STRECK

MDx-Chex® for RLP Supports Performance Verification of Sample-to-Result Respiratory Low Plex Molecular Tests

Katie Meinders, Ph.D., Kathy Hecker, M.S., Caroline Cambridge, MLS (ASCP)CM and Chris Connelly, Ph.D.
Streck Research and Development, La Vista, NE

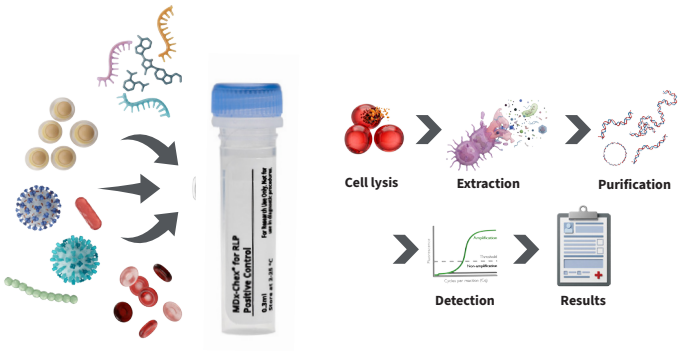
MDX-CHEX MDx-Chex for RLP is for Research Use Only (RUO). Not for use in diagnostic procedures.

Introduction

Molecular testing encompasses a broad collection of laboratory techniques used to analyze genetic material for the detection and identification of pathogens, including those that cause respiratory illness. The sensitivity of these tests can be greatly impacted by the quality and quantity of input nucleic acids (e.g., DNA or RNA). Quality control (QC) measures are vital to maintaining high standards across molecular testing workflows, particularly for respiratory pathogen detection where timely and reliable results are essential. Automated molecular respiratory testing platforms use a combination of PCR and/or hybridization-based technology to detect pathogens in nasopharyngeal or throat swabs in minutes. While these platforms support rapid turnaround within the testing workflow, without proper QC measures, the analytical sensitivity and specificity of an assay can become compromised, leading to unreliable results.

Many commercially available respiratory low plex test controls are formulated to contain only synthetic materials (e.g., plasmids or gene fragments) diluted in buffers or intact organisms in a protein-like matrix, neither of which fully represents a respiratory sample. Therefore, these formulations fail to verify a system's ability to process and remove matrix inhibitory effects or to properly and confidently evaluate an assay's internal controls when exposed to nasal or throat swab samples. Consequences of such failures may include assay recalls or unreliable results, underscoring the importance of robust QC within the respiratory testing workflow. These examples highlight the need to shift away from "conventional" QC designs toward controls that mirror sample composition and provide a representative test experience.

This technical note presents the performance and application of MDx-Chex for RLP, a quality control designed to support routine molecular respiratory low plex testing workflows. These 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 RLP enables laboratories to detect shifts in system performance before they affect reported results.



MDx-Chex for RLP full-process quality control workflow.

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

Results

While integration of rapid molecular respiratory tests into conventional testing workflows allow for faster turnaround times, many current QC measures remain insufficient. To address this gap in coverage, we developed MDx-Chex for RLP. MDx-Chex for RLP is a full-process control that contains intact, inactivated, and test-specific microorganisms suspended in a representative matrix of nasopharyngeal and throat swab components (**Figure 2**).

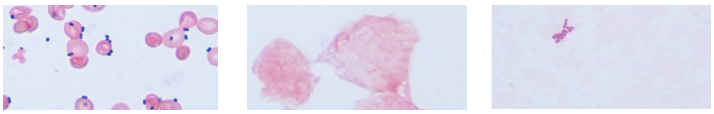
To internally evaluate control precision, we tested 3 independent lots of MDx-Chex for RLP on the Cepheid GeneXpert using the Xpert Xpress CoV-2/Flu/RSV Plus and Strep A panels, and BIOFIRE SPOTFIRE® using the BIOFIRE SPOTFIRE R/ST Mini panel, respectively. Overall precision of MDx-Chex for RLP was 100% positive and 100% negative agreement for all Cepheid Xpert® Xpress assays (**Figure 3A**). Comparable trends were observed for MDx-Chex for RLP with 100% positive and 100% negative agreement for the BIOFIRE SPOTFIRE R/ST Mini assay (**Figure 3B**).

A

Feature comparison: MDx-Chex® for RLP vs. Competitors

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

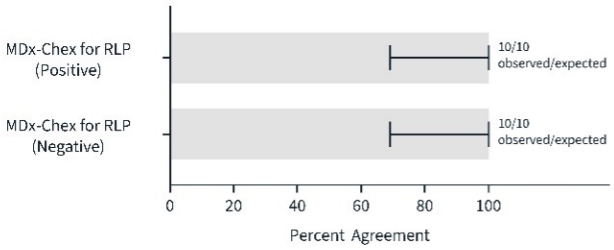
B



MDx-Chex for RLP | Competitor A | Competitor B

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

A



B

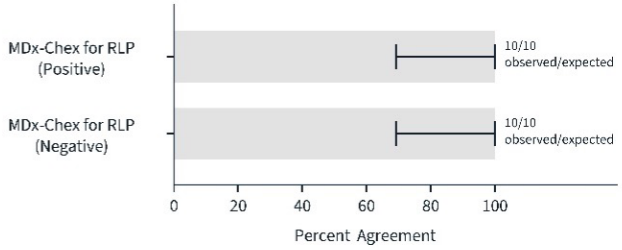


Figure 3. Lot-to-lot precision of MDx-Chex for RLP on Xpert Xpress (A) or SPOTFIRE R/ST Mini (B). Bars represent percent agreement; brackets indicate 95% confidence intervals (Clopper–Pearson exact method).

Conclusion

Collectively, MDx-Chex for RLP controls support reliable performance verification of Cepheid Xpert Xpress CoV-2/Flu/RSV Plus and Strep A, and BIOFIRE® SPOTFIRE R/ST Mini assay-based respiratory testing workflows. Use of these controls supports laboratory efforts to verify assay performance within molecular respiratory testing workflows, while simultaneously improving compliance with accredited standards and guidelines.

Methods

SAMPLE TESTING

Aliquots of each control sample were tested on the Cepheid GeneXpert® platform using the Xpert® Xpress CoV-2/Flu/RSV plus (#XPRSA4PLEX-10, 300 µls) and Xpert Xpress Strep A (#XPRSTREPA-10, 300 µls), or the BIOFIRE® SPOTFIRE® platform using the BIOFIRE SPOTFIRE R/ST Mini (#424537, 300 µls) panels per the Instructions For Use (IFU).

PERFORMANCE EVALUATION

Lot-to-lot precision of the controls was evaluated by testing 3 lots of MDx-Chex for RLP using the respective panels mentioned above. Precision was assessed internally with differences to modules, users, and cartridge lots.

LEARN MORE

streck.com/product/mdx-chex-for-rlp

800-843-0912

STRECK