

NATtrol™ SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls

PRODUCT DESCRIPTION:

NATtrol™ SARS-CoV-2 External Run Controls (NATSARS(COV2)-ERC1 and NATSARS(COV2)-NEG1) contain purified, intact viral particles (positive control) and human A549 cells (negative control). The viral particles have been chemically modified to render them non-infectious and refrigerator stable. The controls are supplied in a proprietary matrix.

INTENDED USE:

NATtrol™ SARS-CoV-2 external run controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of SARS-CoV-2 RNA. NATSARS(COV2)-ERC1 and NATSARS(COV2)-NEG1 enable laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

MATERIALS SUPPLIED:

- Each control pack contains 6 x 1.0 mL vials.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on SARS-CoV-2 stocks used to formulate the controls. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated SARS-CoV-2 and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that has been tested and found to be non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods.
- Heat inactivated Fetal Bovine Serum used in the manufacture of this product meets applicable USDA requirements for abattoir sourced animals, traceability, and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and postmortem at the abattoir as required by the USDA.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ SARS-CoV-2 External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATIONS:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.**
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

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EXPECTED RESULTS:

- The target concentration values provided in Table 1 are tested in ZeptoMetrix in-house real-time PCR assay.
- It is the responsibility of the end user to establish their own target range and limits for the controls using their laboratory's procedures.








Table 1

| Catalog Number | Isolate / Cell Line | Target Concentration |
|--------------------|-----------------------------|----------------------|
| NATSARS(COV2)-ERC1 | USA-WA1/2020 ^{1,2} | 50,000 cp/mL |
| NATSARS(COV2)-NEG1 | A-549 | 50,000 cells/mL |

¹Based on in-house real time PCR assay targeting the N gene region.

²This reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA-WA1/2020, NR-52281.

Symbols used in the labeling of this product:

| | | | |
|---|-----------------------|---|------------------------|
|  | Manufacturer |  | Temperature Limitation |
|  | For Research Use Only |  | Expiration Date |
|  | Catalog Number |  | Biological Risk |
|  | Batch Code | | |