

INTENDED USE:

NATtrol™ CT/NG/TV Positive Control (NATCTNGTV-POS-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 Positive Control contains purified, intact *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* that have been chemically modified to render them non-infectious and refrigerator stable. The control is formulated in a proprietary matrix.

MATERIALS SUPPLIED:

6 x 1.0 mL vials

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

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

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This control contains inactivated microorganisms. Safe practices suggest that the control be considered potentially infectious and to use Universal Precautions when handling.
- 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 Positive 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 Positive Control is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Organism	Expected Result
NATCTNGTV-POS-IVD	<i>Chlamydia trachomatis</i>	Detected
	<i>Neisseria gonorrhoeae</i>	Detected
	<i>Trichomonas vaginalis</i>	Detected

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	<i>In vitro</i> Diagnostic Use		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		Consult Instructions for Use