NATtrol™ *T. vaginalis* Verification Panel

Catalog #: NATTVGP-C

PRODUCT DESCRIPTION:

NATtrol™ *T. vaginalis* Verification Panel (NATTVGP-C) is formulated with purified, intact organisms that have been chemically modified to render them non-infectious and refrigerator stable*. NATTVGP-C panel contains 17 x 0.7 mL vials each containing NATtrol™ targets listed in Table 1. Each panel contains 4 tubes of each of the *T. vaginalis* Positive members and 5 tubes of the *T. vaginalis* Negative member (*N. gonorrhoeae*).
*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ *T. vaginalis* Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of T. vaginalis nucleic acids. NATTVGP-C can also be used for verification of clinical assays, development of diagnostic tests, and training of laboratory personnel.
- NATTVGP-C contains intact organisms and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on each orgainsm stock used to formulate the panel. The inactivation was verified by the absence of growth in validated growth protocols.

PRECAUTIONS:

- Although NATTVGP-C contains inactivated organisms, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipettes for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ *T. vaginalis* Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Xpert® TV ASSAY:

- Vortex NATtrol™ sample for 5-10 seconds.
- Using a clean transfer pipette (supplied in Xpert® TV test kit), insert pipet into transport tube and release the bulb to fill the transfer pipet to the mark (500µL) on the pipet shaft.
- Ensure the pipette is filled with no air bubbles present.
- Empty the pipette's contents into the sample chamber of the cartridge.
- Close cartridge lid and follow manufacturer's instructions.

Table 1: PANEL MEMBERS

Panel Member	Strain	Xpert® TV Expected Result
T. vaginalis	Z158	TV DETECTED
T. vaginalis	Z159	TV DETECTED
T. vaginalis	MTZ Resistant	TV DETECTED
N. gonorrhoeae	Z017	TV NOT DETECTED

DO NOT USE IN HUMANS

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.

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

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