Urgent Field Safety Notice

SBN-RDS-MolecularLab-2022-008

RDS/**cobas**® 5800/6800/8800
Version 2
Sep-2023

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

Product Name	**cobas**® SARS-CoV-2 & Influenza A/B qualitative assay for use on the **cobas**® 6800/8800 Systems (CE-IVD) GMMI: 09233474190 UDI: 00875197006674 **cobas**® SARS-CoV-2 & Influenza A/B qualitative nucleic acid test for use on the **cobas**® 5800/6800/8800 Systems (CE-IVD) GMMI: 09446125190 UDI: 00875197006827
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 **cobas**® SARS-CoV-2 & Influenza A/B v2 for use on **cobas**® 5800/6800/8800 Systems, CE-IVD (GMMI: 10033401190), with an updated influenza A design to improve inclusivity to the H1N1pdm09 variants detected in the influenza season 2022/2023.

The updated design consists of a dual-target approach for influenza A: one target is an updated version of the original influenza A design (matrix proteins 1 and 2) and the second target is a new design targeting another genomic region (polymerase basic protein 2). No changes have been implemented to the designs of the influenza B or SARS-CoV-2 targets when compared to the previous version of the assay.

Important: aside from the described design updates to the influenza A target, the new version of the test remains

unchanged in its formulation and test procedure. In addition, the fully automated sample preparation (nucleic acid extraction, and purification), PCR amplification, and detection remain unchanged. The new version of the test is provided with the same negative and positive controls.

As previously communicated, Roche customer complaints alleging the generation of false negative Influenza A (Flu A) results and late Flu A Target Ct values with the **cobas**® SARS-CoV-2 & Influenza A/B qualitative assay for use on the **cobas**® 5800/6800/8800 Systems in relation to other platforms. These allegations are specific to recently circulating mutations (single or double mutation) in H1N1pdm09 pertinent to the region of interest to the aforementioned tests. The identified mismatches have been increasing among H1N1pdm09 sequences deposited to the GISAID database.

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 assays. 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 the prevalence of circulating strains with one or both SNPs as part of the global surveillance.

Actions to be taken by the customer/user

Customers can order the new **cobas**® SARS-CoV-2 & Influenza A/B v2 for use on **cobas**® 5800/6800/8800 Systems, CE-IVD (GMMI: 10033401190) from their local affiliate organization.

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).>

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.

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

<closing salutations>,

Contact Details

To be completed locally:

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Title
Company Name
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Email name@roche.com

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