

PRODUCT DESCRIPTION:

NATrol™ SARS-CoV-2 Variant Panel* is formulated with purified, intact viral particles. The virus particles have been chemically modified to render them non-infectious and refrigerator stable. NATSARS(COV2)-VP contains 4 x 0.5mL vials of viral NATrol™ as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

INTENDED USE:

NATrol™ SARS-CoV-2 Variant Panel can be used to develop procedures for verification of performance of molecular assays that detect the presence of viral nucleic acids (listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

WARNINGS AND PRECAUTIONS:

- NATrol™ inactivation was carried out on SARS-CoV-2 stocks 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 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 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:

- NATrol™ SARS-CoV-2 Variant Panel 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.

LIMITATION:

- FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Use 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 performance criteria.
- Virus information and target level listed in table below.

TABLE 1: PANEL MEMBERS

| SARS-CoV-2 Panel Member | Isolate | Target Concentration |
|---------------------------------|--|-------------------------------|
| Lineage B.1.1.7 Alpha Variant | England/204820464/2020 ¹ | 50,000 copies/mL ⁵ |
| Lineage B.1.351 Beta Variant | South Africa/KRISP-K005325/2020 ² | |
| Lineage P.1 Gamma Variant | Japan/TY7-503/2021 ³ | |
| Lineage B.1.617.2 Delta Variant | USA/PHC658/2021 ⁴ | |

¹ This reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/England/204820464/2020, NR-54000, contributed by Bassam Hallis.








² This reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/South Africa/KRISP-K005325/2020, NR-54009, contributed by Alex Sigal and Tulio de Oliveira.

³ This reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/Japan/TY7-503/2021 (Brazil P.1), NR-54982, contributed by National Institute of Infectious Diseases.

⁴ This reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/USA/PHC658/2021 (Lineage B.1.617.2; Delta Variant), NR-55611, contributed by Dr. Richard Webby and Dr. Anami Patel.

⁵ Quantitation based on in-house RT-PCR assay targeting N gene region. Quantitation standard assigned copies/mL by dPCR.

PINATSARS(COV2)-VP
Revision: 01
Effective Date: 04/17/2024

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

www.zeptometrix.com

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This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.