

MDx-Chex[®] for CT/NG/TV Ensures Accuracy and Reliability for Molecular-Based Sexually Transmitted Infection Testing

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MDX-CHEX MDx-Chex for CT/NG/TV is for Research Use Only (RUO). Not for use in diagnostic procedures.

Introduction

Together, Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and Trichomonas vaginalis (TV) represent a significant testing burden for laboratories in the United States and globally¹. In 2020, the WHO estimated 128.5 million new CT², 82.4 million NG³, and 156 million TV⁴ infections in adults aged 15–49, underscoring the continued demand for high-volume, high-accuracy molecular testing. According to provisional CDC 2024 surveillance reports, there were over 500,000 reported cases of NG and more than 1.5 million cases of CT in the United States¹.

A high proportion of these infections are asymptomatic across all three organisms⁵, increasing the reliance on sensitive molecular methods to accurately identify positive samples. NAATs (nucleic acid amplification tests) are the accepted testing standard for CT/NG and are recommended for TV because of significantly higher sensitivity compared to wet mount, antigen detection, and culture-based methods⁶.

The shift toward molecular-based STI testing introduces analytical complexity that demands robust quality oversight. Each run of a sample-to-answer NAAT panel depends on a chain of interdependent steps — cell lysis, nucleic acid extraction and purification, target amplification, and signal detection — any one of which can fail silently and compromise results. While kit-supplied internal controls verify the downstream amplification and detection stages, they leave the critical upstream extraction process unmonitored. To close this gap, laboratories require external, full-process controls formulated to behave like real samples so that every stage of the workflow is evaluated, and accreditation requirements for quality assurance are met.

This technical note presents the performance and application of MDx-Chex for CT/NG/TV. These external quality controls combine stabilized human cells with inactivated target organisms in a sample-representative matrix, producing a cellular-based positive and negative control pair that exercises every stage of the analytical process. By challenging lysis, extraction, amplification, and detection in a single run, MDx-Chex for CT/NG/TV enables laboratories to detect shifts in system performance before they affect reported results.

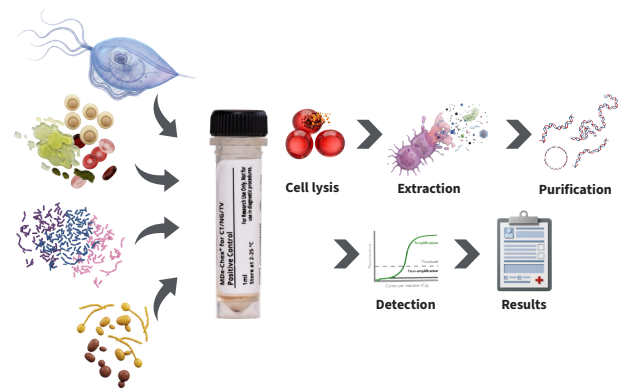


Figure 1. MDx-Chex for CT/NG/TV full-process quality control workflow.

A

Feature comparison: MDx-Chex[®] for CT/NG/TV vs. Competitors

	Intact Pathogens	Representative Sample Matrix	Inhibitor Removal	Ready-to-Use Format	Score
MDx-Chex for CT/NG/TV	✓	✓	✓	✓	4/4
Competitor A	✓	✓	✓		3/4
Competitor B	✓	✓			2/4

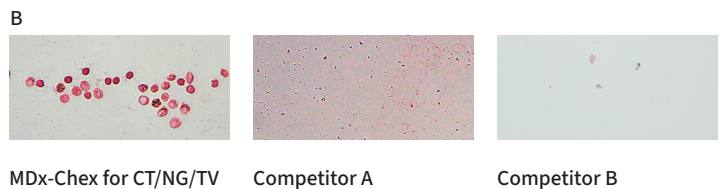


Figure 2. Feature (A) and composition (B) comparison of MDx-Chex[®] for CT/NG/TV to other commercially available controls. Microscope images were taken at 100X under oil immersion. (Clopper–Pearson exact method).

Results

Three lots of MDx-Chex for CT/NG/TV were tested on different days by different operators across multiple cartridge lots to assess precision (Figures 3 and 4). Positive and negative agreement for MDx-Chex for CT/NG/TV was 100% (Figure 3) and MDx-Chex for CT/NG/TV demonstrated similar performance across operators, days, and assay lots (Figure 4).

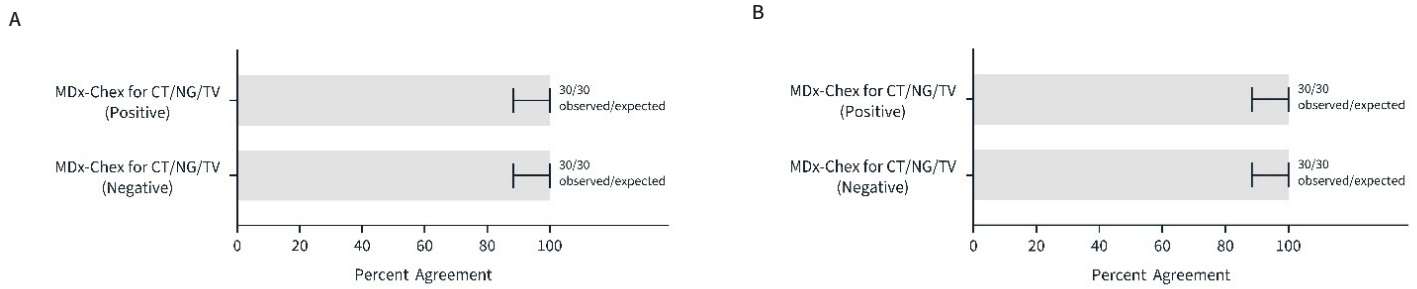


Figure 3. Lot-to-lot precision of MDx-Chex for CT/NG/TV on Xpert® CT/NG (A) or Xpert TV (B). Bars represent percent agreement; brackets indicate 95% confidence intervals (Clopper–Pearson exact method).

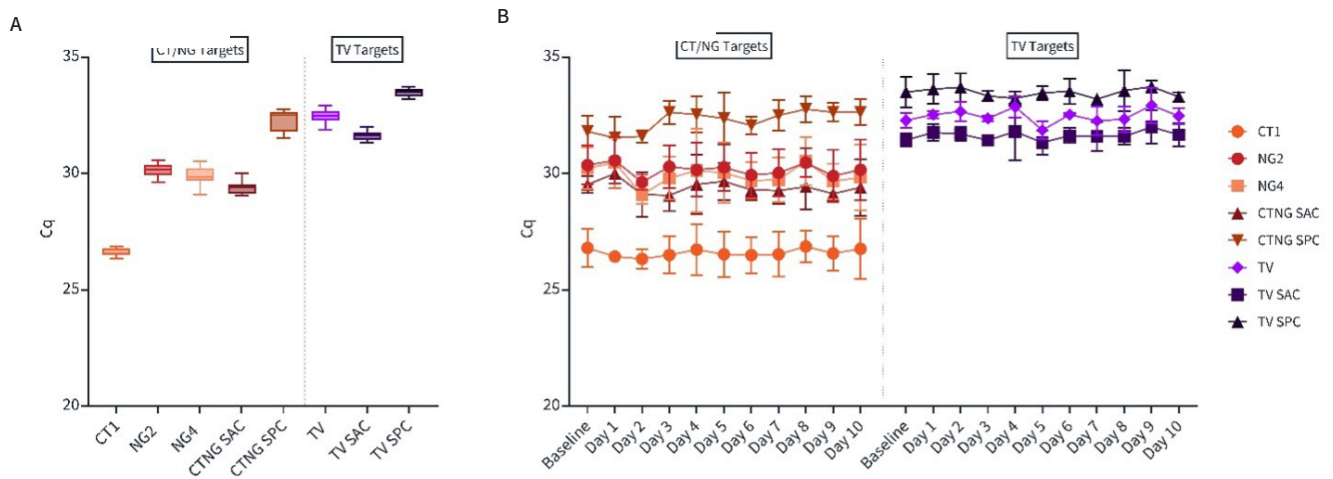


Figure 4. (A) Performance of MDx-Chex for CT/NG/TV across control lots, users and cartridge lots (n=30, min to max shown) (B) Performance of MDx-Chex for CT/NG/TV across control lots, users and cartridge lots over 10 days.

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Conclusion

The data presented here indicate that MDx-Chex for CT/NG/TV provides consistent, full-process quality control for molecular STI testing platforms. By verifying performance from sample lysis through target detection, these controls give laboratories a practical tool for maintaining assay accuracy, strengthening QA programs, and meeting the expectations of accrediting bodies and regulatory guidelines.

Methods

SAMPLE TESTING

Aliquots of each control sample were tested on the Cepheid GeneXpert® System using the Xpert® CT/NG panel (GXCT/NG-10) and the Xpert® TV Assay (GXTV-10), per the manufacturer's instructions for use

PERFORMANCE EVALUATION

Lot-to-lot precision of the controls was evaluated by testing three lots of MDx-Chex for CT/NG/TV on the assays described above, across multiple cartridge lots of each assay, with multiple operators on different days.

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