AMPLIRUN® TOTAL SARS CoV-2 CONTROL (SWAB)

For *in vitro* diagnostic use

MBTC030: Inactivated coronavirus SARS-CoV-2 formulated in viral transport medium and intended to validate and control sample processing, amplification and detection in nucleic acid assays using the product as an external run control.

INTRODUCTION:

SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2) was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China in December 2019. COVID-19, the disease produced by this SARS-CoV-2, is associated with lower respiratory tract infections. Symptoms reported for patients with SARS-CoV-2 include mild to severe respiratory illness with fever, cough, and difficulty breathing. WHO, on March 11th 2020 declared COVID-19 a pandemic.

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 purified from supernatants of infected VERO E6 cells by centrifugation. Viruses are inactivated rendering them non-infectious and diluted in transport medium containing cells obtained from epithelial human cell lines.

KIT CONTENTS:

1 VIRCELL TOTAL SARS-CoV-2 CONTROL (SWAB): 10 vials with lyophilized SARS-CoV-2 (10000-25000 copies/vial). Batch concentration is provided in Certificate of Analysis.

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 *in vitro* diagnosis 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 once reconstituted.
2. Shake with vortex for 30 seconds to dissolve and homogenize completely.
3. Follow diagnostic 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.

LIMITATIONS OF METHOD:

1. This reagent is intended to be used with methods of human diagnostics. This test has not been verified with other methods.
2. The user of this kit is advised to read carefully and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results.
3. Use of this product should be limited only to personnel trained in molecular techniques.
4. This external run control does not substitute internal diagnostic kit controls.
5. Quantification conclusions cannot be drawn from a single point sample of known concentration. Precise clinical sample quantification could only be achieved by the standard curve method using a calibrator.
6. AMPLIRUN® TOTAL has not been designed to be used with a particular diagnostic kit coming from a certain manufacturer. It is used to validate and control sample processing, analysis and detection of a diagnostic laboratory functioning procedure.

PERFORMANCES:

- **IDENTITY TEST**

PCR analysis was performed after extraction with a specific oligonucleotide pair for SARS-CoV-2 previously described in literature. The reaction produced specific amplification.

QUANTIFICATION TEST

Quantification is based on Real-Time qPCR using the standard curve method. Real-time PCR analysis of three replicates of one vial. The concentration (Log copies/vial) is determined by interpolating the Ct value obtained for each replicate on the previously obtained standard curve performed with the corresponding quantification standard. Result: CV% < 0,5.

- **PRECISION**

Real-time PCR analysis including 2 replicates of one vial, two runs per day (with different operators and different thermocyclers) for 20 days. The CV% of within-run precision, between-run precision, between-day precision and between-laboratory precision were analysed.

Results: CV% < 2,2.

SYMBOLS USED IN LABELS:

IVD	*In vitro* diagnostic medical device
	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

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