

PRODUCT DESCRIPTION:

NATtrol™ Coronavirus Type 229E Stock* (qualitative) is formulated with purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable. Each vial contains 1.0 mL of NATtrol™ Coronavirus Type 229E stock in a proprietary matrix.

*Pat.:http://www.zeptometrix.com/patent-information/

INTENDED USE:

 NATtrol™ Coronavirus Type 229E stock is designed to evaluate the performance of nucleic acid tests for determination of the presence of Coronavirus 229E nucleic acid. NATtrol™ Coronavirus Type 229E stock enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on Coronavirus Type 229E stock used to formulate the product. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated microorganisms 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 nonreactive 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 post mortem 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™ Coronavirus Type 229E Stock should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial 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.

LIMITATION:

- 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.

EXPECTED RESULTS:

- Each laboratory must evaluate the product and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

TABLE 1:

Catalog Number	Target Concentration (Ct range)**		
NATCOV(229E)-ST	22-25		

^{**}Cycle threshold (Ct) range based on in-house real time assay targeting the membrane protein (M) gene region.

PCR

PINATCOV(229E)-ST Revision: 08 Effective Date: 03/18/2022

REF	Catalog Number	X	Temperature Limitation
LOT	Batch Code	M	Expiration Date
RUO	For Research Use Only	®	Biological Risk
ш	Manufacturer		