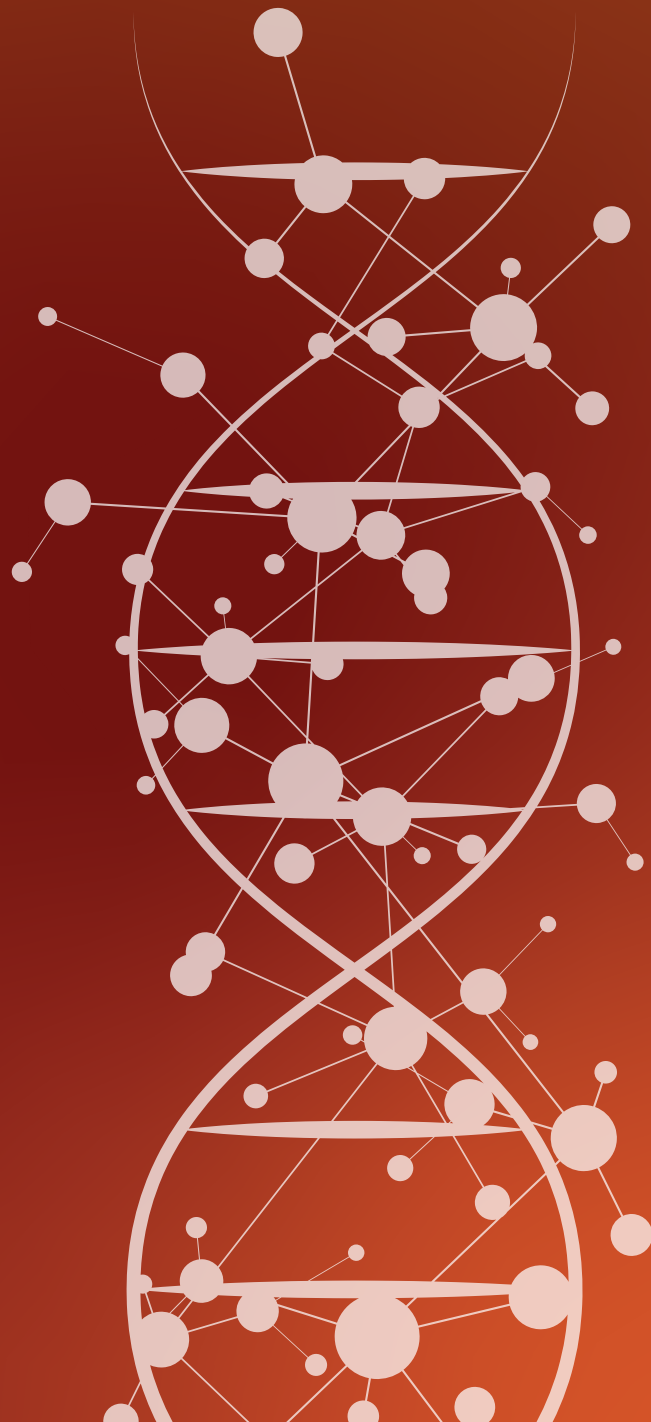


AMPLIRUN TOTAL®

INDEPENDENT MOLECULAR CONTROLS
FOR INFECTIOUS DISEASES TESTING



AMPLIRUN® TOTAL

Complete inactivated microorganism



AMPLIRUN TOTAL 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.
- Applicable for a range of matrices: plasma, swab, sputum, exudate, urine, stool and CSF
- **Multiple platform compatibility.**
- Shelf life: up to 2,5 years from date of manufacture.



PRODUCT APPLICATIONS

- **Third-party external control** to monitor the full analytical process: extraction, amplification, and detection.
- Incorporated into routine analysis as **positive controls** (mainly commercial assays).
- **Daily/weekly control** of molecular assays and diagnostic verification.
- **Cartridge-based POC systems** (e.g., GeneXpert, Biofire, M10) usually lack positive controls. Compatible with most commonly used platforms.
- Validation/verification of new assays, staff, or instrumentation (IQ, OQ, PQ).
- **Monitoring laboratory workflow variations**, including new reagent lots.
- Supports laboratories in meeting **Quality/Certification requirements**.

MULTIPLE PLATFORM COMPATIBILITY

GeneXpert® (Cepheid), BD MAX™ (Becton Dickinson), FilmArray® (BioFire), ELITE InGenius® (ELITechGroup), Vivalytic (Bosch) or Liaison® MDX (Diasorin Molecular), STANDARD™ M10 (SD Biosensor), among others.

CUSTOM SOLUTIONS

With over **30 years of expertise** and advanced biological technologies, Vircell designs and delivers fully customized molecular controls tailored to your specific requirements. Supported by **one of Europe's largest BSL-3 facilities**, we offer amplification controls, extraction & amplification controls, and certified negative matrices. Ideal for **IVD manufacturers, EQA providers**, and laboratories seeking reliable, high-quality bespoke solutions.

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**.



CENTRAL NERVOUS SYSTEM INFECTIONS

DESCRIPTION	CAT. No.	CLASS	FILL VOLUME	PACK SIZE
AMPLIRUN® TOTAL MENINGITIS CONTROL (CSF) • VIRCELL TOTAL MENINGITIS BACT/FUNG CONTROL (CSF): 5 vials with lyophilized cells of <i>Haemophilus influenzae</i>, <i>Listeria monocytogenes</i>, <i>Streptococcus pneumoniae</i>, <i>E. coli</i> K1, <i>Neisseria meningitidis</i>, <i>Streptococcus agalactiae</i> and <i>Cryptococcus neoformans</i>. • VIRCELL TOTAL MENINGITIS VIRUS CONTROL (CSF): 5 vials with lyophilized viral particles of enterovirus 71, herpes simplex 1, herpes simplex 2, HHV-6, varicella zoster, parechovirus 1 and cytomegalovirus	MBTC025-R	RUO	400 µL	10 vials (2x5)



GASTROINTESTINAL INFECTIONS

DESCRIPTION	CAT. No.	CLASS	FILL VOLUME	PACK SIZE
AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL) <i>Clostridium difficile</i> RT027	MBTC026-R	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>	MBTC021	CE	500 µL	10 vials
STOOL MATRIX NEGATIVE CONTROL	MC107	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)	MBTC019-R	RUO	200 µL	10 vials



MYCOBACTERIAL INFECTION

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)	MBTC027	CE	1 mL	10 vials (5X2)
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM) <i>Mycobacterium tuberculosis</i>	MBTC013	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)	MBTC015	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)	MBTC014	CE	1 mL	10 vials (2X5)



RESPIRATORY INFECTIONS

DESCRIPTION	CAT. No.	CLASS	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>	MBTC022-R	RUO	500 µL	10 vials
AMPLIRUN® TOTAL FLU A/FLU B/ RSV CONTROL (SWAB) Influenza A, Influenza B, respiratory syncytial virus	MBTC028	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)	MBTC020	CE	200 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2 CONTROL (SWAB) SARS-CoV-2	MBTC030	CE	500 µL	10 vials
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus	MBTC031	CE	500 µL	10 vials
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	MC110	RUO	500 µL	10 vials
SPUTUM NEGATIVE CONTROL	MC128	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>	MBTC006	CE ₀₃₁₈	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG CONTROL (URINE) <i>Chlamydia trachomatis, Neisseria gonorrhoeae</i>	MBTC003	CE ₀₃₁₈	1 mL	10 vials
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) <i>Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium</i>	MBTC024-R	RUO	1 mL	10 vials
AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB) <i>Mycoplasma genitalium</i> wildtype, <i>Mycoplasma genitalium</i> A2059G mutation (23S), <i>Mycoplasma genitalium</i> A2058G mutation (23S)	MBTC029	CE	1 mL	10 vials (4+3+3)
AMPLIRUN® TOTAL MONKEYPOX VIRUS CONTROL (SWAB) Mpox virus	MBTC032-R	RUO	500 µL	10 vials
AMPLIRUN® TOTAL GENITAL ULCER CONTROL (SWAB) <i>Chlamydia trachomatis</i> serovar LGV, herpes simplex 1, herpes simplex 2, <i>Treponema pallidum</i> , <i>Haemophilus ducreyi</i> , varicella-zoster virus and mpox virus	MBTC034-R	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>	MBTC033-R	RUO	500 µL	10 vials (5x2)



TORCH

DESCRIPTION	CAT. No.	CLASS	FILL VOLUME	PACK SIZE
AMPLIRUN® TOTAL CMV CONTROL (PLASMA) Cytomegalovirus (International Units - hCMV Merlin strain)	MBTC018-R	RUO	200 µL	10 vials
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE) Herpes simplex 1 and 2 and varicella-zoster virus	MBTC016	CE	200 µL	10 vials



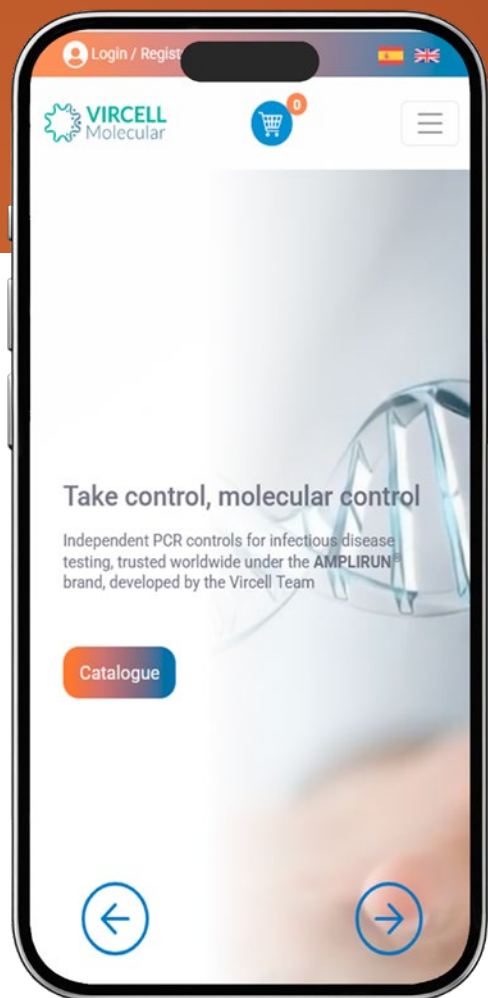
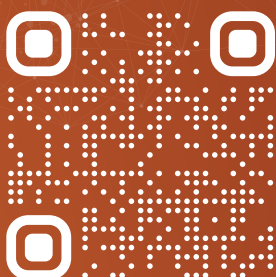
VECTOR TRANSMITTED DISEASES

DESCRIPTION	CAT. No.	CLASS	FILL VOLUME	PACK SIZE
AMPLIRUN® TOTAL ZIKV/DENV/CHIKV CONTROL (PLASMA) Zika virus, dengue virus (1-4), chikungunya virus	MBTC023	CE	200 µL	10 vials

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