AMPLIRUN® SARS-CoV-2 B.1.1.7 RNA CONTROL

Product information

1. Name / reference / description / characteristics / Utilization

Name AMPLIRUN® SARS-CoV-2 B.1.1.7 RNA CONTROL
Reference: MBC138-R
Description:
Purified RNA of Coronavirus SARS-CoV-2 B.1.1.7 lineage (also known as VOC 202012/01 or UK variant) to be used to control techniques based in nucleic acids amplification.

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.

Viral preparation: Grown in Vero C1008 infected cells.
Extract preparation: Commercial genomic RNA extraction method.
Utilization: For research use only

2. Kit contents

- VIRCELL SARS-CoV-2 B.1.1.7 RNA CONTROL:
  1 vial with lyophilized RNA of Coronavirus SARS-CoV-2 B.1.1.7, Spanish clinical isolate, providing 12500-20000 copies/µl once reconstituted. RNA quantification has been performed by real-time PCR.

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

3. Transport and Storage requirements

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

4. 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.

5. Recommendations and precautions:

1. For research use only. Not for use in diagnostic procedures.
2. Sterile tips with aerosol barrier are essential to prevent contamination.
3. Specimens should be handled as in the case of infectious samples using research 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 DNA CONTROL contains Coronavirus SARS-CoV-2 B.1.1.7 nucleic acids. VIRCELL RNA CONTROL contains purified nucleic acids obtained from inactivated microorganisms, 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 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.

6. Preparation of the reagents:

1. Tear the foil pouch containing VIRCELL RNA CONTROL.
2. Centrifuge VIRCELL RNA CONTROL 1 minute at 1000 g.
3. Add 50 µl of VIRCELL CONTROL RECONSTITUTION SOLUTION and mix until completely reconstituted. The concentration will be 12500-20000 copies/µl once reconstituted. The exact concentration and the corresponding batch number appear in the Table 1 in the package insert.
4. Shake with vortex for 30 seconds to dissolve and homogenize completely.

7. 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.

8. Main features of the AMPLIRUN® SARS-CoV-2 B.1.1.7 RNA CONTROL

- Allows validation of RT-PCR assays for COVID-19 (VOC 202012/01 or UK variant) diagnosis.
- Purified nucleic acid, complete microbial genome.
- Any target can be amplified.
- RNA origin from a cultivated Spanish clinical isolate. Full sequence available.
- Precise concentration in copies/µl verified by Digital Droplet PCR (ddPCR).
- Non-infectious material provided with inactivation certificate.
- Lyophilized presentation ensures stability and reduces transport costs.
- Valid for any molecular testing platform.
- AmpliRun® RNA Controls have a shelf life of 2 years from the date of manufacture.

9. Product Applications

- Quality assurance of the amplification testing
- Limit of detection and assay specificity.
- Lot-to-lot verification assay.
- Development, optimization and validation of new assays.
- Training and trial purposes.
- Regulatory requirements and accreditation compliance.