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

For research use only

MBTC031-R: A panel of four purified respiratory viruses pooled, inactivated to render them non-infectious and formulated in viral transport medium. Table 1 lists type of virus, strain and cell-line used in the culture of each respiratory virus included in this control. This reference is intended to validate and control sample processing, amplification and detection in nucleic acid assays based on the molecular identification of respiratory viruses, using the product as an external run control.

CHARACTERISTICS:

The content is lyophilized. It is necessary to reconstitute it before use (refer to "Preparation of the reagents"). Total Controls are designed for single use, excess material should be discarded. Nucleic acid detection requires an extraction step that releases DNA/RNA for amplification and detection.

Product description:

Viral particles were purified from supernatants of infected cells by differential centrifugation (see Table 1 for cell-line used). Viruses were inactivated, rendering them non-infectious, and diluted in viral transport medium containing cells obtained from epithelial human cell lines.

VIRUS	STRAIN	CELL-LINE
SARS-COV-2	Clinical isolate	VERO E6
INFLUENZA A H3N2	A/Perth/16/2009 (H3N2)	MDCK
INFLUENZA B	B/Brisbane/60/2008	MDCK
RESPIRATORY SYNCYTIAL VIRUS	9320	HEP-2

Table 1

KIT CONTENTS:

1 VIRCELL TOTAL SARS-COV-2-FLUA-FLUB-RSV CONTROL (SWAB): 10 vials with a pooled of lyophilized respiratory viruses simulating a respiratory clinical sample. Each virus is in a concentration that ranges from 10000-25000 copies/vial. Batch concentration is provided in Certificate of Analysis.

Quantification validation was performed by real-time PCR.

Materials required but not supplied:

Molecular Biology grade water

Additional extraction and detection kit.

STORAGE REQUIREMENTS:

Special transport conditions not required. Store the lyophilized vial at 2-8ºC. After reconstitution, suspension should be used on the same day. Unused product should be discarded.

STABILITY AND HANDLING OF REAGENTS:

Handle reagents in aseptic conditions to avoid microbial contaminations.

Use only the amount of reagent required for the test.

The product is stable until the expiry date indicated in the label, if the instructions for use are followed.

VIRCELL, S.L. does not accept responsibility for the mishandling of the reagents included in the kit.

RECOMMENDATIONS AND PRECAUTIONS:

1. This product is for research use only and for professional qualified staff.
2. Sterile tips with aerosol barrier are essential to prevent contamination.
3. Specimens should be handled as in the case of infectious samples using safety laboratory procedures. Thoroughly clean and disinfect all work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in deionized or distilled water.
4. In order to perform the test it is essential to have separate working areas.
5. Dispose of unused reagents and waste in accordance with all applicable regulations.
6. The component VIRCELL TOTAL CONTROL could include genetic material or substances of animal and/or human origin. VIRCELL TOTAL CONTROL contains inactivated microorganism, nevertheless, it should be considered potentially infectious and handled with care. Inactivation was verified by the absence of growth under same culture conditions used for each microorganism. No present method can offer complete assurance that these or other infectious agents are absent. All materials should be handled and disposed as of potentially infectious. Observe the local regulations for waste disposal.

PREPARATION OF THE REAGENTS:

1. Add 500 µl of Molecular Biology grade water to vial 1 and mix until completely reconstituted. The concentration will be approximately 35000 copies/ml for each virus in the panel once reconstituted.
2. Shake with vortex for 30 seconds to dissolve and homogenize completely.
3. Follow research kit instructions treating TOTAL CONTROL in an identical manner to a clinical specimen using recommended amount for extraction and detection.

INTERNAL QUALITY CONTROL:

Each batch is subjected to internal quality control testing before releasing. Quality control analysis is performed using a sample preparation kit and real-time PCR for quantification. Final quality control results for each particular lot are available.

INTERPRETATION OF RESULTS AND VALIDATION PROTOCOL FOR USERS:

Refer to indications of additional extraction and detection kit.

SYMBOLS USED IN LABELS:

RUO	For research use only
	Use by (expiration date)
	Store at x-yºC
LOT	Batch code
REF	Catalogue number
	Consult instructions for use
RCNS Xµl	Reconstitute in x µl
SHIP	Shipment temperature
STORE	Storage temperature

For any question please contact:
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REVISED: 2020-10-06
L-MBTC031-R-EN-01