DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30329

URGENT FIELD CORRECTION NOTICE

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel

Influenza A/H5 Subtyping Kit

The H5b component may fail to amplify, resulting in an inconclusive result

Please distribute the attached customer letter. To the Laboratory Manager

4/26/2024

Reference: 20240426 Correction

Impacted products			
Product Name	**Reference Numbers**	**Lot Number**	**Product Expiration Date**
Influenza A/H5 Subtyping Kit	**FluIVD03-11**	**220307**	**2026-01-06**

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Dear Customer,
Our records indicate that your laboratory/firm received the product listed in table above.

This communication is to inform you about an issue we have identified with a recently manufactured Influenza A/H5 Subtyping Kit. This assay contains one Influenza A-specific target, and two redundant H5-specific components, H5a and H5b. As a part of our ongoing quality control process, an internal investigation conducted on the analytes of the Influenza A/H5 Subtyping Kit found decreased performance of the H5b target in lot 220307. At this time, we have only identified lot 220307 as being impacted. There have been no reported inaccurate results based on the use of this test and CDC has no evidence that any H5 cases have been missed. Any inconclusive results would have been sent to CDC for confirmation.

This issue has been observed in two ways:

- **Loss of H5b analyte sensitivity with H5b mixed primer and probes stored at 4 ^{0}C**
- **Intermittent complete loss of function of the H5b analyte regardless of storage condition**

Impact on Test Results:

- Customers may see an H5b target reduction or failure to amplify in the clinical specimen and in the H5 positive control, while all other targets of the assay amplify appropriately, thereby producing inconclusive results.
- The H5b component of the test may show a negative result with the H5 positive control, thereby producing inconclusive results.

These issues may cause a delay in resulting due to the need to repeat any test that produces an inconclusive result. **As such, we are recommending customers halt the use of the H5b component within the 220307 lot.** Continue to use the InfA, H5a, and RP components of lot 220307 for testing suspect H5 cases. Due to the nature of this issue, prior results obtained with this lot (220307) of the Influenza A/H5 Subtyping Kit are valid and do not require retesting.

Clinical samples presumptive positive for Influenza A(H5) should produce a positive signal for InfA and H5a. Such a result should prompt the testing laboratory to reach out to CDC (flusupport@cdc.gov) for further guidance.

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Required actions

In this context, please take the following actions:

- When testing a specimen with the CDC Influenza A/H5 subtyping kit, lot 220307, halt use of the H5b component. Proceed with testing with the InfA, H5a, and RP targets and do not delay resulting.
    - If a specimen is positive for InfA and H5a, that is considered a presumptive H5 positive and should be sent to CDC immediately. Please reach out to CDC flusupport@cdc.gov for further shipping guidance.
    - If a specimen is positive for InfA and negative for H5a and has not yet been tested with the Influenza A Subtyping kit, proceed with testing the specimen with the Influenza A Subtyping kit.
    - If a specimen is negative for all viral targets but positive for RP, that specimen is considered negative for Influenza A, H5.
    - Please reach out to flusupport@cdc.gov with any inconclusive results.

We are currently investigating the root cause and considering additional actions to correct for the issue described above. We will send an updated communication when other actions are identified.

Additional actions:

- Store this notice letter in your documentation system.
- Complete the Acknowledgement Form in **Attachment A** immediately and return it to flusupport@cdc.gov to confirm receipt of this notice. It is important that you return the acknowledgement form to us, even if you determine that this urgent product correction notice does not impact your facility. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact flusupport@cdc.gov.
- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred your product.

Sincerely,

John R. Barnes,

Influenza Division

National Centers for Immunizations and Respiratory Diseases, CDC

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Attachment A: Acknowledgement Form.

URGENT FIELD CORRECTION SAFETY/CORRECTIVE NOTICE

20240426 Correction – Influenza A/H5 Subtyping Kit
The H5b component of the test may show a negative result with the H5 control and result in an inconclusive test.

TO BE RETURNED TO *CUSTOMER SERVICE* AT THE FOLLOWING
EMAIL ADDRESS: flusupport@cdc.gov

Name and Address of the laboratory	
Contact information	
Customer Account Number	

☐ I am not impacted by the issue. Please provide rationale:_____

_____

☐ I have implemented the required actions. I have ____ (number) of affected kits in my current inventory.

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue with the H5b component?

☐ Yes ☐ No

If "Yes", please provide a description of the impact on patients' results, or reports of illness or injury related to the identified issue:

_____

_____

_____

DATE……..... SIGNATURE……

It is important that you complete this Acknowledgement Form and return it to CDC.