103

Colour Compensation r-gene™ is a set of 3 ready-to-use premixes designed to create a colour compensation file in LightCycler© 2.0 software to analyse results obtained in one single capillary containing 2 different fluorophores (530-560 nm).
The colour compensation file corrects the bleed-over caused by this dual-colour reaction. The correction compensates the data which results in a single and complete fluorescent dye signal per LightCycler© 2.0 channel.
Colour Compensation r-gene™ is compliant with the full **Argene R-gene™** range.

Methods for DNA amplification using the Reverse Transcription PCR process and/or the 5 ' Nuclease Detection process are covered by patents issued to F. Hoffmann-La Roche Ltd et Roche Molecular Systems, Inc. Neither anything in this publication nor purchase of this product from ARGENE should be construed as an authorization or implicit license to use these methods.

For research use only.

Quanti HHV8 QS r-gene™ 68-008

Quanti HHV8 QS r-gene™

USE FOR HHV-8 genome quantification range for real-time PCR application with **CMV HHV6,7,8 R-gene™** kit (Argene, **ref.: 69-100**).

• Quanti HHV8 r-gene™	30 reactions		68-008

Quanti HHV8 r-gene™ is designed to quantify herpesvirus 8 genome. **Quanti HHV8 r-gene™** consists of 4 quantification standards (QS1, QS2, QS3, QS4) ranged from 5 000 copies/µL to 5 copies/µL to be amplified with the HHV-8 amplification premix (R8) provided with the **CMV HHV6,7,8 R-gene™** kit (Argene, **ref.: 69-100**).

Bocavirus r-gene™ positive control 68-009

Bocavirus r-gene™ positive control

USE FOR Positive control for 5' nuclease real-time PCR Bocavirus amplification and detection.

• Bocavirus r-gene™ positive control	10 reactions	100 µL	68-009

Bocavirus r-gene™ Positive Control consists of extracted DNA that should be amplified with reagent **71-009** (**Bocavirus r-gene™ Primers/Probe**).

CMV Clear QC Panel 68-020

CMV Clear QC Panel

USE FOR Quantitative or qualitative molecular virology.

USE FOR Research.

USE FOR Conventional and real-time PCR.

• CMV Clear QC Panel	3 vials	Freeze dried	3 x 1 mL	68-020

Clear QC Panels are reference material for internal quality control of molecular virology assays. **Clear QC Panels** undergo the same treatment as the clinical sample during the entire assay (from extraction to detection). Thus, **Clear QC Panels** validate the entire molecular testing process (conventional PCR or real-time PCR) whatever the amplified sequence may be. **Clear QC Panels** are manufactured to **Argene** specifications by QCMD organisation (Quality Control for Molecular Diagnosis). Each **Clear QC Panel** includes several vials which corresponds to standardised levels of concentrations (quantified in viral copies per mL). The different levels of virus concentration have been chosen to cover a wide spectrum corresponding to the usual values found in virology labs. The daily routine use of **Clear QC Panels** corresponds to current laboratory quality control policy (e.g. Good Laboratory Practice). **Clear QC Panels** have been developed to monitor the performance of the molecular testing process and for the detection of random or systematic errors in routine methods. In a research approach, **Clear QC Panels** evaluate the performance and the robustness of different molecular assays.

Methods for DNA amplification using Polymerase Chain Reaction (PCR), RT-PCR process and 5' nuclease are covered by US patents issued to Hoffmann-La Roche. Neither anything in this publication nor purchase of these products from ARGENE should be construed as an authorization or implicit license to use these methods.

For research use only.

Respiratory M.W.S. r-gene™ 71-04X

Respiratory M.W.S. r-gene™ - Range of real-time PCR kits

USE FOR Detection and amplification of respiratory pathogens by real-time PCR.

Acute Respiratory Infections (ARI) account for an estimated 75% of all acute morbidities in industrialized countries and continue to be the leading cause of acute illnesses worldwide. Populations at increased risk for developing a fatal respiratory distress are young infants, immunocompromised persons and the elderly.

Upper Respiratory Tract Infections (URTIs) such as rhinitis, pharyngitis, and laryngitis are among the most common infections in children. URTI can lead to acute asthma exacerbations, acute otitis media, and Lower Respiratory Tract Infections (LRTI) such as bronchitis, brochiolitis, and pneumoniae.
Bacteria and viruses are responsible for the vast majority of respiratory infections. The major causes of ARI in children and adults are Influenza A and B viruses, Parainfluenza viruses type 1, type 2 and type 3, Respiratory Syncytial Virus (RSV A and B), Adenovirus and Rhinovirus. Other pathogens such as Coronavirus, Bocavirus, Enterovirus, Parainfluenzavirus 4, human Metapneumovirus, *Mycoplasma pneumoniae, Chlamydophila pneumoniae and Legionella pneumophila,* also infect the respiratory tract and can cause various diseases from mild self limiting upper respiratory tract infections to potentially life threatening pneumoniae. Clinical symptoms are similar and discrimination of the causative agents is only possible with *in vitro* diagnostic molecular methods. Early and specific detection is essential to rapidly identify the causal respiratory pathogen, leading to patient-tailored therapy. A rapid and accurate diagnosis will also help to control outbreaks, reduce potential antibiotic resistance and facilitate a more rapid patient's recovery. To ensure such a diagnosis, real-time PCR is the method of choice.

Respiratory Multi Well System (MWS) r-gene™ is a brand new concept of real-time PCR complete kits for the simultaneous detection of infectious agents involved in respiratory diseases.
The duplex amplification can be performed following a uniform protocol and the program is common for the entire range of pathogens (both DNA and RNA).
Respiratory Multi Well System (MWS) r-gene™ is an innovative solution in response to the challenges in diagnosis of respiratory infections. Indeed, it is a modular multiplex solution allowing multiple detection strategies using the sensitivity and the specificity of a Taqman® 5' nuclease assay.

The Respiratory MWS r-gene™ allows the simultaneous detection of 35 pathogens within less than one hour and a half after extraction.
The results are validated with positive, negative and cellular controls provided with the kits.

All commonly available real-time PCR platforms are compatible with the Multi Well System r-gene™ range.

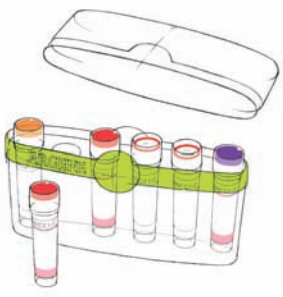
Unlike many others multiplex solutions, MWS r-gene™ does not require any additional equipment or training.

All our premixes are user friendly as they are ready to use. Color codes allow a quick identification of products and reagents. At last, we supply our products in a compact polypropylene packaging for easy storage and the possibility for re-use.

CONTENTS OF MWS r-gene™

All our kits use 5' nuclease TaqMan technology and contain :

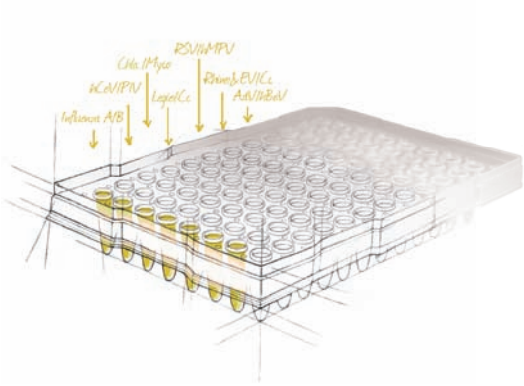
- Reverse Transcriptase (for RNA virus)
- Specific amplification premix
- Negative control (quality PCR water)
- Positive control



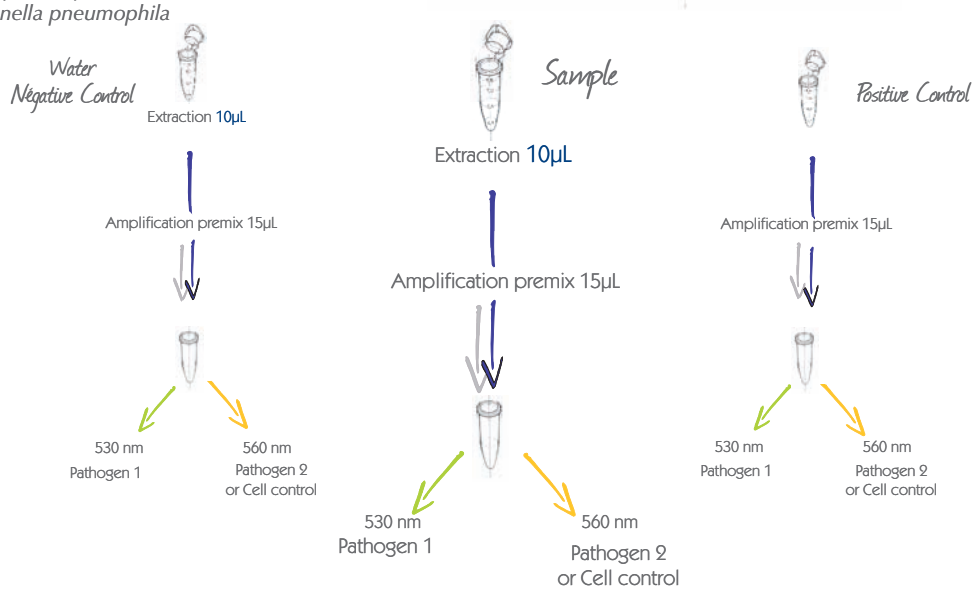
Respiratory M.W.S. r-gene™ - Range of real-time PCR kits

DETECTED PARAMETERS:

- Influenza A
- Influenza B
- Coronavirus (229E, NL63, HKU1, OC43)
- Respiratory Syncytial Virus (A,B)
- Metapneumovirus (A,B)
- Parainfluenzavirus (1,2,3,4)
- Rhinovirus (A,B,C)
- Enterovirus (A,B,C,D)
- Adenovirus (A,B,C,D,E,F,G)
- Bocavirus (1,2,3,4)
- Cell Control
- *Chlamydophila pneumoniae*
- *Mycoplasma pneumoniae*
- *Legionella pneumophila*



PRINCIPLE



RESPIRATORY M.W.S. r-gene™

RANGE OF KITS FOR THE DETECTION OF RESPIRATORY PATHOGENS

PRODUCT INFORMATION

71-04X

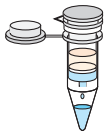
DESIGNATION	INFLUENZA A/B r-gene™ REF.: 71-040	RSV/HMPV r-gene™ REF.: 71-041	RHINO&EV/CC r-gene™ REF.: 71-042	ADV/HBOV r-gene™ REF.: 71-043	CHLA/MYCO PNEUMO r-gene™ REF.: 71-044	HCOV/HPIV r-gene™ REF.: 71-045	LEGIO/CC r-gene™ REF.: 71-046
PRINCIPLE OF THE TEST	DUPLEX DETECTION OF RESPIRATORY PATHOGENS BY REAL-TIME PCR						
TECHNOLOGY	5' NUCLEASE TECHNOLOGY TAQMAN®						
GENE TARGET	INFLUENZA A: M GENE CODING FOR MATRICIAL PROTEIN	RSV: N GENE CODING FOR NUCLEUS PROTEIN	RHINO&EV: 5' NON CODING REGION	ADENOVIRUS: HEXON GENE	*C.PNEUMONIAE*: GENE OMP2 CODING FOR MEMBRAN SURFACE PROTEIN	PARAINFLUENZA: N GENE	*L. PNEUMOPHILA*: UNDER DEVELOPMENT
	INFLUENZA B: M GENE CODING FOR MATRICIAL PROTEIN	HMPV: M GENE CODING FOR MATRICIAL PROTEIN	CELL CONTROL: HPRT1 GENE	BOCAVIRUS: NS1 AND VP1 GENES	*M.PNEUMONIAE*: P1 GENE CODING FOR CYTADHESINE	HCOV: N GENE	CELL CONTROL: HPRT1 GENE
DETECTED PATHOGENS	INFLUENZA A / INFLUENZA B	RSV A, RSV B HMPV A, HMPV B	RHINOVIRUS A,B,C ENTEROVIRUS A,B,C,D	ADV A,B,C,D,E,F,G HBOV 1,2,3,4	*CHLAMYDOPHILA PNEUMONIAE* *MYCOPLASMA PNEUMONIAE*	PARAINFLUENZA 1,2,3,4 HCOV 229E, NL63, HKU1, OC43	*LEGIONELLA PNEUMOPHILA*
SPECIMEN	RESPIRATORY SAMPLES.						
CONTROLS INCLUDED	POSITIVE CONTROL, NEGATIVE CONTROL, CELLULAR CONTROL.						
RESULT WITHIN	1H30 AFTER EXTRACTION.						
NUMBER OF TESTS	60 TESTS.						
KIT STORAGE	-18°/-22°C.						
STATUS	FOR IN VITRO DIAGNOSTIC USE, CE MARKING IN EUROPE - PLEASE INQUIRE. USA: FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.						

Principle of End-Point PCR Molecular Biology kits

ALL KITS FOLLOW THE SAME PROCESS

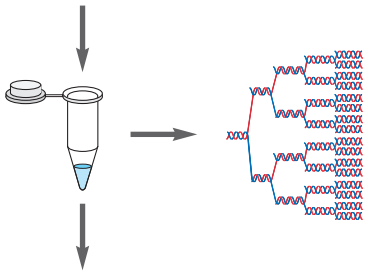
1. DNA or RNA ISOLATION

Silica based



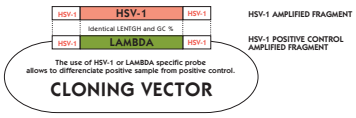
2. CONSENSUS AMPLIFICATION

Ready-to-Use RT and/or Amplification Premix



Positive and Inhibition Controls

Included in All ARGENE Molecular Virology Assays*, the Positive and Inhibition Controls follow the Same Principle:

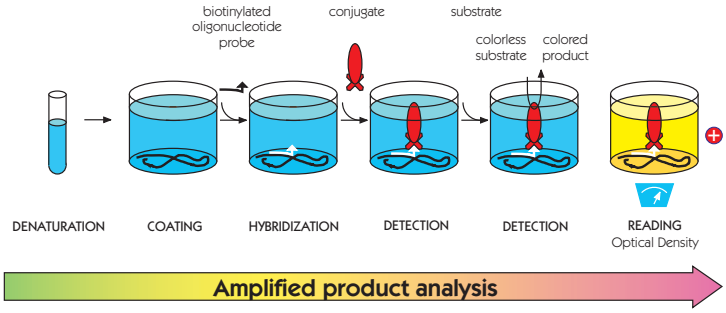


I.e.: for Positive HSV1 Control

*not available as separate reagents

3. HYBRIDOWELL™ DETECTION PROCEDURE

EIA Methodology (96 Wells) with Breackable Strips



- ADVANTAGES -

Complete Kit:	All Reagents provided in the Kit (from Extraction to Detection).
Standardized:	Similar Processing for All Kits.
Results Validation:	Positive, Negative and Inhibition Controls are included in Each Kit.
Rapid:	Results within One Day.
Simple:	Standard Molecular Biology Materials, No Special Equipment is Needed.
User-Friendly:	Ready-to-Use Reagents; Colored Probes.
Suitable for Automation:	HYBRIDOWELL™ Detection Step.
Flexible:	- Many Possible Breaks (before or after Extraction, Amplification or Detection Steps). - Suitable for Small or Large Sample Series; Free Choice of Microplate Map. - All Kits are Available with or without Extraction Kit (Ref.: 67-XXXBC).

HYBRIDOWELL™ Universal 67-012 CE

HYBRIDOWELL™ Universal Assay

USE FOR Universal detection of amplified DNA on microwell plates.

- HYBRIDOWELL™ Universal - Complete kit — 96 tests — 67-012

This kit contains all necessary reagents for the analysis of 96 amplified products by hybridization with biotinylated probes on microwell plates. Amplified fragment is directly coated on the plate then hybridized with the biotinylated probe. Hybrids are detected with a streptavidin peroxidase conjugate and detected with hydrogen peroxide associated with TMB. For some pathogenic agents, **HYBRIDOWELL™** adapted probes are available in our catalog. For **HYBRIDOWELL™** usage in your own systems, use probes biotinylated in 5' during synthesis.

HYBRIDOWELL™ Universal

PRODUCT INFORMATION
67-012

Principle of the Test	Universal Detection of Amplified DNA.
Technology	ELISA Methodology on Microtiter Plate: Hybridization using Biotinylated Probe –> Detection with Streptavidin-Peroxydase Conjugate + TMB Substrate.
Specimen	0.1 to 1 kb Amplified DNA Fragment.
Controls Included	Negative Control.
Results Within	3 H. 25.
Results	Qualitative or Quantitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	96 Tests.
Kit Storage	+2°C/+8°C.
Necessary Equipment	Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire.

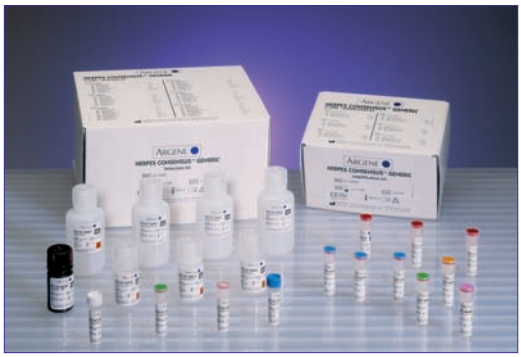
HERPES CONSENSUS GENERIC 67-090 CE

HERPES CONSENSUS GENERIC Assay

USE FOR CMV, HSV-1, HSV-2, VZV, EBV, HHV-6 consensus amplification.

- HERPES CONSENSUS GENERIC - Complete kit — 50 samples — 67-090
- HERPES CONSENSUS GENERIC - Amplification/Detection — 50 samples — 67-090BC

The **HERPES CONSENSUS GENERIC** kit allows the DNA purification, amplification and detection of samples for which the status of herpesvirus positive or herpesvirus negative (CMV, HSV-1, HSV-2, VZV, EBV, HHV-6) will be determined by using a generic probe. Identification of positive samples obtained is performed using a second kit: the **HYBRIDOWELL™ HERPES IDENTIFICATION** (**ref.: 67-050**) kit with the same amplified product. The **HERPES CONSENSUS GENERIC** and **HYBRIDOWELL™ HERPES IDENTIFICATION** kits allow detection of the most common herpes genomes, in biological samples such as cerebrospinal fluids (CSF), aqueous humor and tears. The 6 herpesviruses are the major agents of central nervous system infections. Mortality rate for encephalitis is still high, although some specific antiviral treatments are available. Herpes 1 and 2 are responsible for 20 to 70% of necrosing encephalitis. The clinical signs produced during central nervous attacks do not allow clinical differentiation of the precise herpesvirus etiology. The rapid and precise Herpesvirus determination, along with other clinical supportive data, could allow an early initiation of adapted antiviral therapy to improve patient prognosis. Classical diagnostic procedures for these viruses, particularly cultures, are not adapted to most central nervous system specimens (many inhibitors, high inoculum volumes required). For these reasons **Argene HERPES CONSENSUS GENERIC** kit and **HYBRIDOWELL™ HERPES IDENTIFICATION** kit allow rapid detection and typing of these viral genomes and could be important in these pathologies. Positive samples detected with the **HERPES CONSENSUS GENERIC** kit can be further analyzed through **HYBRIDOWELL™ HERPES IDENTIFICATION** kit (**ref.: 67-050**) in order to determine the exact virus involved. The amplified product obtained with the **HERPES CONSENSUS GENERIC** kit is used again for the identification assay without the need for re-extraction or re-amplification. In this case each amplified product is hybridized with 6 Herpesvirus specific biotinylated probes on a microtiter plate. Detection is performed with a streptavidine peroxidase conjugate and 3,3',5,5' tetramethylbenzidine (TMB). Optical density is read at 450 nm with a microplate reader. The complete set of necessary controls to validate the results obtained are included in the kits.



HERPES CONSENSUS GENERIC

Complete Kit

PRODUCT INFORMATION
67-090

Principle of the Test	Screening of CMV, HSV-1, HSV-2, VZV, EBV, HHV-6 by End-Point PCR.
Technology	End-Point PCR. Consensus Amplification HYBRIDOWELL™ Detection in Microtiter Plate.
Gene Target	Gene Coding for DNA Polymerase of the Six Viruses: CMV, HSV-1, HSV-2, VZV, EBV, HHV-6.
Specimen	CSF, Aqueous Humor, Tears, Gynaecological Specimens. Biopsy, Cutaneous Specimen, BAL, Vesicular Fluid, Urine, Serum, Plasma, Swab from Lesion.
Limit of Detection	CMV: 15 Copies/PCR HSV-1: 15 Copies/PCR HSV-2: 1.5 Copy /PCR VZV: 15 Copies/PCR EBV: 1.5 Copy /PCR HHV-6: 1.5 Copy /PCR
Controls Included	Inhibition Control. Positive Control. Negative Control.
Results Within	1 Day.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	192 Tests.
Kit Storage	+2°C/+8°C for Ref.: 67-000. -18°C/-22°C for Ref.: 67-090B. +2°C/+8°C for Ref.: 67-090C.
Necessary Equipment	Thermocycler. Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

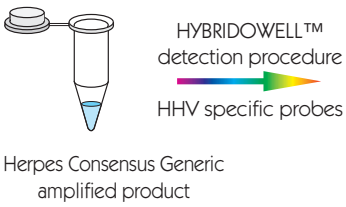
HW™ HERPES Identification 67-050 CE

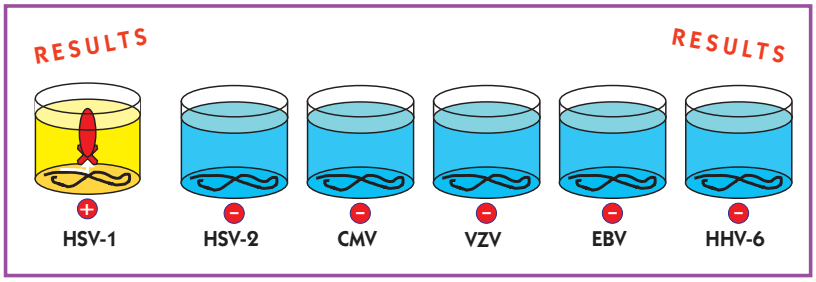
HYBRIDOWELL™ HERPES Identification Assay

USE FOR Identification of positive samples obtained with **HERPES CONSENSUS GENERIC** kit.

- HYBRIDOWELL™ HERPES Identification (for 67-090) 96 tests 67-050

The **HYBRIDOWELL™ HERPES Identification** kit allows the identification of the specific virus present in the positive samples obtained with **HERPES CONSENSUS GENERIC** kit (**ref.: 67-090**). This typing is performed by using the same amplified material obtained with the **HERPES CONSENSUS GENERIC** kit, no further amplification is required. The **HERPES CONSENSUS GENERIC** and **HYBRIDOWELL™ HERPES Identification** kits allow detection of Herpes simplex types 1 and 2 (HSV-1 and HSV-2), Cytomegalovirus (CMV), Varicella Zoster Virus (VZV), Epstein-Barr Virus (EBV), and Herpes virus 6 (HHV-6) which are all major agents of central nervous system infections. Mortality rate for encephalitis is still high, although some specific antiviral treatments are available. Herpes 1 and 2 are responsible for 20 to 70% of necrosing encephalitis. The clinical signs produced during central nervous attacks do not allow clinical differentiation of the precise herpesvirus etiology. The rapid and precise Herpesvirus determination, along with other clinical supportive data, could allow an early initiation of adapted antiviral therapy to improve patient prognosis. Classical diagnostic procedures for these viruses, particularly cultures, are not adapted to most central nervous system specimens (inhibitions, important inoculum volumes). For these reasons **Argene HERPES CONSENSUS GENERIC** kit and **HYBRIDOWELL™ HERPES Identification** kit allow rapid detection and typing of these viral genomes and could be important in these pathologies. Positive samples detected with **HERPES CONSENSUS GENERIC** kit (**ref.: 67-090**) may be further analyzed through **HYBRIDOWELL™ HERPES Identification** kit in order to determine the exact virus involved. The amplified product obtained with **HERPES CONSENSUS GENERIC** kit (**ref.: 67-090**), is used again for the identification assay without the need for re-extraction or re-amplification. Each amplified product is hybridized with 6 Herpesvirus specific biotinylated probes on a microtiter plate. Detection is performed with a streptavidine peroxidase conjugate and 3,3',5,5' tetramethylbenzidine (TMB). Optical density is read at 450 nm with a microplate reader. The complete set of necessary controls to validate the results obtained are included in the kits (including positive controls). This kit allows one to identify up to 14 positive samples depending on the number of tests per series.





HYBRIDOWELL™ HERPES Identification

PRODUCT INFORMATION
67-050

Principle of the Test	CMV, HSV-1, HSV-2, VZV, EBV, HHV-6 Genome Identification.
Technology	HYBRIDOWELL™ Detection in Microtiter Plate.
Specimen	Samples amplified with Argene HERPES CONSENSUS GENERIC Kit (Ref.: 67-090).
Limit of Detection	CMV: 15 Copies/PCR HSV-1: 15 Copies/PCR HSV-2: 1.5 Copy /PCR VZV: 15 Copies/PCR EBV: 1.5 Copy /PCR HHV-6: 1.5 Copy /PCR
Controls Included	Positive Control for Each Virus. Negative Control.
Results Within	3 H. 25.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	96 Tests.
Kit Storage	+2°C/+8°C.
Necessary Equipment	Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

ENTEROVIRUS CONSENSUS 67-080 CE

ENTEROVIRUS CONSENSUS Assay

USE FOR Enterovirus consensus amplification.

- ENTEROVIRUS CONSENSUS - Amplification/Detection 50 samples 67-080BC

ENTEROVIRUS CONSENSUS has been designed to detect the RNA genome of all enterovirus serotypes including Poliovirus 1-3, Coxsackievirus A1-22, A24, Coxsackievirus B1-6, Echovirus 1-9, 11-21, 24-27, 29-33 and Enterovirus 68-71 (recently reclassified in the Parechovirus genus, Echovirus 22 and 23 are not detected with this kit). In temperate climates, enterovirus infections occur seasonally. Enteroviruses are often associated as causal agents of meningitis, but have also been associated with cardiopathic, respiratory disorders, muco-cutaneous pathologies and febrile disease in neonates. The Polioviruses are associated with Poliomyelitis, a disease which is rarely encountered clinically due to widespread vaccination. Diagnosis of enterovirus infections done by viral culture isolation does not allow the detection of all serotypes, particularly Coxsackievirus group A, which does not grow in culture. Moreover enterovirus isolation by cell culture from a CSF specimen is often difficult (inhibitors) and requires several days of incubation.

The **ENTEROVIRUS CONSENSUS** kit allows rapid and sensitive enterovirus-specific genome detection. After RNA isolation, the **ENTEROVIRUS CONSENSUS** assay allows a one step RT-PCR for all enterovirus serotypes in one single reaction tube. The amplified region is in the 5' non coding region of the genome. **HYBRIDOWELL™** detection is performed with a biotinylated enterovirus generic probe. These results are validated with positive and inhibition controls included in the kit. Correlated with other clinical supportive data, the results obtained with **ENTEROVIRUS CONSENSUS** allows an immediate discontinuation of antibacterial therapy and allows an initiation of an appropriate antiviral therapy.

ENTEROVIRUS CONSENSUS

Amplification/Detection Kit

PRODUCT INFORMATION
67-080 BC

Principle of the Test	Detection of ENTEROVIRUS by End-Point PCR.
Technology	End-Point PCR. Reverse Transcription + Consensus Amplification in 1 Step. HYBRIDOWELL™ Detection in Microtiter Plate.
Gene Target	5' Non Coding Region.
Specimen	CSF, Stool, Throat Specimens, Nasopharyngeal Secretions. Palpebral Conjunctiva Specimen, Myocardial Biopsy, Pericardial Fluid.
Limit of Detection	30 Copies/PCR.
Controls Included	Inhibition Control. Positive Control. Negative Control.
Results Within	1 Day.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	192 Tests.
Kit Storage	-18°C/-22°C for Ref.: 67-080B. +2°C/+8°C for Ref.: 67-080C.
Necessary Equipment	Thermocycler. Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire.

JC/BK CONSENSUS 67-130 CE

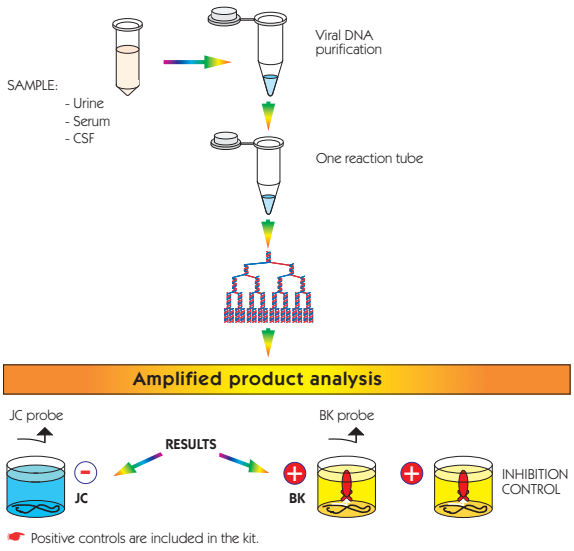
JC/BK CONSENSUS Assay

USE FOR Consensus amplification and differentiation of JCV and BKV.

- JC/BK CONSENSUS - Complete kit — 30 samples — 67-130
- JC/BK CONSENSUS - Amplification/Detection — 30 samples — 67-130BC

The **JC/BK CONSENSUS** kit allows the simultaneous detection and identification of JC virus (JCV) and BK virus (BKV) genomes in urine, serum, plasma, and cerebrospinal fluid (CSF). JC and BK viruses belong to the polyomaviridae family. Primo-infections are asymptomatic or occur with non specific signs from childhood. JCV reactivation in immunocompromized patients is responsible for progressive multifocal leukoencephalopathy (PML). In this case, JCV can be detected in CSF. Severe nephropathies are associated with BKV reactivation for renal or bone marrow transplanted patients. In this case BKV can be detected in urine and/or serum.

The **JC/BK CONSENSUS** kit allows the detection and the identification of both viruses and consequently helps in the therapy and the prognosis orientation of these severe opportunistic infections. After extraction, JCV and BKV are amplified in one single reaction tube and detected in a microtiter plate using hybridization with two specific biotinylated probes. Results are validated via inhibition and positive controls included in the kit.



Positive controls are included in the kit.

JC/BK CONSENSUS

Complete Kit

PRODUCT INFORMATION
67-130

Principle of the Test	Genomic Detection and Discrimination of JCV and BKV by End-Point PCR.
Technology	End-Point PCR. Consensus Amplification. HYBRIDOWELL™ Detection in Microtiter Plate.
Gene Target	JCV: T Antigen Region. BKV: T Antigen Region.
Specimen	Urine, Serum, Plasma, CSF.
Limit of Detection	JCV: 10 Copies/PCR. BKV: 1 Copy/PCR.
Controls Included	Inhibition Control. Positive Control. Negative Control.
Results Within	1 Day.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	192 Tests.
Kit Storage	+2°C/+8°C for Ref.: 67-000. -18°C/-22°C for Ref.: 67-130B. +2°C/+8°C for Ref.: 67-130C.
Necessary Equipment	Thermocycler. Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

ADENOVIRUS CONSENSUS 67-065 CE

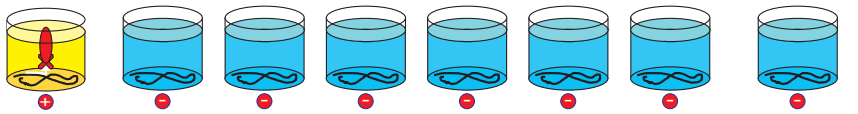
ADENOVIRUS CONSENSUS Assay

USE FOR Human Adenovirus consensus amplification.

- ADENOVIRUS CONSENSUS - Complete kit — 50 samples — 67-065
- ADENOVIRUS CONSENSUS - Amplification/Detection — 50 samples — 67-065BC

The **ADENOVIRUS CONSENSUS** kit allows the detection of adenovirus genomes, in biological samples (nasopharyngeal secretions, stool and biopsy) using hybridization in a microtiter plate with a biotinylated probe following purification of DNA and genomic amplification. The consensus amplification allows the screening of all adenovirus serotypes in one single amplification tube. The detection allows the screening of adenovirus with a generic probe. Specific probes provided with the kit ensure the typing of the 7 adenovirus species (A, B1, B2, C, D, E and F) following the typing protocol. The adenovirus (AdV) group includes more than 50 serotypes divided into 7 species (Human adenovirus followed by a letter) according to their biological properties. Adenovirus infection can be benign to severe especially for immunocompromised patients. The conventional methods like culture, immunofluorescence, agglutination, and immunoenzyme techniques are less sensitive than the genomic detection system used with the **ADENOVIRUS CONSENSUS** kit. **ADENOVIRUS CONSENSUS** allows an early detection of disseminated adenovirus infection and improves the follow up of patients under treatment.

If sample is positive, perform the typing with the same amplified product.



ADENOVIRUS CONSENSUS

Complete Kit

PRODUCT INFORMATION

67-065

Principle of the Test	Screening and Typing of All Adenovirus Species by End-Point PCR.
Technology	End-Point PCR. Consensus Amplification. HYBRIDOWELL™ Detection in Microtiter Plate.
Gene Target	VA RNA Gene.
Specimen	Nasopharyngeal Secretions, Biopsy, Stool. Rectal Swab, Small Intestine, Nasopharyngeal Swab, Ophtalmologic Sample, Urine.
Limit of Detection	60-125 Copies/PCR.
Controls Included	Inhibition Control. Positive Control. Negative Control.
Results Within	1 Day.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	192 Tests.
Kit Storage	+2°C/+8°C for Ref.: 67-000. -18°C/-22°C for Ref.: 67-065B. +2°C/+8°C for Ref.: 67-065C.
Necessary Equipment	Thermocycler. Microtiter Plate Reader.
Status	For *In Vitro* Diagnostic Use, CE Marking in Europe - Please Inquire.

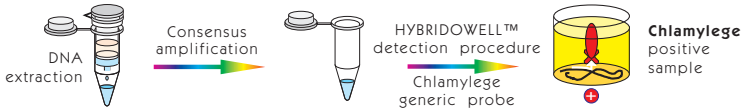
CHLAMYLEGE 67-025 CE

CHLAMYLEGE Assay

USE FOR Amplification and detection of *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae*.

• CHLAMYLEGE - Complete kit	50 samples	67-025
• CHLAMYLEGE - Amplification/Detection	50 samples	67-025BC

The **CHLAMYLEGE** kit allows simultaneous screening and identification of *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae* by amplification in respiratory specimens. *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae* are bacteria frequently found among the pathogenic agents responsible for atypical pneumopathies. These atypical pneumopathies represent a strong proportion (25 to 50%) of the pneumopathies listed even in hospitals. Traditional techniques (immunological tests or culture) are not suitable to guide a quick initial antimicrobial therapy. They are time consuming (longer than 3 days) and are not sensitive enough to get an accurate etiological diagnostic. The use of **CHLAMYLEGE** simplifies the etiologic research of atypical pneumopathies. This sensitive technique makes simultaneous detection of *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae* possible. After DNA isolation, the **CHLAMYLEGE** assay uses a single tube format for genic amplification of *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae*. The amplified products are detected on a microtiter plate after hybridization with biotinylated probes which are generic and/or specific of each bacteria group. In addition, a specific *Legionella pneumophila* probe provided with the kit allows to precise a positive result obtained with the *Legionella* generic probe. The accuracy of the results is validated by the inhibition and the positive controls included with the kit.



If sample is positive, perform the typing with the same amplified product.

Positive and inhibition controls are included in the kit.

CHLAMYLEGE
Complete Kit

PRODUCT INFORMATION
67-025

Principle of the Test	Consensus Amplification and Identification of *Chlamydophila pneumoniae*, *Legionella* and *Mycoplasma pneumoniae*.
Technology	End-Point PCR. Consensus Amplification. HYBRIDOWELL™ Detection in Microtiter Plate.
Gene Target	*Chlamydophila pneumoniae*: OMP2 Region. *Mycoplasma pneumoniae*: P1 Adhesion Gene. *Legionella*: 5S-23S intergenic RNA spacer.
Specimen	Respiratory samples.
Limit of Detection	*Chlamydophila pneumoniae*: 50 Copies/PCR. *Mycoplasma pneumoniae*: 50 Copies/PCR. *Legionella*: 50 Copies/PCR.
Controls Included	Inhibition Control. Positive Control. Negative Control.
Results Within	1 Day.
Results	Qualitative.
Reporting Units	O.D. Units (Optical Density).
Number of Tests	192 Tests.
Kit Storage	+2°C/+8°C for Ref.: 67-000. -18°C/-22°C for Ref.: 67-025B. +2°C/+8°C for Ref.: 67-025C.
Necessary Equipment	Thermocycler. Microtiter plate reader.
Status	For *In Vitro* Diagnostic Use, CE marking in Europe - Please Inquire. USA: for Research Use Only. Not For Use In Diagnostic Procedures.

NOTES

Table of contents

IMMUNOLOGY

Complete kits

Optimized Monoclonal Antibodies

VIRUS

Control Slides

Ancillary Reagents

... See Alphabetical Index

CINAkit HCMV ppUL83 (pp65) RAPID 19-002 CE

CINAkit HCMV ppUL83 (pp65) RAPID ANTIGENEMIA Complete kit

USE FOR HCMV ppUL83 immunofluorescence Antigenemia in 2 hours directly on leukocytes.

USE FOR HCMV ppUL83 Antigenorachia (research use only).

• CINAkit complete kit HCMV ppUL83 (pp65) I.F. Antigenemia	100 tests	19-002
• CINAkit complete kit HCMV ppUL83 (pp65) I.F. Antigenemia	200 tests	19-0028

The optimized blend of clones (**CINApool**) is specific for the internal matrix structural phosphoprotein 65-68 kDa ppUL83 (pp65), which appears in the nuclei of infected cells within one hour post infection, and represents uptake from the virus innoculum. This blend labels two different epitopes expressed in the nuclei of infected peripheral blood polymorphonuclear leukocytes and monocytes, following blood born dissemination (it can also be used on cellular cerebro-spinal fluid). The HCMV isolation from leukocytes of peripheral blood and/or ppUL83 Antigenemia is evidence of an active systemic infection. The ppUL83 Antigenemia appears earlier and is positive for a longer period than viremia as demonstrated by co-culture. It is also a clearly shorter procedure (results within 2 hours). It enables the diagnosis and follow up of HCMV disseminated infections in graft recipients and AIDS patients notably. Immunofluorescence is the only recommended detection method, although others can be used. However different studies show that any technique used to block endogenous enzymatic activity (peroxidase or alkaline phosphatase), also destroys a significant level of the ppUL83 antigen. No cross reactivity with other Herpesviridae.

<u>This blend has multiple advantages</u>:

1/ This antibody pool labels different epitopes expressed in the nuclei of infected peripheral blood polymorphonuclear leukocytes and monocytes, and thus ensures avoiding false negatives that can be caused by a mutation of one of the epitopes recognized, since a double mutation in two specific parts of the antigen is at very low risk.

2/ Improved reading even if the sample does not reach the laboratory under optimum conditions.

3/ This anti ppUL83 pool is also of interest since it stains a higher number of cells in positive samples when compared to a monoclonal alone.

4/ To date, no lack of sensitivity has been reported with this kit regardless of the CMV strain studied.

Important: secondary antibodies other than the one provided in the kit can give cytoplasmic background.

CINAkit HCMV
Complete Kit

PRODUCT INFORMATION
19-002 / 19-0028

Principle of the Test	Detection of HCMV in Peripheral Blood.
Technology	Immunofluorescence.
Epitop Target	ppUL83 (pp65).
Specimen	Peripheral Blood, CSF.
Sensitivity of the Test	96.4% vs Culture.
Result Within	2 Hours.
Reporting Units	Number of Positive Cells for $2x10^5$ Cells.
Number of Tests	19-002: 100 Tests. 19-0028: 200 Tests.
Number of Patients	19-002: 50 Patients. 19-0028: 100 Patients.
Kit Storage	+2°C/+8°C.
Necessary Equipment	Cytocentrifuge (Cytospin 2 or 3, Shandon).
Status	For *In Vitro* Diagnostic Use, CE marking in Europe - Please Inquire. USA: Kit 19-0028 is Registered by FDA for In Vitro Diagnostic Use. Code 19-002 Not Available in the USA.

Reagents for HCMV ppUL83 (pp65)

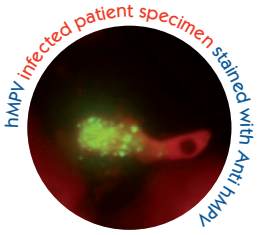
Reagents for HCMV ppUL83 (pp65) Antigenemia

USE FOR Ancillary reagents for HCMV ppUL83 Antigenemia.

• PBS pH: 7.2 without Ca^{2+} and Mg^{2}	powder	-	4 x 1 liter	33-011
• Rapid lysis solution for CINAkit 19-002	-	20x	45 mL	19-002B
• Fixative solution for CINAkit 19-002	-	5x	110 mL	19-002C
• Permeabilization solution for CINAkit 19-002	-	5x	110 mL	19-002E
• Mounting medium for CINAkit 19-002	-	-	4 mL	19-002J
• Dextran 6% for CINAkit 19-002	-	1x	60 mL	19-002K
• Control slide CYTOMEGALOVIRUS IEA-EA	specimen	2+ / 2-	5 slides	40-022
• Antibodies dilution buffer for CINApool 11-002	-	1x	4.5 mL	11-002G
• Evans blue 1% for CINApool 11-002	-	-	250 µL	11-002I

Reagents and complementary small material available through **Argene** for HCMV ppUL83 Antigenemia.

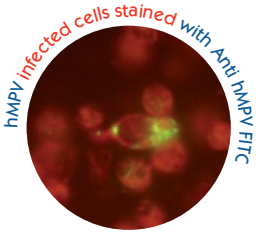
OPTIMIZED RESPIRATORY VIRUSES ANTIBODIES



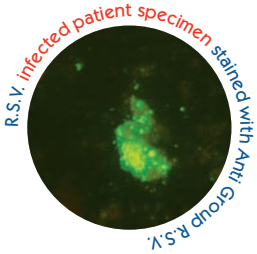
ANTI **hMPV** FITC

REF.: 17-270

This murine monoclonal antibody recognizes a cytoplasmic antigen specific for human metapneumovirus (types A and B).
No cross reactivity with other respiratory viruses.
In immunofluorescence, the antibody shows a cytoplasmic staining.



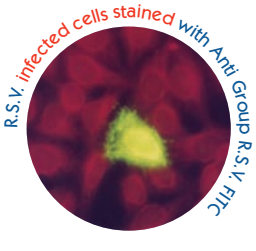
hMPV



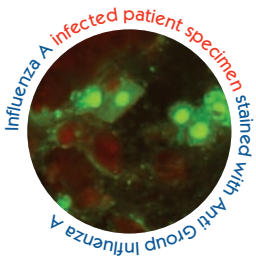
ANTI **R.S.V.** FITC

REF.: 17-042

This murine monoclonal antibody recognizes the F0 (70 kDa) and F1 (48 kDa) subunits of the RSV fusion protein present on all RSV strains (A & B). The affinity of this antibody is exceptionally high, and is responsible for its 100% specificity. It neutralizes the ability of RSV to infect sensitive cells in vitro. It also inhibits the cellular fusion caused by RSV. In immunofluorescence, this antibody shows a cytoplasmic staining. SEE ALSO CONTROL SLIDES.



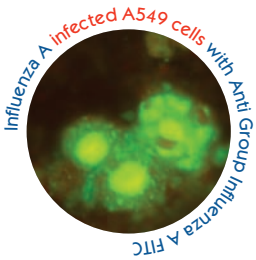
R.S.V.



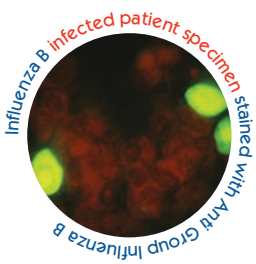
ANTI **INFLUENZA A** FITC

REF.: 17-030

This murine monoclonal antibody recognizes a 60 kDa group specific nucleoprotein common to all Influenza A subtypes (H0N1, H1N1, H2N2, H3N2) and variants tested. No cross reactivity with Influenza B and other respiratory viruses. In immunofluorescence, this antibody shows both a cytoplasmic and nuclear staining. SEE ALSO CONTROL SLIDES.



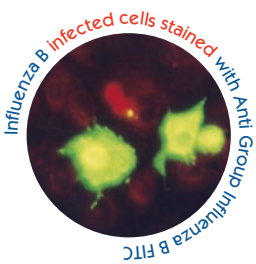
I. A



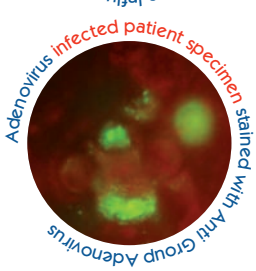
ANTI **INFLUENZA B** FITC

REF.: 17-035

This murine monoclonal antibody recognizes an Influenza B virus group specific antigen.
No cross-reactivity with influenza A or with other respiratory viruses.
In immunofluorescence, this antibody shows a cytoplasmic staining. SEE ALSO CONTROL SLIDES.



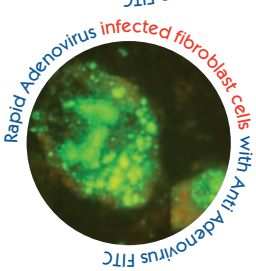
I. B



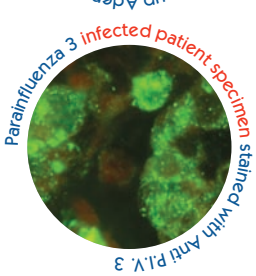
ANTI **ADENOVIRUS** FITC

REF.: 17-020

This optimized pool of murine monoclonal antibodies allows the detection of the entire Adenovirus group.
It can be used in Immunofluorescence on nasopharyngeal secretions or on infected cell culture (MRC-5, A549, H292, HeLa).
In immunofluorescence, those antibodies show a nuclear staining.
SEE ALSO CONTROL SLIDES.



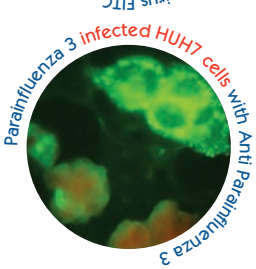
AdV



ANTI **P.I.V. 3** FITC

REF.: 17-038

These murine monoclonal antibodies are Parainfluenza type 3 HA-1 and HN virus antigen specific.
No cross-reactivity with other Parainfluenzae or respiratory viruses.
In immunofluorescence, those antibodies show a cytoplasmic staining.
SEE ALSO CONTROL SLIDES.



P.I.V. 3

For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

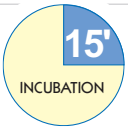
Respiratory Virus Antibodies Product Line

Ready-to-use antibody blends and typing reagents:

FITC Mab - 80 tests - dropper-bottle - 4 mL

Cata. No.:

17-**020**	Anti-ADENOVIRUS GROUP FITC
17-**030**	Anti-INFLUENZA A GROUP FITC
17-**035**	Anti-INFLUENZA B GROUP FITC
17-**036**	Anti-PARAINFLUENZA 1 FITC
17-**037**	Anti-PARAINFLUENZA 2 FITC
17-**038**	Anti-PARAINFLUENZA 3 FITC
17-**040**	Anti-PARAINFLUENZA GROUP FITC
17-**042**	Anti-RSV GROUP FITC
17-**091**	Anti-ADENOVIRUS, INFLUENZA, PARAINFLUENZA GROUP FITC
17-**092**	Anti-ADENOVIRUS, INFLUENZA, PARAINFLUENZA, RSV GROUP FITC
17-**270**	Anti-HUMAN METAPNEUMOVIRUS FITC



All Formats are available:

Cata. No.	Mab Description	# tests	Quantity	Format
17-XXX*	FITC Mab	80 tests	4 mL	Dropper-bottle
11-XXX*	Purified Mab	650 tests	0.5 mL	Concentrated
12-XXX*	FITC Mab	650 tests	0.5 mL	Concentrated

**Use the individual code of each specific respiratory virus antibody.*

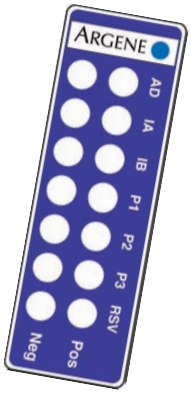
Additional Components:

Product Name	Quantity	Cata. No.	Intended Use
PBS	4 x 1L	33-011	Washing & dilution buffer
Mounting medium for IF	15 mL	33-041	Mount microscope coverslips

Antigen Control Slides:

ref.: 40-121

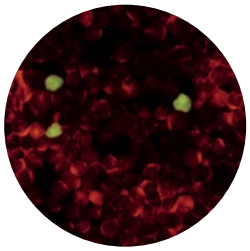
ref.: 40-061



ref.: 40-161

ref.: 40-111

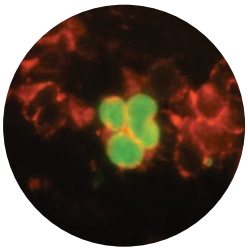
Herpes Virus Antibodies Product Line

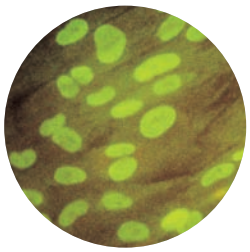


ANTI HCMV ppUL83 (pp65)

CINAkit / CINApool

HCMV ppUL83 Antigenemia after 2 hours directly on peripheral blood leukocytes.

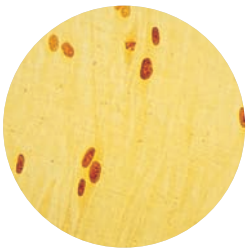


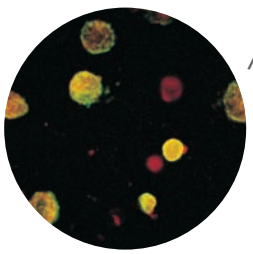


ANTI HCMV

Immediate Early Antigen (I.E.A.)

HCMV Antigen detection in 24-48 h. culture from clinical specimens.



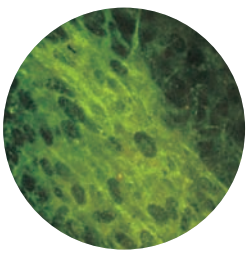


ANTI HSV-1

Infected cell culture detection.

ANTI VZV

Infected cell culture detection (Early detection on MRC-5 cells).



Herpes Virus Antibodies Product Line

Anti CMV ppUL83 (pp65) CINApool

USE FOR HCMV ppUL83 Antigenemia 2 hours directly on peripheral blood leukocytes.

USE FOR HCMV ppUL83 Antigenorachia (research use only).

• anti HCMV ppUL83 (pp65) CINApool purified	330 tests	0.5 mL (20x)	11-002
• anti HCMV ppUL83 (pp65) CINApool & Secondary F(ab')2 FITC	330 tests	0.5 mL (20x)	14-002

The optimized blend of murine clones (**CINApool**) is specific for the internal matrix structural phosphoprotein 65-68 kDa ppUL83 (protein kinase, pp65 or pk65), which appears in the nuclei of infected cells within one hour post infection, and represents uptake from the viral inoculum. This blend labels two different epitopes expressed in the nuclei of infected peripheral blood polymorphonuclear leukocytes and monocytes, following blood borne dissemination (It can also be used on cellular cerebro-spinal fluid). The HCMV isolation from leukocytes of peripheral blood and/or ppUL83 Antigenemia is evidence for an active systemic infection. The ppUL83 Antigenemia appears earlier and is positive for a longer period than viremia as demonstrated by co-culture. It is also a clearly shorter procedure (results within 2 hours). It enables the diagnosis and follow up of HCMV disseminated infections in graft recipients and AIDS patients. Immunofluorescence is the only detection method recommended, although others can be used. However different studies show that any technique used to block endogenous enzymatic activity (peroxidase or alkaline phosphatase), also destroys a significant level of the ppUL83 antigen. No cross-reactivity with other Herpesviridae.

This blend has multiple advantages:
1/ This antibody pool labels different epitopes expressed in the nuclei of infected peripheral blood polymorphonuclear leukocytes and monocytes, and thus ensures avoiding false negatives that can theoretically be caused by mutation of one of the epitope recognized since a double mutation in two specific parts of the antigen is at very low risk.
2/ Improved reading even if the sample does not reach the laboratory under optimum conditions.
3/ This anti ppUL83 pool is also of interest since it stains a higher number of cells in positive samples when compared to a monoclonal alone.
Important: secondary antibodies other than the one recommended can give cytoplasmic background.
SEE ALSO CONTROL SLIDES page 39.

For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

Anti CMV pool I.E.A + E.A

USE FOR HCMV Antigen detection in 24-48 h culture from clinical specimens.

USE FOR HCMV Antigen detection by direct immunofluorescence slide test.

• anti HCMV I.E.A+E.A purified	Concentrated	0.5 ml (50x)	11-004

This pool of murine monoclonal antibodies improves the sensitivity of antigen detection in culture at 48 hours post infection and of direct immunofluorescence slide test in BAL. The first antibody recognizes an Immediate Early Antigen which can be detected 2 h post infection, the second antibody recognizes an Early Antigen which can be detected 12 hours post infection. Both antibodies give nuclear staining. No cross-reactivity with other Herpesviridae. Suitable for use in cultures from blood (Buffy coat), BAL, CSF, urine, amniotic fluid and in immunohistochemistry on lung, liver, kidney, colon, brain, nerves...
SEE ALSO CONTROL SLIDES page 39.

For research use only.

Anti CMV Immediate Early Antigen

USE FOR HCMV Antigen detection in 24-48 h culture from clinical specimens.

USE FOR HCMV Antigen detection on frozen or dewaxed tissue sections.

USE FOR HCMV in vitro sensitivity determination to antiviral drugs.

• anti HCMV I.E.A purified	-	Concentrated	0.5 ml (50x)	11-003

This murine monoclonal antibody recognizes the Immediate Early non structural proteins 52, 72 and 86 kDa. The common epitope labelled is encoded by exon 2 of the Major Immediate Early gene. This antigen appears 2 hours after cell infection, reaches the intensity peak at 48 hours and persists during the entire HCMV infection cycle. It gives a specific nuclear fluorescence. No cross-reactivity with HSV-1, HSV-2, VZV, EBV and ADV. Suitable for use in cultures from blood (Buffy coat), BAL, CSF, urine, amniotic fluid and in immunohistochemistry on lung, liver, kidney, colon, brain, nerve...
SEE ALSO CONTROL SLIDES page 39.

For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

Herpes Virus Antibodies Product Line

Anti HSV-1

USE FOR Infected cell culture detection.
USE FOR Research (Western blot, EIA, Immunofluorescence).

• anti HSV-1 purified	250 tests	7.5 mL	11-088

This murine monoclonal antibody reacts with HSV type 1 cytoplasmic protein. For use on infected cell culture. IF, EIA, and ELISA.
SEE ALSO CONTROL SLIDES page 39.
For research use only.

Anti HSV-2

USE FOR Infected cell culture detection.
USE FOR Research (Western blot, EIA, Immunofluorescence).

• anti HSV-2 purified	250 tests	7.5 mL	11-089

This murine monoclonal antibody is specific for HSV type 2. For use on infected cell culture.
SEE ALSO CONTROL SLIDES page 39.
For research use only.

Anti HSV-1+2 CE

USE FOR Rapid immunofluorescence detection on skin or mucous membrane.
USE FOR Infected cell culture detection (from vesicles or bronchoalveolar lavage).
USE FOR Research (EIA).

• anti HSV-1 + 2 purified	250 tests	7.5 mL	11-090
• anti HSV-1 + 2 FITC	250 tests	7.5 mL	12-090
• anti HSV-1 + 2 FITC	80 tests	2.5 mL	17-090

This murine monoclonal antibody recognizes a HSV type 1 and HSV type 2 common antigen (glycoprotein). It labels direct samples (skin biopsies, genital samples, vesicular or conjunctive rashes and broncho-alveolar lavages) with a very good sensitivity. It can be used also for early and rapid detection of Herpes infection after inoculation of cell culture.
SEE ALSO CONTROL SLIDES page 39.
For in vitro diagnostic use, CE marking in Europe - Please inquire.
USA: For research use only. Not for use in diagnostic procedures.

Herpes Virus Antibodies Product Line

Anti VZV

USE FOR Rapid immunofluorescence detection (on vesicular or conjunctive rash, skin biopsy).
USE FOR Infected cell culture detection (Early detection on MRC-5 cells).
USE FOR Research (Immunohistochemistry).

• anti VARICELLA ZOSTER VIRUS purified	650 tests	0.5 mL (40x)	11-017
• anti VARICELLA ZOSTER VIRUS FITC	80 tests	dropper bottle	17-017

This murine monoclonal antibody is specific for VZV GP63 and shows a nuclear staining in infected cells. No cross-reactivity with other Herpesviridae. In immunocompromised patients (AIDS, or graft recipients). Varicella Zoster Virus (VZV) and Herpes Simplex Virus (HSV) can be responsible for disseminated infections and vesicles which often are difficult to distinguish and are sometimes atypical. Since the antiviral treatment with Zovirax® is more efficient on HSV (10 to 20 times) than on VZV, it is useful to differenciate HSV from VZV.
SEE ALSO CONTROL SLIDES page 39.

For research use only.

Anti VZV

USE FOR Rapid immunofluorescence detection (on vesicular or conjunctive rash, skin biopsy).
USE FOR Infected cell culture detection (Early detection on MRC-5 cells).
USE FOR Research (Immunofluorescence, EIA).

• anti VARICELLA ZOSTER VIRUS purified	650 tests	0.5 mL (40x)	11-018

This murine monoclonal antibody is specific for VZV and shows a cytoplasmic and membrane staining. For early detection of VZV in MRC-5 cells infected with vesicular or conjunctive rash or skin biopsies.
SEE ALSO CONTROL SLIDES page 39.

For research use only.

Product List by Catalog Number

● 11-002	anti HCMV ppUL83 (pp65) CINApool purified	**p.35**	-	0.5 mL (20x)	330 tests
● 11-002G	Antibodies dilution buffer for CINApool 11-002	**p.31**	-	4.5 mL	1x
● 11-002I	Evans blue 1% for CINApool 11-002	**p.31**	-	250 µL	-
● 11-003	anti HCMV I.E.A purified	**p.35**	-	0.5 mL (50x)	Concentrated
11-004	anti HCMV I.E.A+E.A purified	**p.35**	-	0.5 mL (50x)	Concentrated
11-017	anti VARICELLA ZOSTER VIRUS purified	**p.37**	-	0.5 mL (40x)	650 tests
11-018	anti VARICELLA ZOSTER VIRUS purified	**p.37**	-	0.5 mL (40x)	650 tests
● 11-020	anti ADENOVIRUS GROUP purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-030	anti INFLUENZA A GROUP purified	**p.33**	-	0.5 mL (40x)	650 tests
11-033	anti HAV purified		-	250 µg / 0.5 mL	Concentrated
11-034	anti HAV purified		-	250 µg / 0.5 mL	Concentrated
● 11-035	anti INFLUENZA B GROUP purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-036	anti PARAINFLUENZA 1 purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-037	anti PARAINFLUENZA 2 purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-038	anti PARAINFLUENZA 3 purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-040	anti PARAINFLUENZA GROUP purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-042	anti RSV GROUP purified	**p.33**	-	0.5 mL (40x)	650 tests
● 11-045	anti MEASLES purified		-	0.5 mL (40x)	650 tests
11-046	anti MUMPS purified		-	0.5 mL (40x)	650 tests
11-088	anti HSV-1 purified	**p.36**	-	7.5 mL	250 tests
11-089	anti HSV-2 purified	**p.36**	-	7.5 mL	250 tests
● 11-090	anti HSV-1 + 2 purified	**p.36**	-	7.5 mL	250 tests
● 11-091	anti ADENO., INFLU., PARA. purified	**p.33**	-	0.5 mL (40x)	650 tests
● 12-020	anti ADENOVIRUS GROUP FITC	**p.33**	-	0.5 mL (40x)	650 tests
● 12-030	anti INFLUENZA A GROUP FITC	**p.33**	-	0.5 mL (40x)	650 tests
● 12-035	anti INFLUENZA B GROUP FITC	**p.33**	-	0.5 mL (40x)	650 tests
● 12-038	anti PARAINFLUENZA 3 FITC	**p.33**	-	0.5 mL (40x)	650 tests
● 12-040	anti PARAINFLUENZA GROUP FITC	**p.33**	-	1 mL (20x)	650 tests
● 12-042	anti RSV GROUP FITC	**p.33**	-	0.5 mL (40x)	650 tests
● 12-090	anti HSV-1 + 2 FITC	**p.36**	-	7.5 mL	250 tests
● 14-002	anti HCMV ppUL83 (pp65) CINApool & Secondary F(ab')2 FITC	**p.35**	-	0.5 mL (20x)	330 tests
17-017	anti VARICELLA ZOSTER VIRUS FITC	**p.37**	-	dropper bottle	80 tests
● 17-020	anti ADENOVIRUS GROUP FITC	**p.32**	-	dropper bottle	80 tests
● 17-030	anti INFLUENZA A GROUP FITC	**p.32**	-	dropper bottle	80 tests
● 17-035	anti INFLUENZA B GROUP FITC	**p.32**	-	dropper bottle	80 tests
● 17-036	anti PARAINFLUENZA 1 FITC	**p.33**	-	dropper bottle	80 tests
● 17-037	anti PARAINFLUENZA 2 FITC	**p.33**	-	dropper bottle	80 tests
● 17-038	anti PARAINFLUENZA 3 FITC	**p.32**	-	dropper bottle	80 tests
● 17-040	anti PARAINFLUENZA GROUP FITC	**p.33**	-	dropper bottle	80 tests
● 17-042	anti RSV GROUP FITC	**p.32**	-	dropper bottle	80 tests
● 17-090	anti HSV-1 + 2 FITC	**p.36**	-	2.5 mL	80 tests
● 17-091	anti ADENO., INFLU., PARA. FITC	**p.33**	-	dropper botttle	80 tests
● 17-092	anti ADENO., INFLU., PARA., RSV FITC	**p.33**	-	dropper bottle	80 tests
● 17-270	anti human METAPNEUMOVIRUS FITC	**p.32**	-	dropper bottle	80 tests
● **19-002**	**CINAkit - Complete kit** HCMV ppUL83 (pp65) I.F. Antigenemia		**p.30**	**-**	**100 tests**

● = CE marking in Europe

Product List by Catalog Number

●	**19-0028**	**CINAkit - Complete kit** HCMV ppUL83 (pp65) I.F. Antigenemia		**p.30**	**-**	**200 tests**
	19-0028US	CINAkit Complete kit HCMV ppUL83(pp65) I.F. Antigenemia				200tests
●	19-002B	Rapid lysis solution for CINAkit 19-002	**p.31**	-	45 mL	20x
●	19-002C	Fixative solution for CINAkit 19-002	**p.31**	-	110 mL	5x
●	19-002E	Permeabilization solution for CINAkit 19-002	**p.31**	-	110 mL	5x
●	19-002J	Mounting medium for CINAkit 19-002	**p.31**	-	4 mL	-
●	19-002K	Dextran 6% for CINAkit 19-002	**p.31**	-	60 mL	1x
	31-010	IF slides - Teflon coated - 6 mm wells		10 wells	100 slides	-
	31-030	"Kova glasstic slides" for antigenemia		10 wells	100 slides	-
●	33-011	PBS pH: 7.2 without Ca2+ and Mg2+	**p.31**	Powder	4 x 1 liter	-
●	33-030	Evans blue 1%		Liquid	2 mL	-
●	33-041	Mounting medium for immunofluorescence	**p.33**	Liquid	dropper bottle	15 mL
	40-017	Control slide HERPES SIMPLEX TYPE 1 & 2		VR733/VR734	5 Slides	2+ / 2-
	40-022	Control slide CYTOMEGALOVIRUS IEA-EA	**p.31**	Specimen	5 Slides	2+ / 2-
	40-041	Control slide VARICELLA - ZOSTER		Specimen	5 Slides	2+ / 2-
	40-061	Control slide ADENOVIRUS	**p.33**	CDC V5-002	5 Slides	2+ / 2-
	40-071	Control slide INFLUENZA A		CDC V7-002	5 Slides	2+ / 2-
	40-081	Control slide INFLUENZA B		CDC V4-004	5 Slides	2+ / 2-
	40-091	Control slide PARAINFLUENZA 1		CDC V6-004	5 Slides	2+ / 2-
	40-101-1	Control slide PARAINFLUENZA 2		CDC V7-003	5 Slides	2+ / 2-
	40-111	Control slide PARAINFLUENZA 3	**p.33**	CDC V5-003	5 Slides	2+ / 2-
	40-121	Control slide RSV	**p.33**	Specimen	5 Slides	2+ / 2-
	40-161	Control slide PANEL ADV,IA,IB,VRS,P1,P2,P3	**p.33**	Idem	5 Slides	7+ / 7-
●	50-010	anti MOUSE IgG+IgM "human ads." FITC		Polyclonal	0.5 mL	Liquid
●	50-011	anti MOUSE IgG+IgM "human ads." FITC		Polyclonal	1 mL	Liquid
●	50-012	anti MOUSE IgG+IgM "human ads." FITC		Polyclonal	2 mL	Liquid
	50-021	anti MOUSE IgG+IgM "human ads." PEROXIDASE		Polyclonal	1 mL	Liquid
	50-022	anti MOUSE IgG+IgM "human ads." PEROXIDASE		Polyclonal	2 mL	Liquid
●	51-010	F(ab')2 anti MOUSE IgG+IgM "human ads." FITC		Polyclonal	0.5 mL	Liquid
●	51-011	F(ab')2 anti MOUSE IgG+IgM "human ads." FITC		Polyclonal	1 mL	Liquid
	65-001	UNG r-gene™		500 tests	-	-
●	**67-012**	**HYBRIDOWELL™ Universal - Complete kit**		**p.21**	**96 tests**	
●	**67-025**	**CHLAMYLEGE - Complete kit**		**p.27**	**50 samples**	
●	**67-025BC**	**CHLAMYLEGE - Amplification / Detection**		**p.27**	**50 samples**	
●	**67-050**	**HYBRIDOWELL™ HERPES Identification (for 67-090)**		**p.23**	**96 tests**	
●	**67-065**	**ADENOVIRUS CONSENSUS - Complete kit**		**p.26**	**50 samples**	
●	**67-065BC**	**ADENOVIRUS CONSENSUS - Amplification / Detection**		**p.26**	**50 samples**	
●	**67-080BC**	**ENTEROVIRUS CONSENSUS - Amplification / Detection**		**p.24**	**50 samples**	
●	**67-090**	**HERPES CONSENSUS GENERIC - Complete kit**		**p.22**	**50 samples**	
●	**67-090BC**	**HERPES CONSENSUS GENERIC - Amplification / Detection**		**p.22**	**50 samples**	
●	**67-130**	**JC / BK CONSENSUS - Complete kit**		**p.25**	**30 samples**	
●	**67-130BC**	**JC / BK CONSENSUS - Amplification / Detection**		**p.25**	**30 samples**	
	68-006	Quanti FluA r-gene™		**p.15**	30 reactions	-
	68-008	Quanti HHV8 QS r-gene™		**p.17**	30 reactions	-
	68-009	Bocavirus r-gene™ Positive control		**p.17**	10 reactions	100 µL

● *= CE marking in Europe*

Product List by Catalog Number

68-020	CMV Clear QC Panel	3 vials	3 x 1 mL	Freeze dried
● 69-002	**EBV R-gene™ - Quantification Complete kit**	**p.7**	**90 tests**	
● 69-002B	**EBV R-gene™ - Quantification kit**	**p.7**	**90 tests**	
● 69-003	**CMV R-gene™ - Quantification Complete kit**	**p.5**	**90 tests**	
● 69-003B	**CMV R-gene™ - Quantification kit**	**p.5**	**90 tests**	
● 69-004	**HSV1 HSV2 VZV R-gene™ - Quantification Complete kit**	**p.8**	**180 tests**	
● 69-004B	**HSV1 HSV2 VZV R-gene™ - Quantification kit**	**p.8**	**180 tests**	
● 69-005	**ENTEROVIRUS R-gene™ - Real-Time PCR Complete kit**	**p.12**	**90 tests**	
● 69-005B	**ENTEROVIRUS R-gene™ - Real-Time PCR kit**	**p.12**	**90 tests**	
● 69-010	**ADENOVIRUS R-gene™ - Quantification Complete kit**	**p.6**	**90 tests**	
● 69-010B	**ADENOVIRUS R-gene™ - Quantification kit**	**p.6**	**90 tests**	
● 69-011	***BORDETELLA* R-gene™ - Real-Time PCR Complete kit**	**p.13**	**60 tests**	
● 69-011B	***BORDETELLA* R-gene™ - Real-Time PCR kit**	**p.13**	**60 tests**	
● 69-013	**BK Virus R-gene™ - Quantification Complete kit**	**p.10**	**90 tests**	
● 69-013B	**BK Virus R-gene™ - Quantification kit**	**p.10**	**90 tests**	
● 69-100	**CMV HHV6,7,8 R-gene™ - Quantification Complete kit**	**p.4**	**140 tests**	
● 69-100B	**CMV HHV6,7,8 R-gene™ - Quantification kit**	**p.4**	**140 tests**	
69-100R6	**HHV6 amplification premix**		**60 tests**	
69-100R7	**HHV7 amplification premix**		**20 tests**	
69-100R8	**HHV8 amplificatio premix**		**20 tests**	
71-001	Chlamydophila pneumoniae r-gene™ Primers/Probe		60 reactions	2 x 450 µL
71-002	Mycoplasma pneumoniae r-gene™ Primers/Probe		60 reactions	2 x 450 µL
71-003	Legionella species r-gene™Primers/Probes		60 reactions	2 x 450 µL
71-004	JC Virus r-gene™ Primers/Probe	**p.11**	60 reactions	2 x 450 µL
71-005	BK Virus r-gene™ Primers/Probe	**p.11**	60 reactions	2 x 450 µL
71-006	FLU A/B r-gene™ Primers/Probes	**p.15**	60 reactions	2 x 450 µL
71-007	RSV A/B r-gene™ Primers/Probes	**p.14**	60 reactions	2 x 450 µL
71-008	hMPV A/B r-gene™ Primers/Probes	**p.14**	60 reactions	2 x 450 µL
71-009	Bocavirus r-gene™ Primers/Probe	**p.14**	60 reactions	2 x 450 µL
71-010	Adenovirus r-gene™ Primers/Probes	**p.11**	60 reactions	2 x 450 µL
● 71-012	***Bordetella parapertussis* r-gene™**	**p.14**	**60 reactions**	**2 x 450 µL**
● 71-015	**HSV1 r-gene™**	**p.9**	**60 reactions**	**2 x 450 µL**
● 71-016	**HSV2 r-gene™**	**p.9**	**60 reactions**	**2 x 450 µL**
● 71-017	**VZV r-gene™**	**p.9**	**60 reactions**	**2 x 450 µL**
● 71-020	**Parechovirus r-gene™**	**p.11**	**60 tests**	
● 71-040	**Influenza A/B r-gene™**	**p.19**	**60 tests**	
● 71-041	**RSV/hMPV r-gene™**	**p.19**	**60 tests**	
● 71-042	**Rhino&EV/Cc r-gene™**	**p.19**	**60 tests**	
● 71-043	**AdV/hBoV r-gene™**	**p.19**	**60 tests**	
● 71-044	**Chlamydophila/Mycoplasma p. r-gene™**	**p.19**	**60 tests**	
● 71-045	**HCoV/PIV r-gene™**	**p.19**	**60 tests**	
71-100	**DICO Ampli r-gene™**	**p.16**	**100 reactions**	**2 x 750 µL**
71-101	**DICO Extra r-gene™**	**p.16**	**100 reactions**	-
71-103	**COLOUR COMPENSATION r-gene™**	**p.16**	**2 calibration runs**	**3 x 60 µL**
71-105	**RICO Extra r-gene™**	**p.16**	**100 reactions**	-

● = *CE marking in Europe*

Product List by Catalog Number

● 71-106	CELL Control r-gene™	p.15	100 reactions	2 x 750 µL
● 71-300	*Influenza* A(M) Group & H1N1 2009 r-gene™	p.15	60 tests	2 x 450 µL

● = CE marking in Europe

Alphabetical Index

● = CE marking in Europe

Alphabetical Index

● *= CE marking in Europe*

Alphabetical Index

● = *CE marking in Europe*

Alphabetical Index

● *= CE marking in Europe*

NOTES

NOTES

Photographer: Marc Mesplié

ARGENE S.A.
09340 Verniolle
France
Tel: +33 (0)5 61 69 61 00
Fax: +33 (0)5 61 69 61 01

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
www.argene.com
www.biomerieux-diagnostics. com/argene

BIOMÉRIEUX