

ZeptoMetrix[®]

NATtrol™ *T. vaginalis* External Run Controls

Catalog Number:
NATTVPOS-6MC
NATTVNEG-6MC

PRODUCT DESCRIPTION:

NATtrol™ *T. vaginalis* External Run Controls* are formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 X 1.2 mL of NATtrol™ *T. vaginalis* (Z070) or NATtrol™ *N. gonorrhoeae* (Z017).

These controls are provided in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ *T. vaginalis* external run controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of *T. vaginalis* nucleic acid. NATTVPOS-6MC and NATTVNEG-6MC 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 bacterial stocks used to formulate the controls. 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ *T. vaginalis* External Run Controls 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**
- 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:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the product and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

TABLE 1:

Catalog Number	Organism	Expected Result
NATTVPOS-6MC	<i>T. vaginalis</i> (Z070)	<i>T. vaginalis</i> is detected
NATTVNEG-6MC	<i>N. gonorrhoeae</i> (Z017)	<i>T. vaginalis</i> is not detected

ZMC-PI-0008
Revision: 12
Effective Date: 09/20/2023

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

PCA# 23-340
Page 1 of 1