

# ELISA Solution as an aid in the Diagnosis of COVID-19

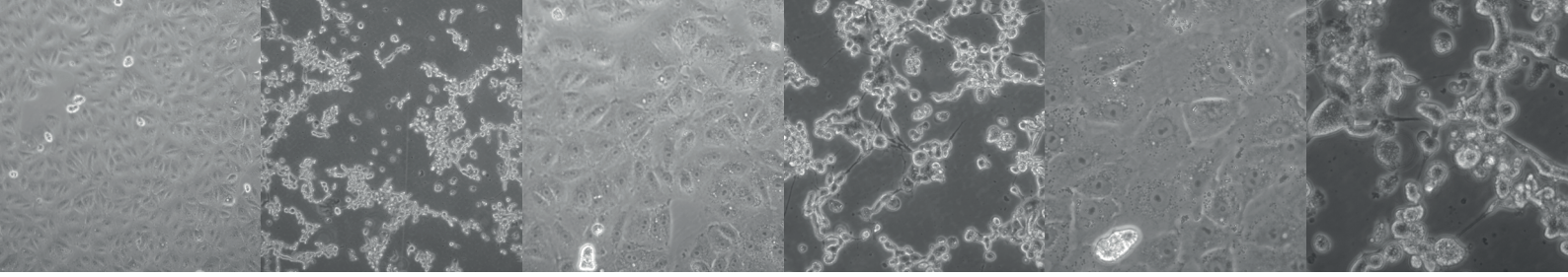
Enzyme-linked immunosorbent assays (ELISA) to detect antibodies against SARS-CoV-2, producing COVID-19, in human serum or plasma.

## COVID-19 ELISA IgM+IgA COVID-19 ELISA IgG

### PRODUCT FEATURES

- Suitable for all automated ELISA systems.
- SARS-CoV-2 specific antigens: spike glycoprotein (S) and nucleocapsid protein (N).
- Excellent performance in samples characterized by PCR.
- Complete solution IgG and IgM+IgA kits available.
- Common protocol allows to perform IgG and IgM+IgA simultaneously in the same run.
- Ready-to-use reagents.





VERO 24H 10X

COVID 48H 10X

VERO 24H 20X

COVID 48H 20X

VERO 24H 40X

COVID 48H 40X

SARS-CoV-2. Vircell culture collection

COVID-19 serology allows confirmation of infection in both symptomatic and asymptomatic patients. ELISA is a simple and easy to automate technique that allows high throughput tests at low cost.

**IgM+IgA detection complements molecular tests** when the viral load decreases or when false negatives are suspected due to unsuitable samples in patients with clear symptoms.

**The combination of IgM+IgA significantly improves sensitivity** since COVID-19 affects the mucous membrane. The early production of IgA antibodies in this kind of infections could be particularly high.

**IgG detection allows disease monitoring** when other molecular and serological markers become negative.

## Excellent performance in samples characterized by PCR\*

### Sensitivity

#### COVID-19 ELISA IgM+IgA

88% in patients, 5 days after a positive PCR result (n=32)

#### COVID-19 ELISA IgG

85% in patients, 10-19 days after a positive PCR result (n=124)

### Specificity

99% in samples from healthy pre-pandemic donors (n=669)

98% in samples from healthy pre-pandemic donors (n=286)

\* Data from internal evaluations

PM100-06/20

## Ordering information and related products

Reference	Description	Kit contents
<b>G1032</b>	<b>COVID-19 ELISA IgG</b>	<b>96 tests</b>
<b>MA1032</b>	<b>COVID-19 ELISA IgM+IgA</b>	<b>96 tests</b>
VCM097	COVID-19 VIRCLIA IgG MONOTEST	24 tests
VCM098	COVID-19 VIRCLIA IgM+IgA MONOTEST	24 tests
RTPCR001	SARS-COV-2 REALTIME PCR KIT	48 tests
MBTC030-R	AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)	10 vials
MBC137-R	AMPLIRUN® SARS-CoV-2 RNA CONTROL	12,500-20,000 copies/μl

# ELISA KITS

## For antibody detection of infectious diseases

With more than 20 years of experience, Vircell offers ELISA kits for detecting specific antibodies against Herpes virus, TORCH and a wide range of infectious agents causing respiratory diseases and sexually transmitted diseases, among others, in human serum/plasma samples.

### MAIN BENEFITS

- Ready-to-use reagents.
- No sample predilution required.
- Colour-coded plates with individual break-apart wells.
- Semiquantitative protocols available for some parameters.
- $\mu$ -Capture technique for TORCH, Dengue and Parvovirus IgM determinations.
- G/M kits allow for customized testing of IgG and/or IgM.

### A SOLUTION FOR ALL

- Bacterial Respiratory Infections
- Viral Respiratory Infections
- TORCH Infections
- Vaccine-preventable Infections
- Vector-borne Infections
- Sexually Transmitted Infections
- Zoonotic Infections

### OTHER THINGS THAT MATTER

- Suitable for all automated ELISA systems.
- In-house production of high-quality antigens.
- Featured in more than 120 scientific publications.
- Vircell takes part in External Quality Control Programs.



# ELISA KITS FOR A WIDE RANGE OF INFECTIOUS DISEASES

## BACTERIAL RESPIRATORY INFECTIONS

<b>G/M1003</b>	CHLAMYDIA ELISA IgG/IgM
<b>A1007</b>	CHLAMYDOPHILA PNEUMONIAE ELISA IgA
<b>G1007</b>	CHLAMYDOPHILA PNEUMONIAE ELISA IgG (incl. calibrators)
<b>M1007</b>	CHLAMYDOPHILA PNEUMONIAE ELISA IgM
<b>G1001</b>	COXIELLA BURNETII ELISA IgG
<b>M1001</b>	COXIELLA BURNETII ELISA IgM
<b>G1000</b>	LEGIONELLA PNEUMOPHILA SG 1 ELISA IgG
<b>M1000</b>	LEGIONELLA PNEUMOPHILA SG 1 ELISA IgM
<b>T1001</b>	LEGIONELLA PNEUMOPHILA SG 1-6 ELISA IgG+IgM
<b>G1002</b>	MYCOPLASMA PNEUMONIAE ELISA IgG
<b>G/M1015</b>	MYCOPLASMA PNEUMONIAE ELISA IgG/IgM
<b>M1002</b>	MYCOPLASMA PNEUMONIAE ELISA IgM
<b>M1040</b>	PNEUMOBACT ELISA IgM <i>L. pneumophila</i> sg 1, <i>M. pneumoniae</i> , <i>C. burnetii</i> and <i>C. pneumoniae</i>

## VIRAL RESPIRATORY INFECTIONS

<b>G/M1004</b>	ADENOVIRUS ELISA IgG/IgM
<b>G/M1007</b>	INFLUENZA A ELISA IgG/IgM
<b>G/M1008</b>	INFLUENZA B ELISA IgG/IgM
<b>G/M1009</b>	PARAINFLUENZA 1 ELISA IgG/IgM
<b>G/M1010</b>	PARAINFLUENZA 2 ELISA IgG/IgM
<b>G/M1011</b>	PARAINFLUENZA 3 ELISA IgG/IgM
<b>G/M1006</b>	RESPIRATORY SYNCYTIAL VIRUS ELISA IgG/IgM

## TORCH INFECTIONS

<b>G1004</b>	CYTOMEGALOVIRUS ELISA IgG (includes calibrators)
<b>M1004</b>	CYTOMEGALOVIRUS ELISA IgM CAPTURE
<b>G/M1012</b>	HERPES SIMPLEX 1 ELISA IgG/IgM (gG1 recombinant)
<b>G/M1016</b>	HERPES SIMPLEX 1+2 ELISA IgG/IgM
<b>G/M1013</b>	HERPES SIMPLEX 2 ELISA IgG/IgM (gG2 purified)
<b>G1026</b>	RUBELLA ELISA IgG (includes calibrators)
<b>M1026</b>	RUBELLA ELISA IgM CAPTURE
<b>G1027</b>	TOXOPLASMA ELISA IgG (includes calibrators)
<b>M1027</b>	TOXOPLASMA ELISA IgM CAPTURE

## VACCINE-PREVENTABLE INFECTIONS

<b>G/M1001</b>	MEASLES ELISA IgG/IgM
<b>G/M1014</b>	MUMPS ELISA IgG/IgM
<b>G1008</b>	TETANUS ELISA IgG (includes calibrators)
<b>G/M1002</b>	VARICELLA-ZOSTER ELISA IgG/IgM

## VECTOR-BORNE INFECTIONS

<b>T1020</b>	CHAGAS ELISA IgG+IgM
<b>G1010</b>	CHIKUNGUNYA ELISA IgG
<b>M1010</b>	CHIKUNGUNYA ELISA IgM
<b>G1018</b>	DENGUE ELISA IgG
<b>M1018</b>	DENGUE ELISA IgM CAPTURE
<b>T1000</b>	LEISHMANIA ELISA IgG+IgM
<b>G/M1005</b>	RICKETTSIA CONORII ELISA IgG/IgM
<b>G1011</b>	ROSS RIVER VIRUS ELISA IgG
<b>M1011</b>	ROSS RIVER VIRUS ELISA IgM
<b>G1023</b>	ZIKA ELISA IgG
<b>M1023</b>	ZIKA ELISA IgM

## SEXUALLY TRANSMITTED INFECTIONS

<b>A1017</b>	CHLAMYDIA TRACHOMATIS ELISA IgA
<b>G/M1017</b>	CHLAMYDIA TRACHOMATIS ELISA IgG/IgM
<b>G1060</b>	SYPHILIS ELISA IgG
<b>T1060</b>	SYPHILIS ELISA IgG+IgM

## ZOONOTIC INFECTIONS

<b>G1003</b>	BRUCELLA ELISA IgG
<b>M1006</b>	BRUCELLA ELISA IgM
<b>G1006</b>	HYDATIDOSIS ELISA IgG

## OTHER INFECTIONS

<b>G1205</b>	EPSTEIN-BARR EA ELISA IgG
<b>G1105</b>	EPSTEIN-BARR EBNA ELISA IgG
<b>G1005</b>	EPSTEIN-BARR VCA ELISA IgG
<b>M1005</b>	EPSTEIN-BARR VCA ELISA IgM
<b>A1022</b>	HELICOBACTER PYLORI ELISA IgA (incl. calibrators)
<b>G1022</b>	HELICOBACTER PYLORI ELISA IgG (incl. calibrators)
<b>M1003</b>	LEPTOSPIRA ELISA IgM
<b>G1031</b>	PARVOVIRUS ELISA IgG
<b>M1031</b>	PARVOVIRUS ELISA IgM CAPTURE

## OTHER ELISA PRODUCTS

<b>S001</b>	ELISA SORBENT (2 x 1.2 ml)
<b>S001-100</b>	ELISA SORBENT (100 ml)
<b>B003</b>	SERUM DILUENT FOR ELISA KITS (500 ml)
<b>B001</b>	WASH BUFFER FOR ELISA KITS (500 ml 20x)

### Vircell, S.L.

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# WIDEST PANEL FOR INFECTIOUS SEROLOGY



## BACTERIAL RESPIRATORY INFECTIONS

- VCM092** BORDETELLA PERTUSSIS TOXIN VIRCLIA® IgG MONOTEST (quant.)
- VCM016** CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgA MONOTEST
- VCM017** CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgG MONOTEST
- VCM018** CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgM MONOTEST
- VCM019** COXIELLA BURNETII VIRCLIA® IgG MONOTEST
- VCM020** COXIELLA BURNETII VIRCLIA® IgM MONOTEST
- VCM049** LEGIONELLA PNEUMOPHILA SG 1 VIRCLIA® IgG MONOTEST
- VCM050** LEGIONELLA PNEUMOPHILA SG 1 VIRCLIA® IgM MONOTEST
- VCM052** LEGIONELLA PNEUMOPHILA SG 1-6 VIRCLIA® IgG+IgM MONOTEST
- VCM062** MYCOPLASMA PNEUMONIAE VIRCLIA® IgG MONOTEST
- VCM064** MYCOPLASMA PNEUMONIAE VIRCLIA® IgM MONOTEST



## VIRAL RESPIRATORY INFECTIONS

- VCM002** ADENOVIRUS VIRCLIA® IgG MONOTEST
- VCM042** INFLUENZA A VIRCLIA® IgG MONOTEST
- VCM045** INFLUENZA B VIRCLIA® IgG MONOTEST
- VCM065** PARAINFLUENZA 1 VIRCLIA® IgG MONOTEST
- VCM068** PARAINFLUENZA 2 VIRCLIA® IgG MONOTEST
- VCM071** PARAINFLUENZA 3 VIRCLIA® IgG MONOTEST
- VCM077** RESPIRATORY SYNCYTIAL VIRUS VIRCLIA® IgG MONOTEST



## VACCINE-PREVENTABLE INFECTIONS

- VCM006** DIPHTHERIA VIRCLIA® IgG MONOTEST (quant.)
- VCM054** MEASLES VIRCLIA® IgG MONOTEST
- VCM057** MEASLES VIRCLIA® IgM MONOTEST
- VCM060** MUMPS VIRCLIA® IgG MONOTEST
- VCM061** MUMPS VIRCLIA® IgM MONOTEST
- VCM004** TETANUS VIRCLIA® IgG MONOTEST (quant.)
- VCM089** VARICELLA-ZOSTER VIRCLIA® IgG MONOTEST
- VCM091** VARICELLA-ZOSTER VIRCLIA® IgM MONOTEST



## VECTOR-BORNE INFECTIONS

- VCM009** BORRELIA VIRCLIA® IgG MONOTEST
- VCM010** BORRELIA VIRCLIA® IgM MONOTEST
- VCM008** CHAGAS VIRCLIA® IgG+IgM MONOTEST
- VCM059** CHIKUNGUNYA VIRCLIA® IgG MONOTEST
- VCM063** CHIKUNGUNYA VIRCLIA® IgM MONOTEST
- VCM023** DENGUE VIRCLIA® IgG MONOTEST
- VCM024** DENGUE VIRCLIA® IgM MONOTEST (capture)
- VCM053** LEISHMANIA VIRCLIA® IgG+IgM MONOTEST
- VCM080** RICKETTSIA CONORII VIRCLIA® IgG MONOTEST
- VCM082** RICKETTSIA CONORII VIRCLIA® IgM MONOTEST
- VCM069** ROSS RIVER VIRUS VIRCLIA® IgG MONOTEST
- VCM070** ROSS RIVER VIRUS VIRCLIA® IgM MONOTEST
- VCM047** TICK-BORNE ENCEPHALITIS VIRCLIA® IgG MONOTEST
- VCM048** TICK-BORNE ENCEPHALITIS VIRCLIA® IgM MONOTEST
- VCM078** WEST NILE VIRUS VIRCLIA® IgG MONOTEST\*
- VCM079** WEST NILE VIRUS VIRCLIA® IgM MONOTEST\*
- VCM033** ZIKA VIRCLIA® IgG MONOTEST
- VCM035** ZIKA VIRCLIA® IgM MONOTEST



## FUNGAL INFECTIONS

- VCM073** ASPERGILLUS GALACTOMANNAN Ag VIRCLIA® MONOTEST\*
- VCM094** INVASIVE CANDIDIASIS (CAGTA) VIRCLIA® IgG MONOTEST



## SEXUALLY TRANSMITTED INFECTIONS

- VCM012** CHLAMYDIA TRACHOMATIS VIRCLIA® IgA MONOTEST
- VCM013** CHLAMYDIA TRACHOMATIS VIRCLIA® IgG MONOTEST
- VCM015** CHLAMYDIA TRACHOMATIS VIRCLIA® IgM MONOTEST
- VCM085** SYPHILIS VIRCLIA® IgG MONOTEST
- VCM086** SYPHILIS VIRCLIA® IgG+IgM MONOTEST
- VCM032** SYPHILIS VIRCLIA® IgM MONOTEST



## TORCH INFECTIONS

- VCM038** CYTOMEGALOVIRUS VIRCLIA® IgG AVIDITY MONOTEST
- VCM021** CYTOMEGALOVIRUS VIRCLIA® IgG MONOTEST
- VCM022** CYTOMEGALOVIRUS VIRCLIA® IgM MONOTEST (capture)
- VCM031** HERPES SIMPLEX 1 VIRCLIA® IgG MONOTEST
- VCM039** HERPES SIMPLEX 1 VIRCLIA® IgM MONOTEST
- VCM034** HERPES SIMPLEX 1+2 VIRCLIA® IgG MONOTEST
- VCM036** HERPES SIMPLEX 1+2 VIRCLIA® IgM MONOTEST
- VCM037** HERPES SIMPLEX 2 VIRCLIA® IgG MONOTEST
- VCM041** HERPES SIMPLEX 2 VIRCLIA® IgM MONOTEST
- VCM083** RUBELLA VIRCLIA® IgG MONOTEST
- VCM084** RUBELLA VIRCLIA® IgM MONOTEST (capture)
- VCM025** TOXOPLASMA VIRCLIA® IgG AVIDITY MONOTEST
- VCM087** TOXOPLASMA VIRCLIA® IgG MONOTEST
- VCM088** TOXOPLASMA VIRCLIA® IgM MONOTEST (capture)



## ZOONOTIC INFECTIONS

- VCM046** BARTONELLA HENSELAE VIRCLIA® IgG MONOTEST
- VCM043** BARTONELLA HENSELAE VIRCLIA® IgM MONOTEST
- VCM005** BRUCELLA VIRCLIA® IgG MONOTEST
- VCM007** BRUCELLA VIRCLIA® IgM MONOTEST
- VCM040** HYDATIDOSIS VIRCLIA® IgG MONOTEST
- VCM011** TULAREMIA VIRCLIA® IgG+IgM



## OTHER INFECTIONS

- VCM026** EPSTEIN-BARR EBNA VIRCLIA® IgG MONOTEST
- VCM027** EPSTEIN-BARR VCA VIRCLIA® IgG MONOTEST
- VCM028** EPSTEIN-BARR VCA VIRCLIA® IgM MONOTEST
- VCM029** HELICOBACTER PYLORI VIRCLIA® IgA MONOTEST
- VCM030** HELICOBACTER PYLORI VIRCLIA® IgG MONOTEST
- VCM066** HEPATITIS E VIRCLIA® IgG MONOTEST
- VCM067** HEPATITIS E VIRCLIA® IgM MONOTEST (capture)
- VCM003** HHV-6 VIRCLIA® IgG MONOTEST
- VCM072** HHV-6 VIRCLIA® IgM MONOTEST\*
- VCM001** INFECTIOUS MONONUCLEOSIS HETEROPHILE VIRCLIA® IgM MONOTEST
- VCM014** LEPTOSPIRA VIRCLIA® IgM MONOTEST
- VCM075** PARVOVIRUS VIRCLIA® IgG MONOTEST
- VCM076** PARVOVIRUS VIRCLIA® IgM MONOTEST (capture)

\* Available soon

**VirClia**<sup>®</sup>  
monotest

## VirClia<sup>®</sup> Monotest

The first fully automated, self-contained monotest, multiparameter CLIA system



**vircell**  
MICROBIOLOGISTS

# VIRCLIA® THE TRUE MONOTEST CONCEPT

Unique, complete, transparent

## VIRCLIA®, THE MOST COMPLETE SOLUTION FOR ALL YOUR INFECTIOUS SEROLOGY

With more than 80 products available, VirClia® is the ideal technique to analyze high-volume parameters, as well as esoteric and low volume tests.

**CLIA automated technology:** Excellent sensitivity and turnaround time

**Monotest format:** All reagents are included and ready to use

**Extensive menu:** Widest panel for infectious serology

**Labour-saving:** Allows pipetting from primary sample tubes

**Cost effective:** No extra consumption of reagents required

**LIS Connectivity:** Host-Query, Data Retrieval, Levey-Jennings

## VIRCLIA® IMPROVES YOUR LABORATORY WORKFLOW

VirClia® represents an innovative solution that can help you optimize your workflows, while guaranteeing security and peace of mind in your results.

1 monotest = 1 Reportable test

Multiparameter = Allows to run any number of different parameters simultaneously

Quality control per strip = Every monotest includes a calibrator for internal validation

Results on the same day = No need to accumulate samples

In-house testing = Stop send away tests



## VIRCLIA® IMPROVES EFFICIENCY IN PATIENT CARE

A patient-centered solution leads to better quality care.

Response time optimization



Obtain results on the same day



More laboratory testing required



Better patient care

# AUTOMATED SOLUTIONS

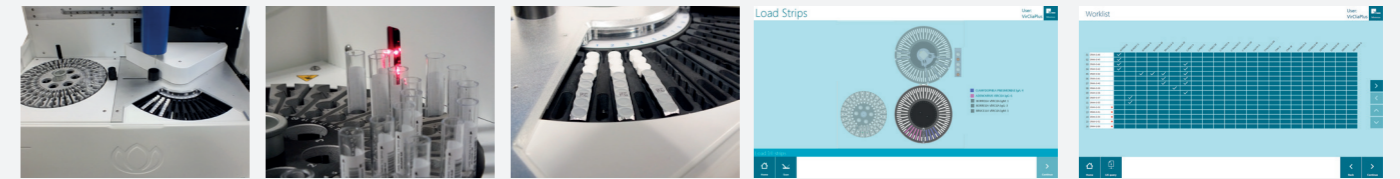
Adapted to your needs



## VIRCLIA® LOTUS SYSTEM

Cat. No. VLTS-CL

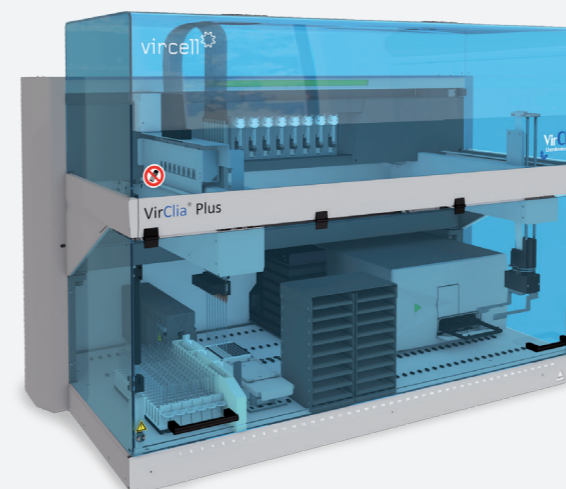
- Method: Chemiluminescence immunoassay
- Operation mode: Random access with continuous loading
- Strip loading capacity: 39 in loading rotor and 40 in reaction rotor
- Speed: First results in 1 h, 40 tests in 1 h 25 min, 80 tests in 2 h 30 min
- Sample tubes: Primary, 12, 13 and 16 mm diameter
- Built-in scanner: Positive identification of samples and strips
- Sample loading capacity: 50 Primary, 50 dilution tubes and 6 bottles of diluent
- Multiparameter: Full compatibility of all VirClia assays
- Dimensions: W 75 cm x D 74 cm x H 65 cm



## VIRCLIA® SYSTEM

Cat. No. TB00300-CL

- Method: EIA + CLIA Immunoassay
- Operation mode: Random access
- Strip loading capacity: 24 monotests
- Speed: 1 test in 50 min, 24 tests in 2 h
- Sample loading capacity: 192 primary sample tubes
- Intelligent racks: Automatic sample location management
- On-board camera: Probe-mounted camera allows remote troubleshooting
- Dimensions: W 64 cm x D 57 cm x H 45 cm



## VIRCLIA® PLUS SYSTEM

Cat. No. VCPLUS-CL

- Method: Chemiluminescence immunoassay
- Operation mode: Random access
- Strip loading capacity: 216 monotests
- Speed: 96 Tests in 3 h; 144 tests in 4 h 30 min
- Sample loading capacity: 6 Sample racks for 96 primary sample tubes
- 8-channel pipetting arm
- Incubator: 6 Slots
- Washable stainless tips
- Dimensions: W 145 cm x D 78 cm x H 112 cm

# AMPLIRUN®

Certify the efficiency,  
quality and reliability  
of your **COVID-19**  
molecular tests

## AMPLIRUN® SARS-CoV-2 RNA CONTROL

First complete genome RNA control for SARS-CoV-2

- Allows validation of RT-PCR assays for COVID-19 diagnosis.
- Purified nucleic acid, complete microbial genome.
- Any target can be amplified.
- RNA origin from a cultivated Spanish clinical isolate. Full sequence available.
- Precise concentration in copies/µl verified by Digital Droplet PCR (ddPCR).
- Non-infectious material provided with inactivation certificate.
- Lyophilized presentation ensures stability and reduces transport costs.
- Valid for any molecular testing platform.



**RUO**

vircell   
MICROBIOLOGISTS



## TAKE CONTROL, MOLECULAR CONTROL

AmpliRun® Amplification Controls catalog has more than 120 products and has been developed to allow the amplification and testing of any region of the genome which is present in natural infections.

### CUSTOM SOLUTIONS

The Vircell R&D team has the experience and capacity to design, develop, and deliver customized biological controls for all kind of instruments and assays. Our company can produce variations of the existing products in terms of concentration or purification requirements, or customize entire new panels to meet your unique needs.

## AMPLIRUN® SARS-CoV-2 RNA CONTROL Ref. MBC137-R

Complete purified RNA of Coronavirus SARS-CoV-2 to be used to control IVD techniques based in nucleic acids amplification.

### KIT CONTENTS

**VIRCELL SARS-CoV-2 RNA CONTROL:** 1 vial with lyophilized RNA of Coronavirus SARS-CoV-2 from a Spanish clinical isolate (12,500-20,000 copies/μl once reconstituted). RNA quantification performed by real-time PCR.

**VIRCELL CONTROL RECONSTITUTION SOLUTION:** 500 μl of molecular biology grade water, DNase, RNase free.

### PRODUCT APPLICATIONS

- Quality assurance of the amplification testing.
- Limit of detection and assay specificity.
- Lot-to-lot verification assay.
- Development, optimization and validation of new assays.
- Training and trial purposes.
- Regulatory requirements and accreditation compliance.

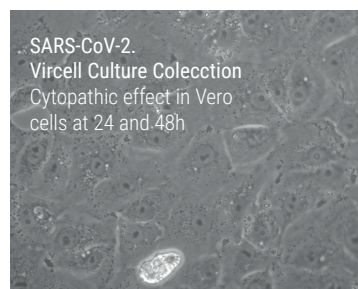
### STORAGE REQUIREMENTS AND SHELF LIFE

No special transportation conditions are required.

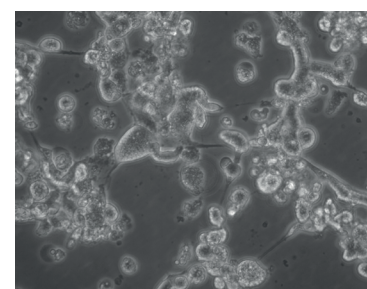
The vial is to be kept lyophilized at 2-8°C inside the foil pouch. Once opened, immediately reconstitute and store between -70°C and -90°C.

AmpliRun® RNA Controls have a shelf life of 2 years from the date of manufacture.

PMET101-06/20



SARS-CoV-2.  
Vircell Culture Coleccion  
Cytopathic effect in Vero  
cells at 24 and 48h



### Informtion and related products

Description	Cat. No.	Content
AMPLIRUN® CORONAVIRUS RNA CONTROL	<b>MBC090</b>	12,500-20,000 copies/μl
AMPLIRUN® CORONAVIRUS OC43 RNA CONTROL	<b>MBC135-R</b>	12,500-20,000 copies/μl
AMPLIRUN® CORONAVIRUS SARS (2003) RNA CONTROL	<b>MBC136-R</b>	12,500-20,000 copies/μl
<b>AMPLIRUN® SARS-CoV-2 RNA CONTROL</b> <b>NEW</b>	<b>MBC137-R</b>	12,500-20,000 copies/μl
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)	<b>MBTC030-R</b>	10 vials



# COVID-19 Molecular Diagnosis

No doubt about it, take control now  
Molecular Control

## AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)

EXTRACTION & AMPLIFICATION CONTROLS FOR NUCLEIC ACID TESTS

- **Inactivated whole pathogen** - Contains the entire genome and is compatible with any analysis.
- **Total control in a matrix that mimics a human specimen** - For monitoring the entire process: extraction, amplification, and detection.
- **Quantified, Low Positive** - Prepared to produce results at a significant clinical concentration.
- **Monodose format and lyophilized presentation** - It guarantees stability and avoids handling and additional transport costs.
- **Non-infectious material with inactivation certificate.**
- **Multiple platform compatibility.**



## AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)

Ref. MBTC030-R

Inactivated Coronavirus SARS-CoV-2 formulated in viral transport medium intended to validate and control nucleic acid assays as an external run control.

### KIT CONTENTS

10 vials with lyophilized SARS-CoV-2 (10,000-25,000 copies/vial).

- Batch concentration is provided in the certificate of analysis.
- The quantification is performed by real-time PCR and it is verified by Droplet Digital PCR (ddPCR).
- Reconstitution volume: 500 µl

### ORIGIN

From purified viral particles obtained in VERO E6 cells. Viruses are inactivated, rendering them non-infectious, and diluted in transport medium containing cells obtained from epithelial human cell lines.

Complete sequence available at GISAID: EPI\_ISL\_429256 (GISAID)

### STORAGE REQUIREMENTS AND SHELF LIFE

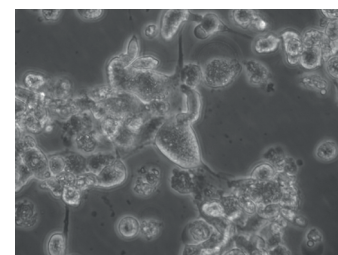
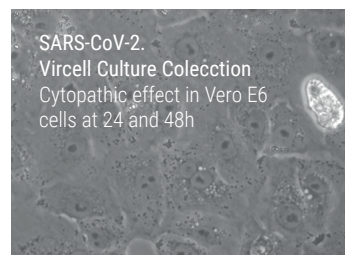
No special transport conditions are required. The vials are to be kept lyophilized at 2-8°C. After reconstitution, suspension should be used on the same day. Unused product should be discarded.

AmpliRun® Total Controls have a shelf life of 30 months from the date of manufacture.



The use of AmpliRun® Total Controls will help your lab to:

- Enhance the quality of the whole testing process: extraction, amplification and detection.
- Monitor the instrument performance in the long term obtaining comparable results.
- Validate and verify new assays.
- Follow variations in laboratory procedures, including batches of assay reagents.
- Comply with lab accreditation requirements.



### INFORMATION AND RELATED PRODUCTS

Description	Cat. No.	Content
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) <b>NEW</b>	<b>MBTC030-R</b>	10 vials
AMPLIRUN® SARS-CoV-2 RNA CONTROL	<b>MBC137-R</b>	12,500-20,000 copies/µl

Improve the quality of samples with a versatile medium

# VIRCELL TRANSPORT MEDIUM



Transport Medium for the collection and preservation of **Viruses, Chlamydia and Mycoplasma**

## MAIN BENEFITS

- Versatile medium, valid for different types of samples, microorganisms and diagnostic methods.
- Avoids the drying up of the sample.
- Improves microorganisms viability between collection and inoculation.
- Decreases bacterial overgrowth in contaminated samples.
- Successfully used for molecular based assays.
- Room temperature viability.
- Customized solution, available in different formats.
- Easy and safe to use, reduces the risk of contamination.



# VIRCELL TRANSPORT MEDIUM

Improve the quality of samples  
with a versatile medium

The success of virus diagnosis depends largely on the quality of the specimen and the conditions under which the specimen is transported and stored before being processed in the laboratory.

Vircell Transport Medium is intended for the collection and transport of clinical specimens containing viruses, chlamydia and mycoplasma from the collection site to the testing laboratory.

## ASSAY PROCEDURE

Collect the sample with the sterile swab and put the swab into the tube containing the transport medium. Cut off the end of the swab stick standing out of the tube, taking care not to touch the rim of the tube. Close the tube tightly, and fill in the data of the patient, type of sample, and date and hour of collection. Send to the laboratory for analysis at room temperature. For prolonged transport, use a refrigerated delivery service at 2-8°C.



## KIT CONTENTS

Vircell Transport Medium is provided in labeled screw-cap tubes - with different presentations - designed to preserve and transport the clinical sample. Some of our references incorporate 1 or 2 sterile swabs to ease specimen collection. Vircell medium consists of Hank's BSS containing HEPES, gelatine, BSA, sucrose and compatible antibiotics.

Cat. No.	Product description	Commercial swab	Pack size
TM011	TRANSPORT MEDIUM - 2 ml	1 sterile Rayon swab	50 units
TM001	TRANSPORT MEDIUM - 2 ml	2 sterile Rayon swabs	50 units
TM003	TRANSPORT MEDIUM - 2 ml	1 sterile Dacron swab	50 units
TM006	TRANSPORT MEDIUM - 2 ml	2 sterile Dacron swabs	50 units
TM005	TRANSPORT MEDIUM - 2 ml	No swab included	50 units
TM002	TRANSPORT MEDIUM - 3 ml	No swab included	50 units
TM008	TRANSPORT MEDIUM - 3 ml	1 sterile nylon microfiber swab	50 units
TM012	TRANSPORT MEDIUM - 2 ml	1 sterile nylon microfiber swab	50 units
TM004	TRANSPORT MEDIUM - 100 ml	No swab included	1 unit



# VIRapid® MONO M&G

The complete diagnostic tool for EBV infectious mononucleosis

Immuno-chromatographic test for the qualitative detection of 4 serological markers of Epstein-Barr virus in serum and plasma samples

## MAIN BENEFITS

- **Multitest diagnosis including the 4 main EBV serological markers**

A single product resolves the diagnostic scheme of EBV infectious mononucleosis (PB HA, VCA IgM, VCA IgG and EBNA IgG)

- **Rapid detection**

Results in 20 minutes to quickly rule out other diseases that should be treated or thoroughly investigated

- **High sensitivity regardless of patient's age**

Superior performance compared to other commercially available rapid tests



Ref. VR001 25 tests

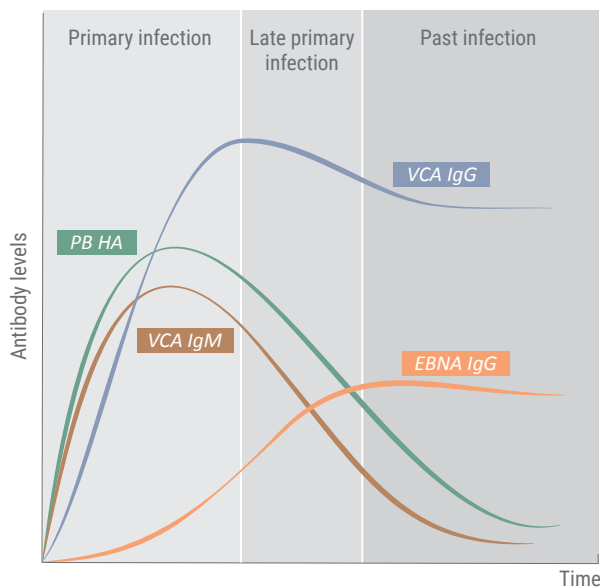
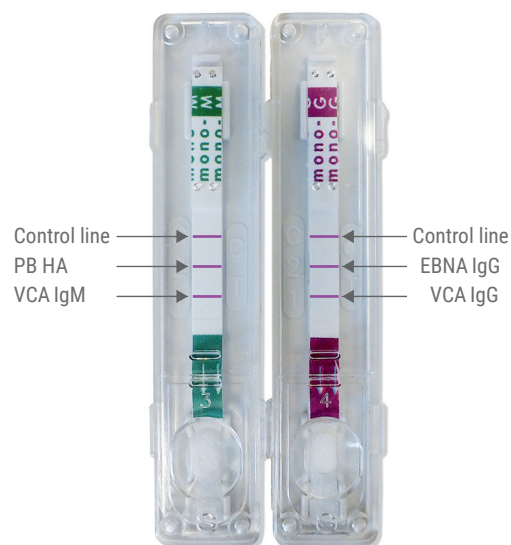


## Multitest detection of the 4 main serological markers of EBV

The rapid slide test for Paul and Bunnell heterophile antibodies (PB HA) is one of the most common techniques currently utilized by clinical laboratories for the infectious mononucleosis diagnosis. However, the immune response to the main serological markers of the disease can vary, depending on the age of the patient.

**PB HA has shown to be an inconclusive detection tool mainly in children under 4 years old.** Other serological markers, such as IgG and IgM antibodies against VCA and IgG antibodies against EBNA, would be required to confirm the diagnosis of infectious mononucleosis and to determine the disease phase (Sumaya, C.V. *et al.* 1985).

**VIRapid® MONO M&G** provides a rapid multitest detection of the main serological markers to diagnose EBV-infectious mononucleosis, regardless of the patient's age. Moreover, it helps to determine the phase of the disease (recent, late primary or past infection) and allows the ruling out of other serious illnesses with similar symptoms.



## Interpretation of results

Anti-EBV antibodies				Condition	Interpretation
PB HA	VCA-IgM	VCA-IgG	EBNA-IgG		
-	-	-	-	No infection	No contact with EBV.
+/-*	+	+/-	-	Recent infection**	*Children younger than 4 years old and 20% of adults do not develop heterophile antibodies. **In the case of getting only the VCA-M positive, it is recommended to analyze a second sample in 1-2 weeks.
+/-	+	+	+	Late primary infection	It is a past infection with IgM levels still detectable.
-	-	+	+/-***	Past infection	***When EBNA-G is positive, it corresponds to a latent past infection without evidence of recent infection. When EBNA-G appears negative, it may be an EBNA-G false negative result and checking with other techniques is recommended.

## High sensitivity and specificity for all parameters

**VIRapid® Mono M&G** has proven excellent performance for all parameters. In an internal evaluation, a large number of samples were assayed against ELISA kits (VCAg, VCAM and EBNA) and commercially available agglutination kits (PB HA).

	Sensitivity (%)	Specificity (%)	Samples tested
VCA M	91	97	197
PB HA	94	99	197
VCA G	92	95	390
EBNA G	91	92	390

# VRapid® Legionella Culture

## Rapid identification of positive cultures

Immuno-chromatographic test for the detection and identification of *Legionella* genus, *L. pneumophila* serogroup 1 and *L. pneumophila* serogroups 1-15 in samples from bacterial cultures.

- Rapid detection in 30 minutes
- Multitest format for the identification of the main groups with clinical interest
- Based on specific and highly purified MAb
- Allows for detection of all Legionella species
- 99% sensitivity and 100% specificity
- Easy to use and minimum handling required
- Product control line in each device
- All reagents included in the kit



Ref. VR002 25 tests



# Virapid® Legionella Culture

## Rapid identification of positive cultures

Cases of legionellosis frequently appear as outbreaks in the community, tourism and nosocomial field so this disease is considered a public health problem and its prevention and control is highly legislated.

### Facilities

The legislation applies to facilities that use water in their operation, produce aerosols and are located on the inside or outside of buildings for collective use, industrial facilities or means of transportation that may be susceptible of becoming hot spots for the spread of the disease. The periodicity of the *Legionella* analysis depends on the facility involved and its location.

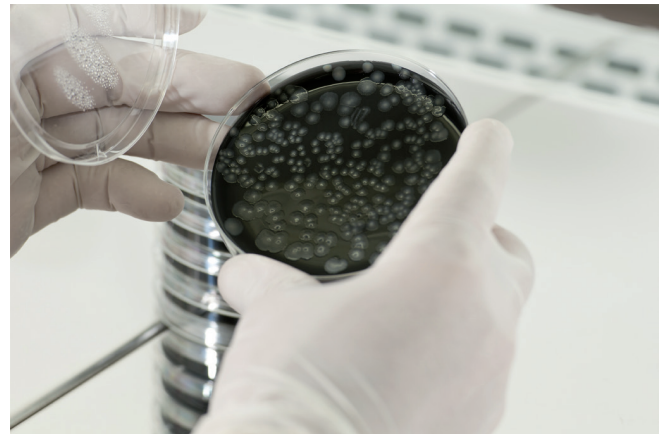
### Laboratories

*Legionella* analysis should be performed in accredited laboratories for the isolation of *Legionella* in water or in laboratories that have implemented a quality control system for this type of testing.

It is important to remark that for the appropriate monitoring of a facility treatment it is necessary, not only to acknowledge the presence of the bacterium, but to establish its viability.

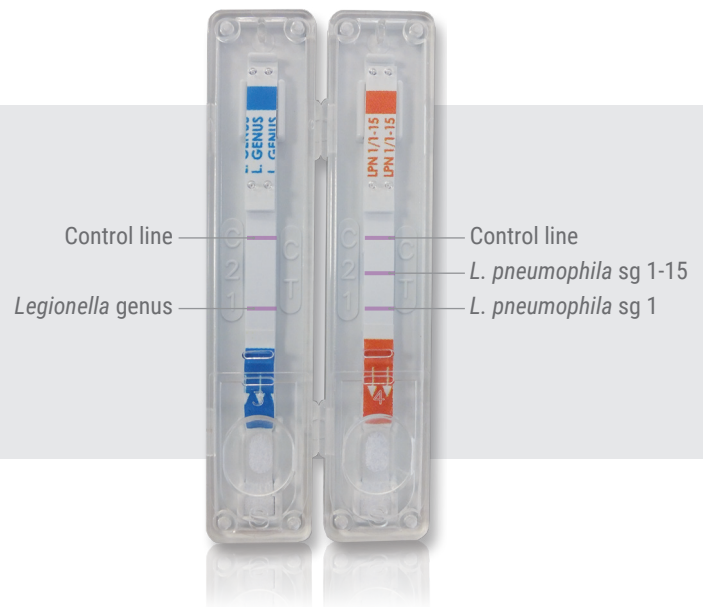
### Preferred method

It is based on the concentration of the sample and the subsequent treatments carried out to allow the survival of *Legionella* genus and to reduce or eliminate the accompanying microbiotics. Subsequently, the use of a culture media to detect and recount the *Legionella* genus bacteria present in the sample is required. Finally, it is necessary to confirm the presence of *Legionella pneumophila*, especially serogroup 1, due to clinical relevance of this species.



## LPN1, LPN1-15 and Legionella genus

### Rapid identification of positive cultures



	Sensitivity (%)	Specificity (%)
LPN1	97	100
LPN1-15	100	100
<i>Legionella</i> genus	100	100
Total	99	100

Samples tested: 204



# COVID-19 Molecular Diagnosis

No doubt about it, take control now  
Molecular Control

## AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)

EXTRACTION & AMPLIFICATION CONTROLS FOR NUCLEIC ACID TESTS

- **Inactivated whole pathogen** - Contains the entire genome and is compatible with any analysis.
- **Total control in a matrix that mimics a human specimen** - For monitoring the entire process: extraction, amplification, and detection.
- **Quantified, Low Positive** - Prepared to produce results at a significant clinical concentration.
- **Monodose format and lyophilized presentation** - It guarantees stability and avoids handling and additional transport costs.
- **Non-infectious material with inactivation certificate.**
- **Multiple platform compatibility.**



## AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)

Ref. MBTC030-R

Inactivated Coronavirus SARS-CoV-2 formulated in viral transport medium intended to validate and control nucleic acid assays as an external run control.

### KIT CONTENTS

10 vials with lyophilized SARS-CoV-2 (10,000-25,000 copies/vial).

- Batch concentration is provided in the certificate of analysis.
- The quantification is performed by real-time PCR and it is verified by Droplet Digital PCR (ddPCR).
- Reconstitution volume: 500 µl

### ORIGIN

From purified viral particles obtained in VERO E6 cells. Viruses are inactivated, rendering them non-infectious, and diluted in transport medium containing cells obtained from epithelial human cell lines.

Complete sequence available at GISAID: EPI\_ISL\_429256 (GISAID)

### STORAGE REQUIREMENTS AND SHELF LIFE

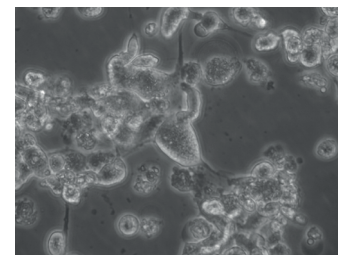
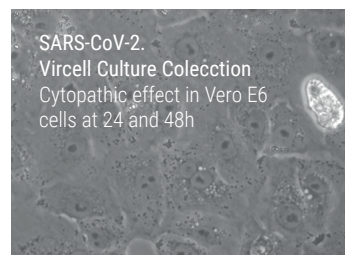
No special transport conditions are required. The vials are to be kept lyophilized at 2-8°C. After reconstitution, suspension should be used on the same day. Unused product should be discarded.

AmpliRun® Total Controls have a shelf life of 30 months from the date of manufacture.



The use of AmpliRun® Total Controls will help your lab to:

- Enhance the quality of the whole testing process: extraction, amplification and detection.
- Monitor the instrument performance in the long term obtaining comparable results.
- Validate and verify new assays.
- Follow variations in laboratory procedures, including batches of assay reagents.
- Comply with lab accreditation requirements.



### INFORMATION AND RELATED PRODUCTS

Description	Cat. No.	Content
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) <b>NEW</b>	<b>MBTC030-R</b>	10 vials
AMPLIRUN® SARS-CoV-2 RNA CONTROL	<b>MBC137-R</b>	12,500-20,000 copies/µl

# AMPLIRUN<sup>®</sup> TOTAL

A RELIABLE QUALITY CONTROL SOURCE FOR  
NUCLEIC ACID TESTS







02 AMPLIRUN® TOTAL

04 RESPIRATORY INFECTIONS

05 TUBERCULOSIS INFECTIONS

06 GASTROINTESTINAL INFECTIONS

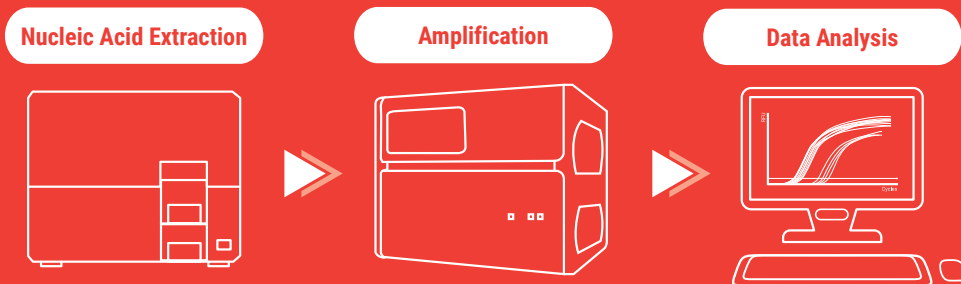
06 MONONUCLEOSIS INFECTIONS

07 SEXUALLY TRANSMITTED INFECTIONS

08 TORCH INFECTIONS

08 VECTOR-BORNE INFECTIONS

# FULL PROCESS CONTROLS DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE COMPLETE ANALYTICAL PROCESS



AmpliRun® Total

## REGULATORY REQUIREMENTS REINFORCE THE NEED TO USE THIRD PARTY CONTROLS



*Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.*

ISO 15189:2012 Medical Laboratories. Requirements for Quality and competence.

*Controls independent of those produced by the manufacturer of the test or analyser should be used.*

**National Association of Testing Authorities (NATA) Australia.** AS 4633 (ISO 15189) – Supplemental Requirements for accreditation in the field of Medical testing.

*Quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure's performance in its entirety, including the procedure for calibration of the measurement.*

**Clinical and Laboratory Standards Institute (CLSI).** C24-A3 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition, 6.2.1

*For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.*

**Clinical Laboratory Improvement Amendments (CLIA).** Code of Federal Regulations – Title 42 Part 493 Laboratory requirements. §493.1256 Standard: Control procedures.



# AMPLIRUN® TOTAL THIRD PARTY CONTROLS

Achieve independent assessment of your diagnostic devices and methods, comply with lab accreditation and improve patient care.



## FEATURES

Whole pathogen controls with complete genome.  
Quantified controls (low positive).  
Shelf life: up to 2,5 years from date of manufacture.  
Lyophilized presentation to ensure stability and avoid extra transport costs.  
Monodose format.  
Non-infectious microorganisms.  
For IVD use.



## MATRICES

Applicable for a range of matrices: plasma, swab, sputum, exudate, urine, stool and CSF.



## MULTIPLE PLATFORM COMPATIBILITY

GeneXpert (Cepheid), BD MAX (Becton Dickinson), Panther (Hologic), Filmarray (BioFire), or Liaison MDX (Diasorin Molecular), among others.



## CUSTOM SOLUTIONS

Vircell R&D team has both the experience and capacity to design, develop, and deliver customized biological controls for all kind of instruments and assays. We can produce variations of the existing products in terms of concentration or purification requirements, or we can customize entire new panels to meet your unique needs.



## EXTERNAL RUN CONTROLS

Vircell is a leading provider of independent external run controls for Nucleic Acid Testing (NAT) with a long-term trajectory in infectious disease diagnostics.



**AmpliRun® Total Controls** are designed to be used as run controls for routine customer use to guarantee efficient nucleic acid extraction, amplification and detection. These inactivated whole-organism positive controls are provided in a matrix that mimics different human samples formulated to produce low level positive results at a clinically significant concentration. The control should be extracted and amplified alongside unknown samples and treated in an identical manner to a clinical specimen.



Each single-use vial is intended to help laboratories monitor and maintain consistent, accurate and meaningful performance of their molecular infectious diseases assays.



Quality control practices are essential in the routine molecular diagnostic laboratories for infectious diseases to ensure accuracy and reproducibility of lab test results. Start guaranteeing today the integrity and confidence of your results with **AmpliRun® Total Controls**.

# RESPIRATORY INFECTIONS

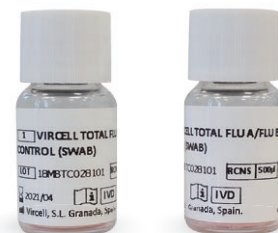
## AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)

**Code:** MBTC022  
**Analytes:** *Bordetella pertussis*, *Chlamydomphila pneumoniae*, *Chlamydomphila psittaci*, *Coxiella burnetii*, *Legionella pneumophila*, *Mycoplasma pneumoniae*  
**Matrix:** Swab  
**Copies/vial:** 10,000 to 25,000  
**Fill volume:** 500 µL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials



## AMPLIRUN® TOTAL FLU A/FLU B/RSV CONTROL (SWAB)

**Code:** MBTC028  
**Analytes:** Influenza A, influenza B, RSV  
**Matrix:** Swab  
**Copies/vial:** 10,000 to 25,000  
**Fill volume:** 500 µL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials



## AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)

**Code:** MBTC020  
**Analytes:** Adenovirus 4, coronavirus, influenza A H3N2, influenza B, novel influenza A H1N1, parainfluenza 1, parainfluenza 2, parainfluenza 3, RSV (subtype A), RSV (subtype B)  
**Matrix:** Swab  
**Copies/vial:** 4,000 to 10,000  
**Fill volume:** 200 µL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials





# TUBERCULOSIS INFECTIONS

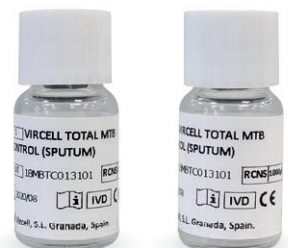
## AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)

**Code:** MBTC027  
**Analytes:** 2 vials x *Mycobacterium tuberculosis*  
2 vials x *Mycobacterium tuberculosis* RIF resistant rpoB mutation (S531L)  
2 vials x *Mycobacterium tuberculosis* RIF resistant rpoB mutation (H526D)  
2 vials x *Mycobacterium tuberculosis* INH RESISTANT katG mutation (S315T)  
2 vials x *Mycobacterium tuberculosis* INH RESISTANT inhA mutation (C15T)  
**Matrix:** Sputum  
**Copies/vial:** 20,000 to 50,000  
**Fill volume:** 1 mL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials (5x2)



## AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)

**Code:** MBTC013  
**Analytes:** *Mycobacterium tuberculosis*  
**Matrix:** Sputum  
**Copies/vial:** 20,000 to 50,000  
**Fill volume:** 1 mL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials



## AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)

**Code:** MBTC015  
**Analytes:** 5 vials x *Mycobacterium tuberculosis* katG mutation (S315T)  
5 vials x *Mycobacterium tuberculosis* inhA mutation (C15T)  
**Matrix:** Sputum  
**Copies/vial:** 20,000 to 50,000  
**Fill volume:** 1 mL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials (2x5)



## AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)

**Code:** MBTC014  
**Analytes:** 5 vials x *Mycobacterium tuberculosis* rpoB mutation (S531L)  
5 vials x *Mycobacterium tuberculosis* rpoB mutation (H526D)  
**Matrix:** Sputum  
**Copies/vial:** 20,000 to 50,000  
**Fill volume:** 1 mL  
**Copies/ml:** 35,000  
**Kit size:** 10 vials (2x5)





## GASTROINTESTINAL INFECTIONS

### AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE CONTROL (STOOL)\*

Code: MBTC026  
Analyte: *Clostridium difficile* RT027  
Matrix: Stool  
Copies/vial: 10,000 to 25,000  
Fill volume: 500 µL  
Copies/ml: 35,000  
Kit size: 10 vials

### AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)

Code: MBTC021  
Analytes: *Campylobacter jejuni*, *Clostridium difficile*, *Escherichia coli* (EHEC),  
*Salmonella enteritidis*, *Shigella flexneri*, *Yersinia enterocolitica*  
Matrix: Stool  
Copies/vial: 10,000 to 25,000  
Fill volume: 500 µL  
Copies/ml: 35,000  
Kit size: 10 vials

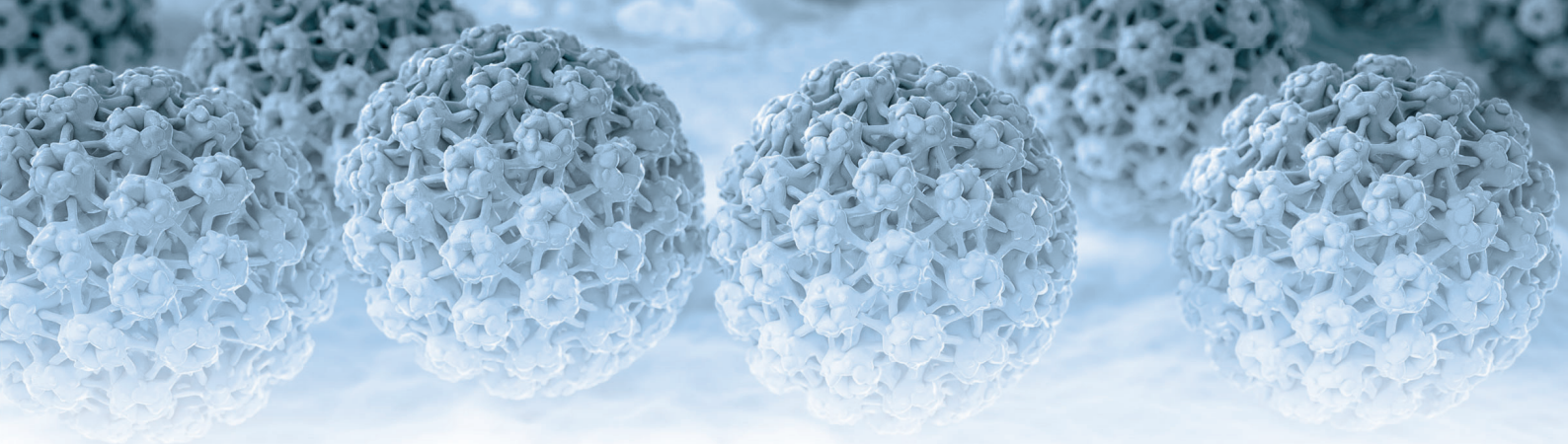


## MONONUCLEOSIS INFECTIONS

### AMPLIRUN® TOTAL EBV CONTROL (PLASMA)

Code: MBTC019  
Analyte: Epstein-Barr virus (International Units - EBV B95-8 strain)  
Matrix: Plasma  
Copies/vial: 4,000 to 10,000  
Fill volume: 200 µL  
Copies/ml: 35,000  
Kit size: 10 vials

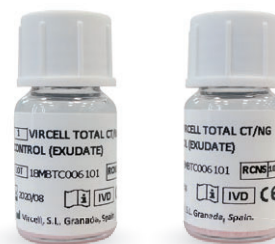




# SEXUALLY TRANSMITTED INFECTIONS

## AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)

Code: MBTC006  
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*  
 Matrix: Exudate  
 Copies/vial: 2,500 to 10,000  
 Fill volume: 1 mL  
 Copies/ml: 5,000  
 Kit size: 10 vials



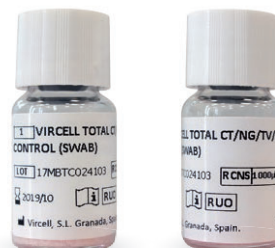
## AMPLIRUN® TOTAL CT/NG CONTROL (URINE)

Code: MBTC003  
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*  
 Matrix: Urine  
 Copies/vial: 2,500 to 10,000  
 Fill volume: 1 mL  
 Copies/ml: 5,000  
 Kit size: 10 vials



## AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)

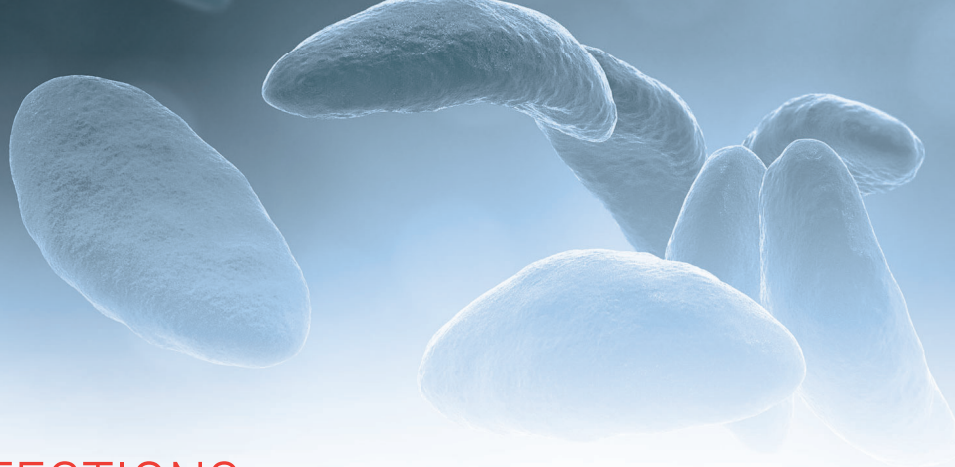
Code: MBTC024  
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma genitalium*  
 Matrix: Swab  
 Copies/vial: 20,000 to 50,000  
 Fill volume: 1 mL  
 Copies/ml: 35,000  
 Kit size: 10 vials



## AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE)

Code: MBTC016  
 Analytes: Herpes simplex virus & Varicella-zoster virus  
 Matrix: Exudate  
 Copies/vial: 4,000 to 10,000  
 Fill volume: 200 µL  
 Copies/ml: 35,000  
 Kit size: 10 vials





## TORCH INFECTIONS

### AMPLIRUN® TOTAL CMV CONTROL (PLASMA)

Code: MBTC018  
 Analytes: Cytomegalovirus (International Units - hCMV Merlin strain)  
 Matrix: Plasma  
 Copies/vial: 4,000 to 10,000  
 Fill volume: 200 µl  
 Copies/ml: 35,000  
 Kit size: 10 vials



### AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (CSF)

Code: MBTC009  
 Analytes: Herpes simplex virus 1 & 2  
 Matrix: CSF  
 Copies/vial: 4,000 to 10,000  
 Fill volume: 200 µL  
 Copies/ml: 35,000  
 Kit size: 10 vials



### AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (PLASMA)

Code: MBTC012  
 Analytes: Herpes simplex virus 1 & 2  
 Matrix: Plasma  
 Copies/vial: 4,000 to 10,000  
 Fill volume: 200 µL  
 Copies/ml: 35,000  
 Kit size: 10 vials



## VECTOR-BORNE INFECTIONS

### AMPLIRUN® TOTAL ZIKV-DENV-CHIKV CONTROL (PLASMA)

Code: MBTC023  
 Analytes: Zika virus, dengue virus (1-4), chikungunya virus  
 Matrix: Plasma  
 Copies/vial: 4,000 to 10,000  
 Fill volume: 200 µL  
 Copies/ml: 35,000  
 Kit size: 10 vials





## Ordering Information

### Placing orders

When ordering, please specify:

- Company name.
- Ship to and bill to address.
- Product catalogue number and description.
- Unit size and quantity.
- Special shipping conditions, if any.

### Free samples policy

Samples are available free of charge for testing purposes. Please contact your Area Manager to ask for our sample request form.

### Order cancellation

Requests for cancellation should be submitted one week in advance for cell culture products. For the rest of the product lines, three days advanced notice is required.

## Terms and Conditions

### Prices

Product price shall be the prices specified in our current price list on the date of order. We reserve the right to revise our prices at any time with at least 1 month prior notice. Unless we state otherwise in writing, all prices are ex-works.

The validity period for preorders/orders awaiting prepayment will be one month. After that time, order confirmation is required.

## Technical Support

For technical assistance and product information, please visit our website or contact our Technical Service Department at [customerservice@viracell.com](mailto:customerservice@viracell.com)

We strive to answer all emails within 24 hours, and most are answered in substantially less time.

## RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)	MBTC022
AMPLIRUN® TOTAL FLU A/FLU B/RSV (SWAB)	MBTC028
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)	MBTC020

## MYCOBACTERIAL INFECTIONS

AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)	MBTC027
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)	MBTC013
AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)	MBTC015
AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)	MBTC014

## GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE CONTROL (STOOL)*	MBTC026
AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)	MBTC021

## MONONUCLEOSIS INFECTIONS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)	MBTC019
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## SEXUALLY TRANSMITTED INFECTIONS

AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)	MBTC006
AMPLIRUN® TOTAL CT/NG CONTROL (URINE)	MBTC003
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)	MBTC024
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE)	MBTC016

## TORCH INFECTIONS

AMPLIRUN® TOTAL CMV CONTROL (PLASMA)	MBTC018
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (CSF)	MBTC009
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (PLASMA)	MBTC012

## VECTOR-BORNE INFECTIONS

AMPLIRUN® TOTAL ZIKV-DENV -CHIKV CONTROL (PLASMA)	MBTC023
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# AMPLIRUN®

DNA/RNA AMPLIFICATION CONTROLS





## TAKE CONTROL, MOLECULAR CONTROL



### AMPLIRUN® FEATURES

Quantitated PCR controls for viruses, bacteria and protozoa.

Purified nucleic acid, complete microbial genome.

Any target can be amplified.

Precise concentration in copies/μl determined by qPCR.

Can be used across various molecular testing platforms.

Non-infectious.

Lyophilized presentation.

CE marked products.

Strain and NCBI sequences available at [www.vircell.com](http://www.vircell.com).



### PRODUCT APPLICATIONS

Quality assurance of the amplification testing.

Limit of detection and assay specificity.

Assay lot-to-lot verification.

Assay development, optimization and validation.

Training/trial purposes.

Regulatory requirements/accreditation process compliance.



### CUSTOM SOLUTIONS

Vircell R&D team has both the experience and capacity to design, develop, and deliver customized biological controls for all kind of instruments and assays. We can produce variations of the existing products in terms of concentration or purification requirements, or we can customize entire new panels to meet your unique needs.





# AMPLIRUN® DNA/RNA AMPLIFICATION CONTROLS

Certify the efficiency, quality and reliability of your molecular infectious disease testing

Vircell's range of DNA and RNA controls has been developed to allow the amplification and testing of any region of the genome which is present in natural infections.

Our controls are obtained from virus-infected cells and bacteria, serving as positive controls in nucleic acid amplification reactions, as well as controls for the detection of viral and bacterial sequences in nucleic acid hybridization reactions.

Description	Cat. No.	Copies/µl
AMPLIRUN® ACANTHAMOEBA CASTELLANII DNA CONTROL	<b>MBC054</b>	10,000-20,000
AMPLIRUN® ADENOVIRUS 41 DNA CONTROL	<b>MBC114</b>	10,000-20,000
AMPLIRUN® ADENOVIRUS DNA CONTROL	<b>MBC001</b>	10,000-20,000
AMPLIRUN® ASPERGILLUS FUMIGATUS DNA CONTROL	<b>MBC002</b>	10,000-20,000
AMPLIRUN® BACILLUS CEREUS DNA CONTROL	<b>MBC004</b>	10,000-20,000
AMPLIRUN® BARTONELLA HENSELAE DNA CONTROL	<b>MBC005</b>	10,000-20,000
AMPLIRUN® BARTONELLA QUINTANA DNA CONTROL	<b>MBC006</b>	10,000-20,000
AMPLIRUN® BK VIRUS DNA CONTROL	<b>MBC051</b>	10,000-20,000
AMPLIRUN® BORDETELLA HOLMESII DNA CONTROL	<b>MBC092</b>	10,000-20,000
AMPLIRUN® BORDETELLA PARAPERTUSSIS DNA CONTROL	<b>MBC007</b>	10,000-20,000
AMPLIRUN® BORDETELLA PERTUSSIS DNA CONTROL	<b>MBC008</b>	10,000-20,000
AMPLIRUN® BORRELIA AFZELII DNA CONTROL	<b>MBC078</b>	10,000-20,000
AMPLIRUN® BORRELIA BURGDORFERI DNA CONTROL	<b>MBC076</b>	10,000-20,000
AMPLIRUN® BORRELIA GARINII DNA CONTROL	<b>MBC077</b>	10,000-20,000
AMPLIRUN® BRUCELLA ABORTUS DNA CONTROL	<b>MBC009</b>	10,000-20,000
AMPLIRUN® CAMPYLOBACTER JEJUNI DNA CONTROL	<b>MBC088</b>	10,000-20,000
AMPLIRUN® CANDIDA ALBICANS DNA CONTROL	<b>MBC010</b>	10,000-20,000
AMPLIRUN® CANDIDA AURIS DNA CONTROL	<b>MBC127</b>	10,000-20,000
AMPLIRUN® CHIKUNGUNYA VIRUS RNA CONTROL	<b>MBC099</b>	12,500-20,000
AMPLIRUN® CHLAMYDIA TRACHOMATIS DNA CONTROL	<b>MBC012</b>	10,000-20,000
AMPLIRUN® CHLAMYDOPHILA PNEUMONIAE DNA CONTROL	<b>MBC011</b>	10,000-20,000
AMPLIRUN® CHLAMYDOPHILA PSITTACI DNA CONTROL	<b>MBC013</b>	10,000-20,000
AMPLIRUN® CLOSTRIDIUM DIFFICILE DNA CONTROL	<b>MBC043</b>	10,000-20,000
AMPLIRUN® COCCIDIOIDES IMMITIS DNA CONTROL	<b>MBC014</b>	10,000-20,000
AMPLIRUN® CORONAVIRUS RNA CONTROL	<b>MBC090</b>	12,500-20,000
AMPLIRUN® CORONAVIRUS OC43 RNA CONTROL	<b>MBC135-R</b>	12,500-20,000
AMPLIRUN® CORONAVIRUS SARS (2003) RNA CONTROL	<b>MBC136-R</b>	12,500-20,000
AMPLIRUN® COXIELLA BURNETII DNA CONTROL	<b>MBC018</b>	10,000-20,000
AMPLIRUN® COXSACKIE A6 RNA CONTROL	<b>MBC063</b>	12,500-20,000
AMPLIRUN® COXSACKIE B1 RNA CONTROL	<b>MBC061</b>	12,500-20,000
AMPLIRUN® COXSACKIE B5 RNA CONTROL	<b>MBC062</b>	12,500-20,000
AMPLIRUN® CRYPTOCOCCUS NEOFORMANS DNA CONTROL	<b>MBC015</b>	10,000-20,000
AMPLIRUN® CRYPTOSPORIDIUM PARVUM DNA CONTROL	<b>MBC126</b>	700-2,000
AMPLIRUN® CYTOMEGALOVIRUS DNA CONTROL	<b>MBC016</b>	10,000-20,000
AMPLIRUN® DENGUE 1 VIRUS RNA CONTROL	<b>MBC055</b>	12,500-20,000
AMPLIRUN® DENGUE 2 VIRUS RNA CONTROL	<b>MBC056</b>	12,500-20,000
AMPLIRUN® DENGUE 3 VIRUS RNA CONTROL	<b>MBC057</b>	12,500-20,000
AMPLIRUN® DENGUE 4 VIRUS RNA CONTROL	<b>MBC058</b>	12,500-20,000

Description	Cat. No.	Copies/µl
AMPLIRUN® EASTERN EQUINE ENCEPHALITIS RNA CONTROL	<b>MBC097</b>	12,500-20,000
AMPLIRUN® ECHOVIRUS 5 RNA CONTROL	<b>MBC064</b>	12,500-20,000
AMPLIRUN® ENTEROCOCCUS FAECALIS (vanB) DNA CONTROL	<b>MBC115</b>	10,000-20,000
AMPLIRUN® ENTEROCOCCUS FAECIUM (vanA) DNA CONTROL	<b>MBC116</b>	10,000-20,000
AMPLIRUN® ENTEROVIRUS 68 RNA CONTROL	<b>MBC125</b>	12,500-20,000
AMPLIRUN® ENTEROVIRUS 71 RNA CONTROL	<b>MBC019</b>	12,500-20,000
AMPLIRUN® EPSTEIN-BARR VIRUS DNA CONTROL	<b>MBC065</b>	10,000-20,000
AMPLIRUN® ESCHERICHIA COLI (EAEC) DNA CONTROL	<b>MBC121</b>	10,000-20,000
AMPLIRUN® ESCHERICHIA COLI (EIEC) DNA CONTROL	<b>MBC122</b>	10,000-20,000
AMPLIRUN® ESCHERICHIA COLI (EPEC) DNA CONTROL	<b>MBC123</b>	10,000-20,000
AMPLIRUN® ESCHERICHIA COLI (ETEC) DNA CONTROL	<b>MBC124</b>	10,000-20,000
AMPLIRUN® ESCHERICHIA COLI (VTEC) DNA CONTROL	<b>MBC022</b>	10,000-20,000
AMPLIRUN® FRANCISELLA TULARENSIS DNA CONTROL	<b>MBC110</b>	10,000-20,000
AMPLIRUN® GARDNERELLA VAGINALIS DNA CONTROL	<b>MBC108</b>	10,000-20,000
AMPLIRUN® GIARDIA INTESTINALIS DNA CONTROL	<b>MBC119</b>	10,000-20,000
AMPLIRUN® HAEMOPHILUS DUCREYI DNA CONTROL	<b>MBC021</b>	10,000-20,000
AMPLIRUN® HAEMOPHILUS INFLUENZAE DNA CONTROL	<b>MBC020</b>	10,000-20,000
AMPLIRUN® HELICOBACTER PYLORI DNA CONTROL	<b>MBC049</b>	10,000-20,000
AMPLIRUN® HERPES SIMPLEX 1 DNA CONTROL	<b>MBC023</b>	10,000-20,000
AMPLIRUN® HERPES SIMPLEX 2 DNA CONTROL	<b>MBC024</b>	10,000-20,000
AMPLIRUN® HHV-6 DNA CONTROL	<b>MBC025</b>	10,000-20,000
AMPLIRUN® HHV-8 DNA CONTROL	<b>MBC128</b>	10,000-20,000
AMPLIRUN® HUMAN PARAINFLUENZA 1 RNA CONTROL	<b>MBC105</b>	12,500-20,000
AMPLIRUN® INFLUENZA A H1 RNA CONTROL	<b>MBC028</b>	12,500-20,000
AMPLIRUN® INFLUENZA A H3 RNA CONTROL	<b>MBC029</b>	12,500-20,000
AMPLIRUN® INFLUENZA A H5 RNA CONTROL	<b>MBC052</b>	12,500-20,000
AMPLIRUN® INFLUENZA B RNA CONTROL	<b>MBC030</b>	12,500-20,000
AMPLIRUN® JAPANESE ENCEPHALITIS RNA CONTROL	<b>MBC134</b>	12,500-20,000
AMPLIRUN® KLEBSIELLA PNEUMONIAE (NDM-1) DNA CONTROL	<b>MBC107</b>	10,000-20,000
AMPLIRUN® LEGIONELLA PNEUMOPHILA DNA CONTROL	<b>MBC031</b>	10,000-20,000
AMPLIRUN® LEISHMANIA CHAGASI DNA CONTROL	<b>MBC060</b>	10,000-20,000
AMPLIRUN® LEISHMANIA INFANTUM DNA CONTROL	<b>MBC032</b>	10,000-20,000
AMPLIRUN® LISTERIA MONOCYTOGENES DNA CONTROL	<b>MBC033</b>	10,000-20,000
AMPLIRUN® MEASLES RNA CONTROL	<b>MBC046</b>	12,500-20,000
AMPLIRUN® MERS CORONAVIRUS RNA CONTROL	<b>MBC132</b>	12,500-20,000
AMPLIRUN® MORAXELLA CATARRHALIS DNA CONTROL	<b>MBC117</b>	10,000-20,000
AMPLIRUN® MUMPS RNA CONTROL	<b>MBC040</b>	12,500-20,000
AMPLIRUN® MYCOBACTERIUM AVIUM DNA CONTROL	<b>MBC086</b>	10,000-20,000
AMPLIRUN® MYCOBACTERIUM INTRACELLULARE DNA CONTROL	<b>MBC087</b>	10,000-20,000
AMPLIRUN® MYCOBACTERIUM KANSASII DNA CONTROL	<b>MBC095</b>	10,000-20,000
AMPLIRUN® MYCOBACTERIUM TUBERCULOSIS DNA CONTROL	<b>MBC034</b>	10,000-20,000
AMPLIRUN® MYCOBACTERIUM ULCERANS DNA CONTROL	<b>MBC094</b>	10,000-20,000
AMPLIRUN® MYCOPLASMA GENITALIUM DNA CONTROL	<b>MBC085</b>	10,000-20,000
AMPLIRUN® MYCOPLASMA HOMINIS DNA CONTROL	<b>MBC084</b>	10,000-20,000
AMPLIRUN® MYCOPLASMA PNEUMONIAE DNA CONTROL	<b>MBC035</b>	10,000-20,000
AMPLIRUN® NEISSERIA GONORRHOEAE DNA CONTROL	<b>MBC075</b>	10,000-20,000
AMPLIRUN® NEISSERIA MENINGITIDIS SG A DNA CONTROL	<b>MBC036</b>	10,000-20,000

Description	Cat. No.	Copies/µl
AMPLIRUN® NEISSERIA MENINGITIDIS SG B DNA CONTROL	<b>MBC066</b>	10,000-20,000
AMPLIRUN® NEISSERIA MENINGITIDIS SG C DNA CONTROL	<b>MBC053</b>	10,000-20,000
AMPLIRUN® NOROVIRUS RNA CONTROL	<b>MBC111</b>	700-2,000
AMPLIRUN® NOVEL INFLUENZA A H1N1 RNA CONTROL	<b>MBC082</b>	12,500-20,000
AMPLIRUN® ORIENTIA TSUTSUGAMUSHI DNA CONTROL	<b>MBC106</b>	10,000-20,000
AMPLIRUN® PAPILLOMAVIRUS TYPE 16 DNA CONTROL	<b>MBC067</b>	10,000-20,000
AMPLIRUN® PAPILLOMAVIRUS TYPE 18 DNA CONTROL	<b>MBC068</b>	10,000-20,000
AMPLIRUN® PARAINFLUENZA 1 RNA CONTROL	<b>MBC037</b>	12,500-20,000
AMPLIRUN® PARAINFLUENZA 2 RNA CONTROL	<b>MBC038</b>	12,500-20,000
AMPLIRUN® PARAINFLUENZA 3 RNA CONTROL	<b>MBC039</b>	12,500-20,000
AMPLIRUN® PARAINFLUENZA 4 A RNA CONTROL	<b>MBC050</b>	12,500-20,000
AMPLIRUN® PARECHOVIRUS 1 RNA CONTROL	<b>MBC102</b>	12,500-20,000
AMPLIRUN® PARVOVIRUS B19 (plasmid) DNA CONTROL	<b>MBC080</b>	10,000-20,000
AMPLIRUN® RESPIRATORY SYNCYTIAL VIRUS (subtype A) RNA CONTROL	<b>MBC041</b>	12,500-20,000
AMPLIRUN® RESPIRATORY SYNCYTIAL VIRUS (subtype B) RNA CONTROL	<b>MBC083</b>	12,500-20,000
AMPLIRUN® RHINOVIRUS RNA CONTROL	<b>MBC091</b>	12,500-20,000
AMPLIRUN® RICKETTSIA CONORII DNA CONTROL	<b>MBC042</b>	10,000-20,000
AMPLIRUN® ROSS RIVER VIRUS RNA CONTROL	<b>MBC130</b>	12,500-20,000
AMPLIRUN® ROTAVIRUS RNA CONTROL	<b>MBC026</b>	12,500-20,000
AMPLIRUN® RUBELLA RNA CONTROL	<b>MBC113</b>	12,500-20,000
AMPLIRUN® SALMONELLA ENTERITIDIS DNA CONTROL	<b>MBC003</b>	10,000-20,000
AMPLIRUN® SALMONELLA TYPHI DNA CONTROL	<b>MBC044</b>	10,000-20,000
AMPLIRUN® SARS-CoV-2 RNA CONTROL	<b>MBC137-R</b>	12,500-20,000
AMPLIRUN® SHIGELLA FLEXNERI DNA CONTROL	<b>MBC089</b>	10,000-20,000
AMPLIRUN® ST LOUIS ENCEPHALITIS VIRUS RNA CONTROL	<b>MBC101</b>	12,500-20,000
AMPLIRUN® STAPHYLOCOCCUS AUREUS (mecA-) DNA CONTROL	<b>MBC073</b>	10,000-20,000
AMPLIRUN® STAPHYLOCOCCUS AUREUS (mecA+) DNA CONTROL	<b>MBC074</b>	10,000-20,000
AMPLIRUN® STREPTOCOCCUS AGALACTIAE DNA CONTROL	<b>MBC071</b>	10,000-20,000
AMPLIRUN® STREPTOCOCCUS PNEUMONIAE DNA CONTROL	<b>MBC070</b>	10,000-20,000
AMPLIRUN® TICK-BORNE ENCEPHALITIS VIRUS RNA CONTROL	<b>MBC045</b>	12,500-20,000
AMPLIRUN® TOSCANA VIRUS RNA CONTROL	<b>MBC129</b>	12,500-20,000
AMPLIRUN® TOXOPLASMA GONDII DNA CONTROL	<b>MBC047</b>	10,000-20,000
AMPLIRUN® TREPONEMA PALLIDUM DNA CONTROL	<b>MBC109</b>	700-2,000
AMPLIRUN® TRICHOMONAS VAGINALIS DNA CONTROL	<b>MBC079</b>	10,000-20,000
AMPLIRUN® TRYPANOSOMA CRUZI DNA CONTROL	<b>MBC059</b>	10,000-20,000
AMPLIRUN® TRYPANOSOMA RANGELI DNA CONTROL	<b>MBC093</b>	10,000-20,000
AMPLIRUN® UREAPLASMA PARVUM DNA CONTROL	<b>MBC133</b>	10,000-20,000
AMPLIRUN® UREAPLASMA UREALYTICUM DNA CONTROL	<b>MBC112</b>	10,000-20,000
AMPLIRUN® VARICELLA-ZOSTER VIRUS DNA CONTROL	<b>MBC048</b>	10,000-20,000
AMPLIRUN® VENEZUELAN EQUINE ENCEPHALITIS RNA CONTROL	<b>MBC096</b>	12,500-20,000
AMPLIRUN® VIBRIO CHOLERAЕ DNA CONTROL	<b>MBC118</b>	10,000-20,000
AMPLIRUN® WEST NILE VIRUS RNA CONTROL	<b>MBC069</b>	12,500-20,000
AMPLIRUN® WESTERN EQUINE ENCEPHALITIS RNA CONTROL	<b>MBC098</b>	12,500-20,000
AMPLIRUN® YELLOW FEVER VIRUS RNA CONTROL	<b>MBC100</b>	12,500-20,000
AMPLIRUN® YERSINIA ENTEROCOLITICA DNA CONTROL	<b>MBC027</b>	10,000-20,000
AMPLIRUN® ZIKA VIRUS (ASIAN LINEAGE) RNA CONTROL	<b>MBC103</b>	12,500-20,000
AMPLIRUN® ZIKA VIRUS RNA CONTROL	<b>MBC072</b>	12,500-20,000

