Urgent Field Safety Notice
SBN-RDS-MolecularLab-2022-008

RDS/**cobas**® 5800/6800/8800
Version 4
Sep-2024

Potential false negative Influenza A H1N1 Results with select Roche assays used on the cobas® 5800/6800/8800 systems

Product Name	**cobas**® Influenza A/B & RSV UC (Utility Channel) Qualitative nucleic acid test for use on the **cobas**® 6800/8800 Systems (CE-IVD) GMMI: 09233962190 UDI: 00875197006773
Production Identifier (Lot No./Serial No.)	N/A
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche is pleased to announce the availability of the **cobas**® Respiratory flex (GMMI: 09623701190), a respiratory viral panel for the detection and differentiation of up to 12 targets for use on **cobas**® 5800/6800/8800 systems. The **cobas**® Respiratory flex is available in CE-mark accepting countries and replaces the **cobas**® Influenza A/B & RSV UC test on the **cobas**® 6800/8800 Systems, CE-IVD, which was impacted by the H1N1pdm09 variants detected in the previous influenza seasons. With relation to H1N1pdm09 variants, the **cobas**® Respiratory flex was designed to better withstand Influenza A (FluA) mutations under the forward primer and an extra reverse primer to improve inclusivity.

As previously communicated, Roche received customer complaints alleging the generation of false negative Influenza A (Flu A) results and late Flu A Target Ct values with **cobas**® Influenza A/B & RSV UC Qualitative nucleic acid test for use on the **cobas**® 6800/8800 Systems in relation to other platforms. These allegations were specific to circulating mutations (single or double mutation) in H1N1pdm09 pertinent to the region of interest to the aforementioned test.

The CAPA investigation determined that the root cause of the issue is the influenza A target design of the assay, which was not inclusive for the current mutations that evolved subsequent to the development of the assay. These mutations result in delayed Ct values or even in failure to detect the presence of the Influenza A virus.

Actions taken by Roche Diagnostics (if applicable)

Roche continues to monitor and respond to emerging pathogens via the Global Surveillance program.

Roche will schedule visits to assist customers with the implementation of the **cobas**® Respiratory flex at customer laboratories.

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Actions to be taken by the customer/user

Customers can order the new **cobas**® Respiratory flex, CE-IVD (GMMI: 09623701190) from their local affiliate organization.

Until the **cobas**® Respiratory flex is used at customer sites, customers that utilize the **cobas**® Influenza A/B & RSV UC test on the **cobas**® 6800/8800 Systems, CE-IVD, must continue to follow instructions in the original Urgent Field Safety Notice (v1) as long as the **cobas**® Influenza A/B & RSV UC test on the **cobas**® 6800/8800 Systems, CE-IVD, is utilized for testing.

- As a reminder, the "Procedural Limitations" section of the corresponding Instructions for Use states "As with any molecular test, mutations within the target regions of **cobas**® Influenza A/B & RSV UC could affect primer and/or probe binding resulting in failure to detect the presence of virus." Additionally, the "Intended Use" sections note "Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions."

- Customers should monitor for negative influenza A results that are inconsistent with clinical presentation and/or other clinical and epidemiological information. Authorized or licensed Influenza NAATs are available for confirmation if clinically indicated for at-risk patients. The following tests are known not to be affected by these variants:
  cobas® Liat® System assays for influenza:
  - **cobas**® SARS-CoV-2 & Influenza A/B (CE-IVD); GMMI: 09211101190
  - **cobas**® Influenza A/B & RSV (CE-IVD); GMMI: 08160104190

- In the case of testing for Influenza, uncovering false results more than 1 day old would be unlikely to change patient management due to the acute nature of influenza and the short time period for therapeutic intervention. Therefore, reviewing previously generated influenza A negative results is not recommended.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).>

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The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Molecular Systems, Inc.,- SRN: US-MF-000018066 (legal manufacturer)
Roche Diagnostics GmbH- SRN: DE-AR-000006262 (EU authorized representative)