

AMPLIRUN TOTAL[®]

INDEPENDENT MOLECULAR CONTROLS
FOR INFECTIOUS DISEASES TESTING



VIRCELL
Molecular

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	MBTC026-R	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	MBTC021	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	MBTC019	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	MBTC025-R	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	MBTC022-R	500 µL	10 vials
AMPLIRUN® TOTAL FLUA/FLUB/RSV CONTROL (SWAB) Influenza A, Influenza B, respiratory syncytial virus (RSV)	CE	MBTC028	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	MBTC020	200 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) SARS-CoV-2	CE	MBTC030	500 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) SARS-CoV-2, influenza A, influenza B, RSV	CE	MBTC031	500 µL	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	RUO	MC110	500 µL	10 vials
SARS-CoV-2 ALPHA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Alpha variant	RUO	MC129	500 µL	10 vials
SARS-CoV-2 BETA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Beta variant	RUO	MC130	500 µL	10 vials
SARS-CoV-2 GAMMA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Gamma variant	RUO	MC131	500 µL	10 vials
SARS-CoV-2 DELTA VARIANT TOTAL CONTROL (NEUTRAL MATRIX) SARS-CoV-2 Delta variant	RUO	MC133	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 ₀₃₁₈	MBTC006	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG CONTROL (URINE) <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i>	CE ₀₃₁₈	MBTC003	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	MBTC024-R	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	MBTC029	1 mL	10 vials (4+3+3)
AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB) Monkeypox virus	RUO	MBTC032-R	500 µL	10 vials

TORCH

Description		Cat. No.	Fill volume	Pack size
AMPLIRUN® TOTAL CMV CONTROL (PLASMA) Cytomegalovirus (International Units - hCMV Merlin strain)	RUO	MBTC018-R	200 µL	10 vials
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE) Herpes simplex virus & Varicella-zoster virus	CE	MBTC016	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	MBTC027	1 mL	10 vials (5x2)
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM) <i>Mycobacterium tuberculosis</i>	CE	MBTC013	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	MBTC015	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	MBTC014	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	MBTC023	200 µL	10 vials

GASTROINTESTINAL INFECTIONS

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

INFECTIOUS MONONUCLEOSIS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)	CE	MBTC019
--------------------------------------	----	----------------

MENINGITIS

AMPLIRUN® TOTAL MENINGITIS CONTROL (CSF)*	RUO	MBTC025-R
---	-----	------------------

RESPIRATORY INFECTIONS

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

SEXUALLY TRANSMITTED DISEASES

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

TORCH

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

MYCOBACTERIAL INFECTIONS

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

VECTOR-BORNE INFECTIONS

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

* Available soon



Vircell, S.L. Parque Tecnológico de la Salud, Avicena 8. 18016 Granada, Spain. info@vircell.com · www.vircell.com

Distributed by Abacus dx

1800 ABACUS (AUS) 0800 222 170 (NZ) | info@abacusdx.com | www.abacusdx.com

abacus dx