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Six Checks Before Respiratory Season Opens

A pre-season verification framework for sample-to-result respiratory molecular assays

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Verification decisions before the respiratory season

Respiratory testing volume is seasonal. Verification work is not, but it behaves as though it were, because the window to do it properly closes at almost exactly the moment demand opens.

This guide helps you decide how to structure verification and analytical performance assessment for a respiratory molecular assay, and how to choose a control that will actually exercise the workflow you are trying to qualify.



What a sealed cartridge hides

Sample-to-result respiratory platforms return answers in minutes from a nasopharyngeal or throat swab. That speed is the entire point, and it is also what makes verification design consequential. When lysis, extraction, purification, amplification and detection all happen inside a sealed cartridge, there are very few places left to observe the process. A control that only proves the detection chemistry works tells you very little about the four steps ahead of it.

Many commercially available respiratory low-plex controls are formulated with synthetic material such as plasmids or gene fragments diluted in buffer, or with intact organisms suspended in a protein-like matrix. Neither composition fully represents a respiratory specimen, so neither can demonstrate that a system removes matrix inhibitory effects, or that an assay's internal controls behave correctly when the input resembles a real nasal or throat swab.



The practical consequence is uncomfortable: a verification study can pass while the process it was meant to qualify stays unproven. That gap tends to surface later, under volume, when there is no bench time left to investigate it.

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The Pre-Season Verification Framework

1 Match the matrix to the specimen type you actually run

For respiratory work, the relevant specimen is a nasopharyngeal or throat swab, and the relevant question is whether the control's matrix challenges the extraction and inhibitor-removal steps the way that specimen would. A cellular matrix containing intact organisms plus human cells exercises every stage of the analytical process. A synthetic target in buffer only exercises detection.

Both have a place. Only one of them supports a full-process claim about your workflow, and conflating them adds a level of risk that can easily be avoided.

2 Confirm analysis mode before running controls

Some instruments rely on a mode setting (control or patient mode) to return the correct result. When QC materials containing all assay targets are tested in patient mode, an error message may occur. This is expected, as patient mode is optimized for clinical sample analysis and is not intended to identify every target present in comprehensive QC materials. Running controls in the wrong operational mode, or against a stale or incorrectly configured protocol, returns a failure message that looks like a control problem but is not one — the control failed because of user error, not performance.

3 Mix cellular controls the recommended way, and treat synthetic ones differently

For vials containing cellular material, vortex for 30 seconds, follow with a centrifuge flash spin, then pipette up and down five times before loading. The vortex resuspends settled cellular pellet material, the flash spin recovers anything caught in the cap, and the pipetting confirms full suspension at the moment of transfer. Where no vortex is available, vigorous manual shaking followed by a flash spin is the documented fallback.

Synthetic and solution-based materials behave differently, because they do not settle. They often require no mixing at all and can go directly into the cartridge. Applying cellular-material mixing technique to synthetic controls wastes time; applying synthetic technique to cellular controls could produce under-recovered targets and unexplained variability.

Write the correct procedure for each control type into the verification protocol. Do not leave it to operator memory, particularly if verification runs are shared across shifts.

4 Use the transfer volume the assay specifies

Volume error is quiet. It rarely produces an obvious failure and often produces a slightly shifted result, which is worse in a precision study than an outright error would be. Disposable transfer pipettes supplied with an assay have a limited reservoir and assume an exact fill. Micropipette accuracy should be verified rather than assumed.

5 Plan storage and cold-chain logistics before the calendar compresses

Control format drives how much bench time is consumed. Materials requiring freezer or refrigerated storage need to equilibrate to room temperature before reconstitution and mixing, which can absorb 15 to 20 minutes per session before any testing begins. Frozen formats also carry freeze-thaw exposure, which can affect nucleic acid and organism integrity across repeated cycles.

This is exacerbated during verification, when you multiply the above process per-session overhead by the number of runs in a lot-to-lot precision study. If your verification window is already narrow, control format (room temperature stable) is one of the few variables you have the ability to select with the right provider.

6 Design lot-to-lot precision in from the start

Single-lot verification tells you the assay worked once, with one set of materials. It does not characterize the variability your program will actually encounter.

A defensible design tests multiple independent control lots and deliberately varies the things that drift in real use: instrument modules, operators, and cartridge lots. For reference, internal precision work on one respiratory low-plex control tested three independent lots across varied modules, users and cartridge lots, and reported 100% positive and 100% negative agreement on the Cepheid Xpert® Xpress CoV-2/Flu/RSV Plus and Xpert Xpress Strep A assays, and on the BIOFIRE SPOTFIRE® R/ST Mini assay, with 95% confidence intervals calculated by the Clopper-Pearson exact method.

That is the shape of a study that answers questions later instead of raising them.

Where verification plans usually break

Three failure points recur, and none of them are technique problems.

Format was treated as a preference rather than a schedule input. Cold storage, thaw time and reconstitution steps are fixed costs per run. In a compressed pre-season window, they determine how many runs actually fit.

Documentation of mixing and volume technique lived in someone's head. Verification studies frequently span operators and shifts. Undocumented technique becomes unexplained variability in the data set.

Lot-to-lot variability, new assay cartridge lots and user technique add complexity and stress test both your platform during times of highest use (like flu season).

How Streck supports respiratory verification work

Streck's respiratory molecular controls are full-process controls: intact, inactivated microorganisms suspended in a stabilized, patient-like matrix of blood cells and epithelial cells, designed to exercise the workflow from extraction through detection rather than detection alone.

For Research Use Only. Not for use in diagnostic procedures. Streck recommends verifying that control target coverage is adequate for your sample-to-result system of choice.

Two products cover the respiratory portfolio, split by plex level.





	MDx-Chex® for RLP	MDx-Chex® for RP
Plex level	Low-plex respiratory assays	High-plex respiratory assays
Targets	Influenza A, Influenza B, human rhinovirus, human respiratory syncytial virus (RSV), SARS-CoV-2 and *S. pyogenes* (Group A Strep)	Comprehensive coverage of significant respiratory pathogens, detailed in the MDx-Chex for RP IFU
Platform scope	Platform agnostic	Compatible with bioMérieux respiratory panels, for research applications
Item number	250100	250101
Configuration	5 tubes positive control, 5 tubes negative control	5 tubes positive control, 5 tubes negative control
Format	Single-use vials, room temperature storage	Single-use vials, room temperature storage
Supported activities	Research, development, optimization, verification and analytical performance assessment	Research, development, optimization, verification and analytical performance assessment

Both use the same workflow: mix, pipette in like a patient sample, scan and run.

A technical note covering lot-to-lot precision for MDx-Chex for RLP on the Cepheid GeneXpert and BIOFIRE SPOTFIRE platforms is available, along with instructions for use, assay sheets and certificates of conformance. Learn more.

KEY TAKEAWAYS

1. Detection-only controls cannot support a full workflow claim. If the claim covers extraction and inhibitor removal, the matrix has to challenge those steps.
2. Make analysis mode and software protocol confirmation a documented pre-run step.
3. Write per-control-type mixing and transfer volume procedures into the protocol, especially where runs span operators.
4. Build storage format into the verification schedule: room temperature stable material removes pre-run equilibration and fits more runs in the window.
5. Build multi-lot precision into the design at the start. It cannot be added once volume arrives.

Download the MDx-Chex for RLP technical note

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Built for your molecular QC workflow.

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