Catalog Numbers: NATCTNGTV-POS NATCTNGTV-NEG

ZeptoMetrix® NATtrol™ CT/NG/TV Positive Control NATtrol™ CT/NG/TV Negative Control

PRODUCT DESCRIPTION:

NATtrol[™] CT/NG/TV Positive Control* is formulated with purified, intact microorganisms. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATtrol[™] CT/NG/TV Negative Control* is formulated in the absence of any microorganisms. Each control pack contains 6 x 1.0 mL of NATtrol[™] CT/NG/TV Positive Control or NATtrol[™] CT/NG/TV Negative Control. These controls are provided in a proprietary matrix.

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

INTENDED USE:

 NATtrol[™] CT/NG/TV Positive Control and NATtrol[™] CT/NG/TV Negative Control are designed to evaluate the performance of nucleic acid tests for determination of the presence of *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* DNA. NATtrol[™] CT/NG/TV Positive Control and NATtrol[™] CT/NG/TV Negative Control enable 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 *C.* trachomatis, *N.* gonorrhoeae, and *T.* vaginalis 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 proprietary diluent used in the manufacture of this product contains buffers and preservative.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

 NATtrol[™] CT/NG/TV Positive Control and NATtrol[™] CT/NG/TV Negative Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tubes vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acids 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.
- Organism information and expected results listed in table below.

TABLE 1:

Catalog Number	Organism	Strain	Expected Result	
NATCTNGTV-POS	C. trachomatis	LGVII 434	CT Positive NG Positive TV Positive	
	N. gonorrhoeae	Z017		
	T. vaginalis	Z070		
NATCTNGTV-NEG	N/A		CT Negative NG Negative TV Negative	

ZMC-PI-0039 Revision: 07 Effective Date: 08/01/2023

REF	Catalog Number	X	Temperature Limitation	
LOT	Batch Code	R	Expiration Date	
RUO	For Research Use Only	B	Biological Risk	
www.ZeptoMetrix.com				

PCA# 23-265

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.