

# AMPLIRUN TOTAL®

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.	Fill volume	Pack size
AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL) <i>Clostridium difficile</i> RT027	RUO	<b>MBTC026-R</b>	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>	CE	<b>MBTC021</b>	500 µL	10 vials

### INFECTIOUS MONONUCLEOSIS

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

### MENINGITIS

Description		Cat. No.	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>	RUO	<b>MBTC025-R</b>	200 µL	10 vials (5x2)

\* Available soon

## RESPIRATORY INFECTIONS

Description		Cat. No.	Fill volume	Pack size
AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB) <i>Bordetella pertussis</i> , <i>Chlamydomphila pneumoniae</i> , <i>Chlamydomphila psittaci</i> , <i>Coxiella burnetii</i> , <i>Legionella pneumophila</i> , <i>Mycoplasma pneumoniae</i>	RUO	<b>MBTC022-R</b>	500 µL	10 vials
AMPLIRUN® TOTAL FLUA/FLUB/RSV CONTROL (SWAB) Influenza A, Influenza B, respiratory syncytial virus (RSV)	CE	<b>MBTC028</b>	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)	CE	<b>MBTC020</b>	200 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) SARS-CoV-2	CE	<b>MBTC030</b>	500 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) SARS-CoV-2, influenza A, influenza B, RSV	CE	<b>MBTC031</b>	500 µL	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	RUO	<b>MC110</b>	500 µL	10 vials
SARS-CoV-2 ALPHA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Alpha variant	RUO	<b>MC129</b>	500 µL	10 vials
SARS-CoV-2 BETA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Beta variant	RUO	<b>MC130</b>	500 µL	10 vials
SARS-CoV-2 GAMMA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Gamma variant	RUO	<b>MC131</b>	500 µL	10 vials
SARS-CoV-2 DELTA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Delta variant	RUO	<b>MC133</b>	500 µL	10 vials

## SEXUALLY TRANSMITTED DISEASES

Description		Cat. No.	Fill volume	Pack size
AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE) <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i>	CE <sub>0318</sub>	<b>MBTC006</b>	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG CONTROL (URINE) <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i>	CE <sub>0318</sub>	<b>MBTC003</b>	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Trichomonas vaginalis</i> , <i>Mycoplasma genitalium</i>	RUO	<b>MBTC024-R</b>	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	CE	<b>MBTC029</b>	1 mL	10 vials (4+3+3)
AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB) Monkeypox virus	RUO	<b>MBTC032-R</b>	500 µL	10 vials

## TORCH

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

## MYCOBACTERIAL INFECTIONS

Description		Cat. No.	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)	CE	<b>MBTC027</b>	1 mL	10 vials (5x2)
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM) <i>Mycobacterium tuberculosis</i>	CE	<b>MBTC013</b>	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)	CE	<b>MBTC015</b>	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)	CE	<b>MBTC014</b>	1 mL	10 vials (2x5)

## VECTOR-BORNE INFECTIONS

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

## GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL)	RUO	<b>MBTC026-R</b>
AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)	CE	<b>MBTC021</b>

## INFECTIOUS MONONUCLEOSIS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)	CE	<b>MBTC019</b>
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## MENINGITIS

AMPLIRUN® TOTAL MENINGITIS CONTROL (CSF)*	RUO	<b>MBTC025-R</b>
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## RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)	RUO	<b>MBTC022-R</b>
AMPLIRUN® TOTAL FLUA/FLUB/RSV CONTROL (SWAB)	CE	<b>MBTC028</b>
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)	CE	<b>MBTC020</b>
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB)	CE	<b>MBTC030</b>
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)	CE	<b>MBTC031</b>
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	RUO	<b>MC110</b>
SARS-CoV-2 ALPHA VARIANT TOTAL CONTROL (NEUTRAL MATRIX)	RUO	<b>MC129</b>
SARS-CoV-2 BETA VARIANT TOTAL CONTROL (NEUTRAL MATRIX)	RUO	<b>MC130</b>
SARS-CoV-2 GAMMA VARIANT TOTAL CONTROL (NEUTRAL MATRIX)	RUO	<b>MC131</b>
SARS-CoV-2 DELTA VARIANT TOTAL CONTROL (NEUTRAL MATRIX)	RUO	<b>MC133</b>

## SEXUALLY TRANSMITTED DISEASES

AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)	CE <sub>0318</sub>	<b>MBTC006</b>
AMPLIRUN® TOTAL CT/NG CONTROL (URINE)	CE <sub>0318</sub>	<b>MBTC003</b>
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)	RUO	<b>MBTC024-R</b>
AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)	CE	<b>MBTC029</b>
AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB)	RUO	<b>MBTC032-R</b>

## TORCH

AMPLIRUN® TOTAL CMV CONTROL (PLASMA)	RUO	<b>MBTC018-R</b>
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE)	CE	<b>MBTC016</b>

## MYCOBACTERIAL INFECTIONS

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

## VECTOR-BORNE INFECTIONS

AMPLIRUN® TOTAL ZIKV/DENV/CHIKV CONTROL (PLASMA)	CE	<b>MBTC023</b>
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\* Available soon

