

AMPLIRUN[®] TOTAL

A RELIABLE MOLECULAR QUALITY CONTROL
SOURCE FOR INFECTIOUS DISEASES TESTING



Take Control, Molecular Control.





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04 RESPIRATORY INFECTIONS

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07 GASTROINTESTINAL INFECTIONS

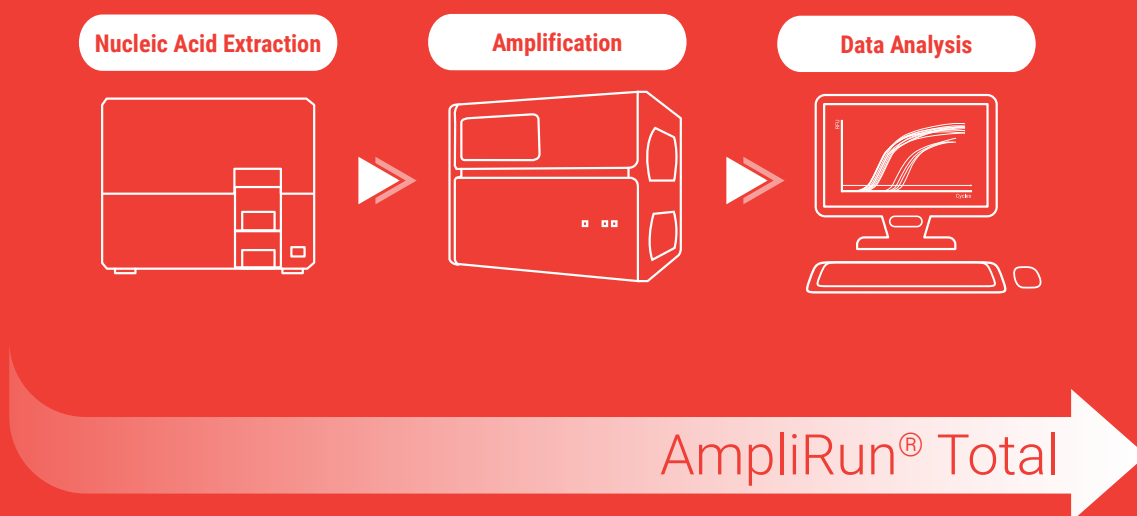
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FULL PROCESS CONTROLS DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE COMPLETE ANALYTICAL PROCESS



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

- **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) 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: 24B63022
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
Kit size: 10 vials



AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)

Code: 24B63019
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
Kit size: 10 vials



AMPLIRUN® TOTAL FLUA/FLUB/RSV CONTROL (SWAB)

Code: 24B63026
Analytes: Influenza A, influenza B, RSV
Matrix: Swab
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Kit size: 10 vials



RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL SARS-COV-2 CONTROL (SWAB)

Code: 24B63028
Analytes: SARS-CoV-2
Matrix: Swab
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Kit size: 10 vials



AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)

Code: 24B63030
Analytes: SARS-CoV-2, influenza A H3N2, influenza B, RSV
Matrix: Swab
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Kit size: 10 vials



RESPIRATORY SWAB MATRIX NEGATIVE CONTROL

Code: 24B63031
Matrix: Swab
Fill volume: 500 µL
Kit size: 10 vials



TUBERCULOSIS INFECTIONS

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

Code:	24B63025
Analytes:	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)
Matrix:	Sputum
Copies/vial:	20,000 to 50,000
Fill volume:	1 mL
Kit size:	10 vials (5x2)



AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)

Code:	24B63014
Analytes:	<i>Mycobacterium tuberculosis</i>
Matrix:	Sputum
Copies/vial:	20,000 to 50,000
Fill volume:	1 mL
Kit size:	10 vials



AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)

Code:	24B63015
Analytes:	5 vials x <i>Mycobacterium tuberculosis</i> katG mutation (S315T) 5 vials x <i>Mycobacterium tuberculosis</i> inhA mutation (C15T)
Matrix:	Sputum
Copies/vial:	20,000 to 50,000
Fill volume:	1 mL
Kit size:	10 vials (2x5)



AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)

Code:	24B63016
Analytes:	5 vials x <i>Mycobacterium tuberculosis</i> rpoB mutation (S531L) 5 vials x <i>Mycobacterium tuberculosis</i> rpoB mutation (H526D)
Matrix:	Sputum
Copies/vial:	20,000 to 50,000
Fill volume:	1 mL
Kit size:	10 vials (2x5)



GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL *CLOSTRIDIUM DIFFICILE* RT027 CONTROL (STOOL)

Code: 24B63027
Analyte: *Clostridium difficile* RT027
Matrix: Stool
Copies/vial: 300,000 to 750,000
Fill volume: 500 µL
Kit size: 10 vials



AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)

Code: 24B63021
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
Kit size: 10 vials



MONONUCLEOSIS INFECTIONS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)

Code: 24B63006
Analyte: Epstein-Barr virus (International Units - EBV B95-8 strain)
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Kit size: 10 vials



VECTOR-BORNE INFECTIONS

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

Code: 24B63023
Analytes: Zika virus, dengue virus (1-4), chikungunya virus
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Kit size: 10 vials



SEXUALLY TRANSMITTED INFECTIONS

AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)

Code: 24B63004
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*
 Matrix: Exudate
 Copies/vial: 2,500 to 10,000
 Fill volume: 1 mL
 Kit size: 10 vials



AMPLIRUN® TOTAL CT/NG CONTROL (URINE)

Code: 24B63005
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*
 Matrix: Urine
 Copies/vial: 2,500 to 10,000
 Fill volume: 1 mL
 Kit size: 10 vials



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

Code: 24B63024
 Analytes: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma genitalium*
 Matrix: Swab
 Copies/vial: 20,000 to 50,000
 Fill volume: 1 mL
 Kit size: 10 vials



AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)

Code: 24B63029
 Analytes: 4 vials x *Mycoplasma genitalium* sensitive type strain
 3 vials x *Mycoplasma genitalium* harboring the A2059G mutation in 23S rRNA gene
 3 vials x *Mycoplasma genitalium* harboring the A2058G mutation in 23S rRNA gene
 Matrix: Swab
 Copies/vial: 20,000 to 50,000
 Fill volume: 1 mL
 Kit size: 10 vials



TORCH INFECTIONS

AMPLIRUN® TOTAL CMV CONTROL (PLASMA)

Code: 24B63001
Analytes: Cytomegalovirus (International Units - hCMV Merlin strain)
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µl
Kit size: 10 vials



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

Code: 24B63008
Analytes: Herpes simplex virus 1 & 2
Matrix: CSF
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Kit size: 10 vials



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

Code: 24B63010
Analytes: Herpes simplex virus 1 & 2
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Kit size: 10 vials



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

Code: 24B63011
Analytes: Herpes simplex virus & Varicella-zoster virus
Matrix: Exudate
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
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 three days in advance.

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@vircell.com

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

RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL SARS-COV-2 CONTROL (SWAB)	24B63028
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB)	24B63030
AMPLIRUN® TOTAL FLUA/FLUB/RSV (SWAB)	24B63026
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)	24B63019
AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)	24B63022
RESPIRATORY SWAB MATRIX NEGATIVE CONTROL	24B63031

MYCOBACTERIAL INFECTIONS

AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)	24B63025
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)	24B63014
AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)	24B63015
AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)	24B63016

GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL)	24B63027
AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)	24B63021

MONONUCLEOSIS INFECTIONS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)	24B63006
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VECTOR-BORNE INFECTIONS

AMPLIRUN® TOTAL ZIKV-DENV -CHIKV CONTROL (PLASMA)	24B63023
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SEXUALLY TRANSMITTED INFECTIONS

AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)	24B63004
AMPLIRUN® TOTAL CT/NG CONTROL (URINE)	24B63005
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)	24B63024
AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)	24B63029

TORCH INFECTIONS

AMPLIRUN® TOTAL CMV CONTROL (PLASMA)	24B63001
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (CSF)	24B63008
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (PLASMA)	24B63010
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE)	24B63011