

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	<i>C. trachomatis</i>	LGVII 434	CT Positive NG Positive TV Positive
	<i>N. gonorrhoeae</i>	Z017	
	<i>T. vaginalis</i>	Z070	
NATCTNGTV-NEG	N/A		CT Negative NG Negative TV Negative

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