

Certificate of Analysis

Product Description: NATtrol™ SARS-Related Coronavirus 2 (SARS-CoV-2) Stock

Isolate: USA-WA1/2020*

Catalog Number: NATSARS(COV2)-ST

Lot Number: 330228

Expiration Date: 2023-10-11

Storage Temperature: 2-8°C

Safety Precautions: Use Universal Precautions.

Test	Specification	Concentration	Result
SARS-CoV-2 virus RNA detection by PCR	7.94E+05 - 1.26E+06 cp/mL	8.87E +05 cp/mL	Pass
Inactivation verification**	Inactive		Pass

**Endpoint dilution assays were used to evaluate inactivation of the NATtrol™ master stock used in the manufacture of this product. Three independent samples were inoculated into VeroE6 cells (n=4) and incubated for 7 days at 37°C. The inoculated cell cultures were observed for signs of cytopathic effects (CPE). All inactivated samples must demonstrate no CPE to verify inactivation.

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

Statement of Conformance:

The results reported in this Certificate of Analysis comply with the requirements of ZeptoMetrix's Quality Management System and specifications described in the Master Production Record.

***This 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.**

Date: 11/11/2022

Subject: **Product Change Notification**

Ref: P-22-04

Dear ZeptoMetrix Customer,

To meet our commitment to provide a reliable supply of quality products we have qualified a second manufacturer of 0.5 ml and 2.0 ml sterile polypropylene microtubes for the primary packaging of the following products.

Catalog Number	Description
NATFRC-6C	NATtrol Flu/RSV/SARS-CoV-2 Positive Control (6 x 0.5mL)
NATCV9-6C	NATtrol Flu/RSV/SARS-CoV-2 Negative Control (6 x 0.5mL)
NATSARS(CoV2)-ERC	NATtrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 0.5 mL)
NATSARS(CoV2)-ST	NATtrol SARS-Related Coronavirus 2 (SARS-CoV-2) Stock
NATSARS(CoV2)-NEG	NATtrol SARS-Related Coronavirus 2 (SARS-CoV-2) Negative Control (6 x 0.5 mL)
NATGIP-BIO	NATtrol GI Panel (22 x 0.25mL; 4 x 0.85 mL)
NATBCP2-BIO	NATtrol BCID2 Panel (35 x 0.2m)
NATRVP2.1-BIO	NATtrol Respiratory Verification Panel 2.1 (24 x 0.6mL)
NATRPP-1	NATtrol Respiratory Pathogen Panel -1 (6 x 0.25 mL)
NATGIC-BIO	NATtrol GI Controls (12 x 0.2 mL)
0831042	SARS-CoV-2 (recombinant) Stock (1 x 1.0mL)

ZeptoMetrix has determined the new microtubes are comparable to the current microtubes in design, sterility, material composition, and performance. There will be no impact on the affected products. The manufacturing process, packaging configurations, product performance, and quality standards will remain unchanged.

Effective immediately, individual lots of the products listed will be supplied in microtubes from one of either approved manufacturer. For questions about this change notice, contact us at (800) 274-5487 or ZMC-CustomerService@antylia.com.

Best Regards,
ZeptoMetrix LLC



Diane Waterman
Director QA/RA