

September 19, 2025

Dear Public Health Laboratory partners,

This letter is to inform you that the CDC Influenza Division is removing some non-critical tests from our CLIA testing program. These determinations were made based on the tests being noncritical for patient care and due to redundancies that allow for other existing CLIA tests to diagnose influenza virus infections and for reporting of results.

The following tests will no longer be reported via CDC's CLIA diagnostic test reports.

- CDC Flu rRT-PCR Dx Panel B Genotyping Kit
 - o InfB can still be reported via our Influenza A/B typing kit
 - o RUO kits are available to PHLs for surveillance purposes if requested
- H3N2v Assay (LDT) and H3v 2010 Assay (LDT)
 - o H3 variant (H3v) viruses can be reported via interpretation of results from the CDC Influenza A Subtyping kit
 - o Genetic sequencing can complement test results to delineate different H3 clades/lineages
- LAIV Assay (LDT)
 - o Genetic sequencing can delineate LAIV viruses versus seasonal virus infections
- Human N2 Assay (LDT)
 - o Genetic sequencing can delineate different lineages of N2 NAs

Each of these tests will be retained for surveillance purposes and can be re-introduced into CDC's CLIA portfolio if needed (e.g., if B/Yamagata were to circulate again).

Please reach out to flusupport@cdc.gov if you have any questions.

Thank you