

PRODUCT DESCRIPTION:

NATtrol™ SARS-CoV-2 (recombinant) Stock* is formulated with purified, intact bacterial cells containing synthetic SARS-CoV-2 sequence. The cells have been chemically modified to render them non-infectious and refrigerator stable. Each vial contains 1.0 mL of NATtrol™ SARS-CoV-2 (recombinant) Stock in a purified protein matrix.

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

INTENDED USE:

- NATtrol™ SARS-CoV-2 (recombinant) Stock is designed to evaluate the performance of nucleic acid tests for determination of the presence of SARS-CoV-2 **N gene**. NATtrol™ SARS-CoV-2 (recombinant) Stock can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the stock used to formulate this product. The inactivation was verified in a standard microbiological growth protocol.
- Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin (HSA) that has been tested and found 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 (FBS) used in the manufacture of this product meet 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.

PRECAUTIONS:

- Although NATtrol™ SARS-CoV-2 (recombinant) Stock contains inactivated bacteria, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ SARS-CoV-2 (recombinant) Stock* should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract nucleic acid prior to use in downstream assays.

TABLE 1:








Catalog Number	Concentration (Ct Range)**
0831042	22-25

**Cycle threshold (Ct) range based on in-house real time PCR assay targeting the SARS-CoV-2 N gene region.

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

PI0831042
Revision: 02
Effective Date: 12/13/2021

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

www.ZeptoMetrix.com

ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 USA • Tel (800) 274-5487

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

PCA# 21-112
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