

Technical Bulletin

Laboratory Care Delivery System

SPORADIC FALSE POSITIVE RAPID MOLECULAR FLUID RESULTS

Roche recently identified some sporadic false positive results associated with their cobas Liat SARS-CoV-2 + Influenza A/B molecular multiplex test (**SARS COV-2 (COVID-19), INFLUENZA A + B, MULTIPLEX NAA [87636A]**), particularly for the Influenza B target. They proactively reported these events to the FDA and are conducting an in-depth investigation to fully understand the cause and to determine next steps.

According to the FDA, the false positive results may be related to two issues observed by Roche:

- Roche identified that the assay tubes may sporadically leak, causing an obstructed optical path in the Liat analyzer, producing abnormal PCR growth curves. This could lead to invalid or erroneous positive results, particularly for the Flu B test. If a tube leak occurs, later testing runs may have an increased likelihood of false positive Flu B results.
- Roche determined that abnormal PCR cycling in the reaction tubes may also produce abnormal PCR growth curves, leading to erroneous results. The issue is sporadic and may be caused by multiple factors happening at the same time, such as hardware positioning, volume movement, and curve interpretation. This issue may cause false positive results for multiple analytes (Influenza A, Influenza B and/or SARS-CoV-2) in a single testing run.

The FDA recommends users of the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System:

- Monitor for unexpected clusters of positive Flu B results, as this may indicate the cobas Liat System has experienced a tube leak.
- Repeat tests when two or three analytes are positive. Different results on the repeat test may indicate abnormal PCR cycling.
- Stop using the cobas Liat System and contact Roche if you suspect either of these two issues has occurred.

In addition to following the FDA recommendations above, the LCDS will send repeatedly multi-analyte positive results to the RRL for confirmation testing by way of the following assay: **SARS-COV-2 (COVID-19), INFLUENZA A, INFLUENZA B, MULTIPLEX NAA, HIGH THROUGHPUT [258971]**.

QUESTIONS?

- Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077
- Jonathan C. Gullett, MD, Physician Director of Microbiology, jonathan.c.gullett@kp.org
- Ken Van Horn, PhD, D(ABMM), Technical Director of Microbiology, ken.van-horn@kp.org
- Tam Van, PhD, D(ABMM); Technical Director of Microbiology, tam.t.van@kp.org