

INTENDED USE:

NATtrol™ CT/NG/TV Negative Control (NATCTNGTV-NEG-IVD) is a qualitative *in vitro* diagnostic control intended to be used with molecular assays for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae and Trichomonas vaginalis* for the evaluation of test performance.

SUMMARY AND EXPLANATION:

Control should be used according to an assay manufacturer's instructions. The routine use of external controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, the effect of adverse environmental conditions, and can aid in the identification of random or systematic error.

PRINCIPLE:

NATtrol™ CT/NG/TV Negative Control is formulated in the absence of any microorganisms and contains proprietary matrix only.

MATERIALS SUPPLIED:

6 x 1.0 mL vials

ADDITIONAL NATtrol™ CT/NG/TV external control (sold separately):

NATCTNGTV-POS-IVD (6 X 1.0 mL) NATtrol™ CT/NG/TV Positive Control.

WARNINGS AND PRECAUTIONS:

- Disposal must follow the established procedures of the laboratory, federal, state, and local regulations.
- 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 Negative Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix each vial vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- · Each vial is intended for single use.

LIMITATIONS:

- For In Vitro Diagnostic Use.
- Intended for professional use only.
- 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 device.

EXPECTED RESULTS:

The table below is for informational purposes, each laboratory must evaluate the control and establish their own performance criteria. NATtrol™ CT/NG/TV Negative Control is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Expected Result
NATCTNGTV-NEG-IVD	Chlamydia trachomatis Not Detected
	Neisseria gonorrhoeae Not Detected
	Trichomonas vaginalis Not Detected

Symbols used in the labeling of this product:

	Manufacturer	1	Temperature Limitation
IVD	<i>In vitro</i> Diagnostic Use	Σ	Expiration Date
REF	Catalog Number	&	Biological Risk
LOT	Batch Code	(II	Consult Instructions for Use

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Revision: 00

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