

MDx-Chex[®] Controls Ensure Accuracy and Reliability for Molecular-Based Multiplex Vaginal Panel Testing

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MDX-CHEX

MDx-Chex for MVP is for Research Use Only (RUO). Not for use in diagnostic procedures.

Introduction

Bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC) are the leading infectious causes of vaginitis worldwide. BV affects approximately 23 - 29% of women of reproductive age globally¹. VVC is similarly widespread; an estimated 50% of women experience at least one episode of VVC in their lifetime^{2,3}. These prevalence figures drive substantial testing volumes for laboratories performing vaginal panel assays.

Despite the high prevalence of vaginitis, a 2025 study found that between 2018–2022, only approximately 25% of nonpregnant and 48% of pregnant symptomatic individuals in the United States received any form of laboratory testing⁴. Among those tested, nucleic acid amplification tests (NAATs) remained underutilized at approximately 7% of all vaginitis testing for both cohorts. Unlike traditional methods, molecular-based assays can differentiate BV from *Candida* spp. and identify mixed infections, improving the accuracy and specificity of test results⁵.

As adoption of molecular-based vaginal panels grows, so does the need for external quality controls that can adequately verify system performance. Multiplex NAAT panels are often automated for complex sample-to-answer systems in which multiple analytical steps, including lysis, extraction, amplification, and detection, must function correctly across several targets simultaneously. While internal controls provided with assay kits monitor the amplification and detection steps, they do not assess the upstream processes of sample lysis and nucleic acid extraction that are critical to accurate results. External, full-process controls that mimic the composition of actual samples are therefore essential to evaluate the complete analytical workflow and to meet the quality assurance requirements of accrediting organizations.

Here we describe the performance and application of MDx-Chex for MVP (Multiplex Vaginal Panels), external quality controls containing stabilized cells in a sample-representative matrix with inactivated microorganisms, simulating positive and negative samples associated with BV, VVC, and *Trichomonas vaginalis* (see companion technical note, MDx-Chex for CT/NG/TV Ensures Accuracy and Reliability for Molecular-Based Sexually Transmitted Infection Testing, for *Trichomonas* background and statistics). MDx-Chex for MVP is designed to monitor the entire sample-to-answer workflow — from lysis through detection — to help laboratories identify variations in system performance that may lead to inaccurate results.

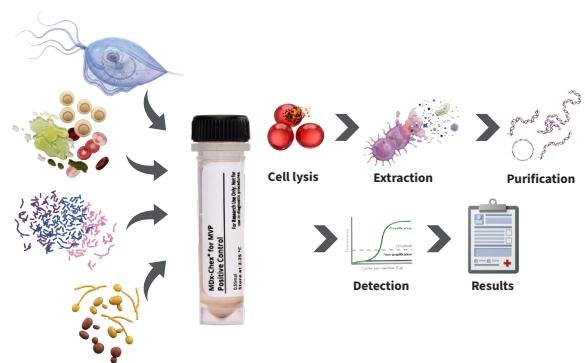


Figure 1. MDx-Chex for MVP full-process quality control workflow.

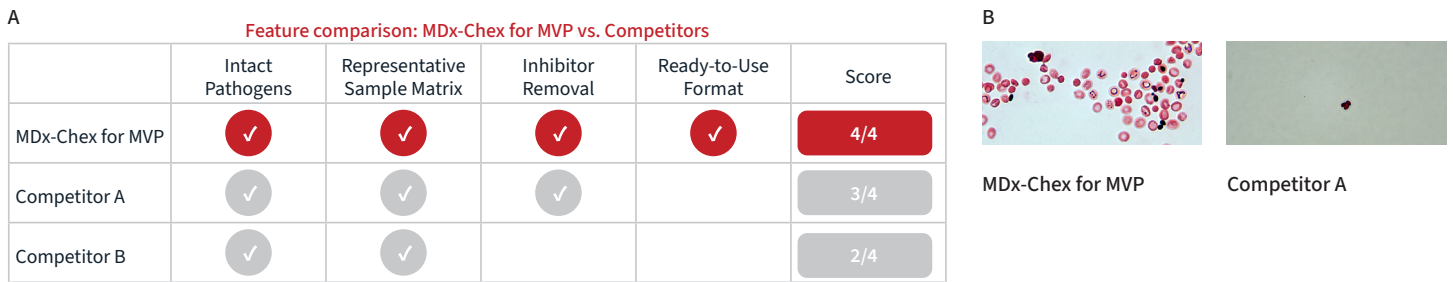


Figure 2. Feature (A) and composition (B) comparison of MDx-Chex® for MVP to other commercially available controls. Microscope images were taken at 100X under oil immersion. (Clopper–Pearson exact method).

Results

Three lots of MDx-Chex for MVP 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 MVP was 100% (Figure 3) and MDx-Chex for MVP demonstrated similar performance across operators, days, and cartridge lots (Figure 4).

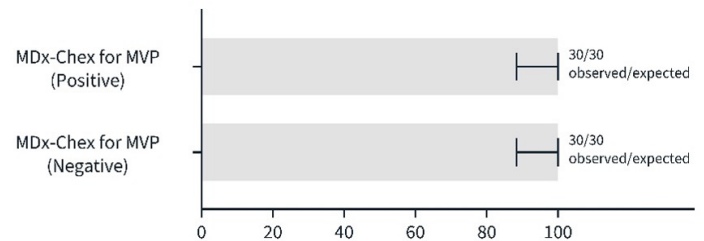


Figure 3. Lot-to-lot precision of MDx-Chex for MVP on Xpert® Xpress MVP. Bars represent percent agreement; brackets indicate 95% confidence intervals (Clopper–Pearson exact method).

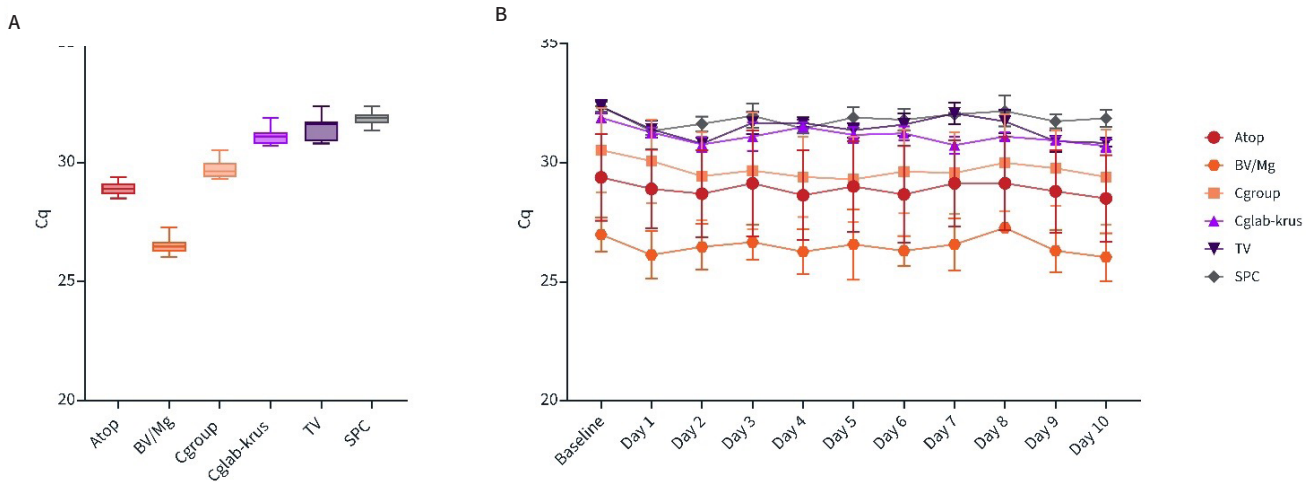


Figure 4. (A) Performance of MDx-Chex for MVP across control lots, users and cartridge lots (n=30, min to max shown) (B) Performance of MDx-Chex for MVP across control lots, users and cartridge lots over 10 days.

Conclusion

MDx-Chex for MVP supports reliable and accurate quality monitoring for molecular-based vaginal panel testing workflows. Incorporating these full-process controls into routine laboratory operations helps verify the performance of sample-to-answer systems, strengthen quality assurance programs, and improve compliance with accrediting standards and regulatory guidelines.

Methods

SAMPLE TESTING

Aliquots of each control sample were tested on the Cepheid GeneXpert® System using the Xpert® Xpress MVP panel (XPRSMVP-10), according to 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 MVP on the assay described above, across multiple cartridge lots, with multiple operators on different days.

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