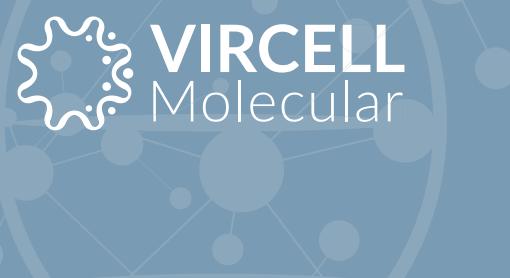


# AMPLIRUN TOTAL<sup>®</sup>

INDEPENDENT MOLECULAR CONTROLS  
FOR INFECTIOUS DISEASES TESTING



# AMPLIRUN® TOTAL

## Independent Molecular Controls



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



### MAIN FEATURES

- 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.
- Quantified, low positive controls - 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.
- Shelf life: up to 2,5 years from date of manufacture.



### 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), ELITe InGenius® (ELITechGroup), Vivalytic (Bosch) 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.



# AMPLIRUN® TOTAL

## Independent Molecular Controls for infectious diseases testing

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.

### GASTROINTESTINAL INFECTIONS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL) <i>Clostridium difficile</i> RT027	<b>MBTC026-R</b>	RUO	500 µL	10 vials
AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL) <i>Campylobacter jejuni</i> , <i>Clostridium difficile</i> , <i>Escherichia coli</i> (EHEC), <i>Salmonella enteritidis</i> , <i>Shigella flexneri</i> , <i>Yersinia enterocolitica</i>	<b>MBTC021</b>	CE	500 µL	10 vials
STOOL MATRIX NEGATIVE CONTROL	<b>MC107</b>	RUO	500 µL	10 vials

### INFECTIOUS MONONUCLEOSIS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL EBV CONTROL (PLASMA) Epstein-Barr virus (International Units - EBV B95-8 strain)	<b>MBTC019-R</b>	RUO	200 µL	10 viales

### MENINGITIS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL MENINGITIS CONTROL (CSF)* Enterovirus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, human parechovirus, varicella zoster virus, cytomegalovirus, <i>Escherichia coli</i> K1, <i>Haemophilus influenzae</i> , <i>Listeria monocytogenes</i> , <i>Neisseria meningitidis</i> , <i>Streptococcus agalactiae</i> , <i>Streptococcus pneumoniae</i> , <i>Cryptococcus neoformans</i>	<b>MBTC025-R</b>	RUO	400 µL	10 viales (5x2)

\* Available soon

## RESPIRATORY INFECTIONS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB) <i>Bordetella pertussis, Chlamydophila pneumoniae, Chlamydophila psittaci, Coxiella burnetii, Legionella pneumophila, Mycoplasma pneumoniae</i>	<b>MBTC022-R</b>	RUO	500 µL	10 vials
AMPLIRUN® TOTAL FLUA/FLUB/RSV CONTROL (SWAB) Influenza A, Influenza B, respiratory syncytial virus (RSV)	<b>MBTC028</b>	CE	500 µL	10 vials
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB) Adenovirus 4, coronavirus, influenza A H3N2, influenza B, novel influenza A H1N1, parainfluenza 1, parainfluenza 2, parainfluenza 3, RSV (subtype A), RSV (subtype B)	<b>MBTC020</b>	CE	200 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) SARS-CoV-2	<b>MBTC030</b>	CE	500 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) SARS-CoV-2, influenza A, influenza B, RSV	<b>MBTC031</b>	CE	500 µL	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	<b>MC110</b>	RUO	500 µL	10 vials
SPUTUM NEGATIVE CONTROL	<b>MC129</b>	RUO	500 µL	10 vials

## SEXUALLY TRANSMITTED DISEASES

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE) <i>Chlamydia trachomatis, Neisseria gonorrhoeae</i>	<b>MBTC006</b>	CE 0318	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG CONTROL (URINE) <i>Chlamydia trachomatis, Neisseria gonorrhoeae</i>	<b>MBTC003</b>	CE 0318	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) <i>Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium</i>	<b>MBTC024-R</b>	RUO	1 mL	10 vials
AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB) 4 vials x <i>Mycoplasma genitalium</i> sensitive type strain 3 vials x <i>Mycoplasma genitalium</i> harboring the A2059G mutation in 23S rRNA gene 3 vials x <i>Mycoplasma genitalium</i> harboring the A2058G mutation in 23S rRNA gene	<b>MBTC029</b>	CE	1 mL	10 vials (4+3+3)
AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB) Monkeypox virus	<b>MBTC032-R</b>	RUO	500 µL	10 vials
AMPLIRUN® TOTAL GENITAL ULCER CONTROL (SWAB)* <i>Chlamydia trachomatis serovar LGV, herpes simplex 1, herpes simplex 2, Treponema pallidum, Haemophilus ducreyi, varicella-zoster virus and mpox virus</i>	<b>MBTC034-R</b>	RUO	500 µL	10 vials
AMPLIRUN® TOTAL VAGINAL PANEL CONTROL (SWAB)* <i>Lactobacillus crispatus, Candida albicans, Atopobium vaginae, Gardnerella vaginalis, Trichomonas vaginalis, Candida krusei</i>	<b>MBTC033-R</b>	RUO	500 µL	10 vials (5x2)

\* Available soon

## TORCH

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL CMV CONTROL (PLASMA) Cytomegalovirus (International Units - hCMV Merlin strain)	<b>MBTC018-R</b>	RUO	200 µL	10 vials
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE) Herpes simplex virus & Varicella-zoster virus	<b>MBTC016</b>	CE	200 µL	10 vials

## MYCOBACTERIAL INFECTIONS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM) 2 vials x <i>Mycobacterium tuberculosis</i> 2 vials x <i>Mycobacterium tuberculosis</i> RIF resistant rpoB mutation (S531L) 2 vials x <i>Mycobacterium tuberculosis</i> RIF resistant rpoB mutation (H526D) 2 vials x <i>Mycobacterium tuberculosis</i> INH resistant katG mutation (S315T) 2 vials x <i>Mycobacterium tuberculosis</i> INH resistant inhA mutation (C15T)	<b>MBTC027</b>	CE	1 mL	10 vials (5x2)
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM) <i>Mycobacterium tuberculosis</i>	<b>MBTC013</b>	CE	1 mL	10 vials
AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM) 5 vials x <i>Mycobacterium tuberculosis</i> katG mutation (S315T) 5 vials x <i>Mycobacterium tuberculosis</i> inhA mutation (C15T)	<b>MBTC015</b>	CE	1 mL	10 vials (2x5)
AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM) 5 vials x <i>Mycobacterium tuberculosis</i> rpoB mutation (S531L) 5 vials x <i>Mycobacterium tuberculosis</i> rpoB mutation (H526D)	<b>MBTC014</b>	CE	1 mL	10 vials (2x5)

## VECTOR-BORNE INFECTIONS

Description	Cat. No.	Class	Fill volume	Pack size
AMPLIRUN® TOTAL ZIKV/DENV/CHIKV CONTROL (PLASMA) Zika virus, dengue virus (1-4), chikungunya virus	<b>MBTC023</b>	CE	200 µL	10 vials



More information

PMS003-05/25



Vircell, S.L. Parque Tecnológico de la Salud, Avicena 8. 18016 Granada, Spain. [info@vircell.com](mailto:info@vircell.com) · [www.vircell.com](http://www.vircell.com)

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