

AMPLIRUN® SARS-CoV-2 RNA CONTROL

For *in vitro* diagnostic use

MBC137: Purified RNA of coronavirus SARS-CoV-2 to be used to control *in vitro* diagnosis techniques based in nucleic acids amplification.

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 lyophilized nucleic acid is included in a thermo-sealed foil pouch containing a silica gel bag. It is necessary to reconstitute it before use (refer to "Preparation of reagents").

Preparation: Grown in Vero E6 infected cells.

Extract preparation: Commercial genomic RNA extraction method.

KIT CONTENTS:

1 VIRCELL SARS-CoV-2 RNA CONTROL: 1 vial with lyophilized RNA of coronavirus SARS-CoV-2, (Spanish clinical isolate), (12500-20000 copies/μl once reconstituted (see Table 1)). RNA quantification has been performed by real-time PCR.

2 VIRCELL CONTROL RECONSTITUTION SOLUTION: 500 μl of molecular biology grade water, DNase, RNase free.

Lot number	
Concentration	copies/μl

Table 1.

Materials required but not supplied:
Additional diagnosis kit.

STORAGE REQUIREMENTS:

Special transport conditions not required. Store the lyophilized vial at 2-8°C inside the foil pouch. Once the pouch is opened, reconstitute the lyophilized vial immediately and store between -70°C and -90°C after reconstitution (temperature indicated on the label).

STABILITY AND HANDLING OF REAGENTS:

Handle reagents in aseptic conditions to avoid microbial contaminations.

Use only the amount of reagent required for the test.

After control resuspension RNA solution should be aliquoted in order to avoid multiple freeze-thaw cycles. 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 RNA CONTROL could include genetic material or substances of animal and/or human origin. VIRCELL RNA CONTROL contains coronavirus SARS-CoV-2 nucleic acids. VIRCELL RNA CONTROL contains purified nucleic acids obtained from inactivated microorganism, nevertheless, it should be considered potentially infectious and handled with care. 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 clinical waste disposal.
7. Dilutions below 1000 copies/μl should be made immediately before use. Freezing of product dilutions containing less than 1000 copies/μl is not recommended as partial RNA degradation might occur.

PREPARATION OF THE REAGENTS:

1. Tear the foil pouch containing VIRCELL RNA CONTROL 1.
2. Centrifuge VIRCELL RNA CONTROL 1 1 minute at 1000 g.
3. Add 50 μl of VIRCELL CONTROL RECONSTITUTION SOLUTION 2 and mix until completely reconstituted. The concentration will be 12500-20000 copies/μl once reconstituted (see Table 1).
4. Shake with vortex for 30 seconds to dissolve and homogenize completely.
5. It is recommended to prepare VIRCELL RNA CONTROL aliquots. In case dilutions were to be prepared use VIRCELL CONTROL RECONSTITUTION SOLUTION 2 for this purpose.

TEST PROCEDURE:

Once nucleic acid is reconstituted, use it according to indications of additional diagnosis kit. Use resuspended VIRCELL CONTROL as an extracted clinical sample adding it directly to amplification reagents.

INTERNAL QUALITY CONTROL:

Each batch is subjected to internal quality control testing before releasing. Quality control analysis is performed by real-time PCR. Final quality control results for each particular lot are available.

INTERPRETATION OF RESULTS AND VALIDATION PROTOCOL FOR USERS:

Refer to indications of additional diagnosis kit.

LIMITATIONS OF METHOD:

1. This reagent is intended to be used with methods of human diagnosis. 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. The identity test was carried out with some specific primers according to publicly available sequences of the microorganism. Changes in the sequences of the primers of the reaction may produce a range of different sizes or may not display product amplification.

5. This control does not substitute internal diagnostic kit controls.

6. The quantification was carried out by own brand qPCR against a standard used as a calibrator. Results may vary with the amplification conditions of the end user.

7. AMPLIRUN® has not been designed to be used with a particular diagnostic kit coming from a certain manufacturer. It is used to control amplification of a diagnostic laboratory functioning procedure.

PERFORMANCES:

• IDENTITY TEST

RT-PCR analysis of RNA control: RNA Control was analysed by RT-PCR using the 1:1000 dilution with a specific oligonucleotide pair. RT-PCR reaction was positive. RNA amplification was performed using oligonucleotides described in the literature (see Certificate of Analysis).

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 is determined by interpolating the Ct value obtained for each replicate on the previously obtained standard curve performed with the corresponding quantification standard. Concentration was in the acceptable range: 12500 – 20000 copies/μl.

• 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.

Less than 10% coefficient of variance was observed between all assays.

SYMBOLS USED IN LABELS:

	In vitro diagnostic medical device
	Use by (expiration date)
	Store at x-y°C
	Batch code
	Catalogue number
	Consult instructions for use
	Reconstitute in x μl
	Shipment temperature
	Storage temperature
	Do not open until use

BIBLIOGRAPHY:

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