Field Safety Notice (FSN)

Panther Fusion® System with the Panther Fusion® SARS-CoV-2/Flu A/B/RSV Assay

Catalog Number: PRD-07400

Zaventem, January 15th, 2024 MISC-09565-EUR-EN Rev.001

Hologic Ref.: FA-00242

Information on Affected Devices.

The Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is a fully automated multiplexed real-time RT-PCR test intended for the qualitative detection and differentiation of RNA from SARS-CoV-2 virus, influenza A virus (Flu A), influenza B virus (Flu B) and respiratory syncytial virus (RSV).

Reason for Field Safety Corrective Action.

Description of the product problem.

While testing the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay on Panther Fusion System, there is a potential risk of a false Flu B positive result in samples that are also SARS-CoV-2 positive. Customers may identify samples that have been affected by this issue by reviewing the associated amplification curves on the Panther Fusion system. In reviewing the curves, the atypical amplification curve for Flu B may appear unusually "flat". It is important to note that occurrence of this issue does not impact test results for the other analytes in the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay. In addition, no other Panther Fusion assays are affected by this issue.

Hazard giving rise to the FSCA.

Hologic has evaluated the risk of false Flu B positive results, in conjunction with a true SARS-CoV-2 positive result. Briefly, for patients that require hospitalization, the COVID-19 Treatment Guidelines Panel recommends that hospitalized patients who are suspected of having either influenza or COVID-19 be started on empiric treatment for influenza with oseltamivir as soon as possible and without waiting for influenza test results. In addition, there are no clinically significant drug-drug interactions between the antiviral agents or immunomodulators that are used to prevent or treat COVID-19 and the antiviral agents that are used to treat influenza. Therefore, it is improbable that serious harm will occur with false Flu B positive results when a patient's sample is SARS-CoV-2 positive.

Per our risk evaluation, we identified two risks from which the worst case "The risk of false Flu B positive result when a patient sample is SARS-CoV-2 positive" was classified as severity "Serious" and probability of "Improbable".

This worst case risk was further evaluated and Hologic deems there is a risk for indirect harm due to the false positive flu B result, which could lead to a temporary serious deterioration in the state of health of a patient. Hologic determined that this risk is however extremely unlikely to occur.

Background on Issue.

As of January 09, 2024, Hologic has sold about 995,000 Panther Fusion SARS-CoV-2/Flu A/B/RSV tests; over that time, Hologic has received complaints from a total of eight global customer sites related to this issue. None of the complaints have indicated any associated patient adverse events.

We are currently in the process of determining the specific root cause of this issue that occurs in false positive Flu B results with the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay when a sample was also SARS-CoV-2 positive and will provide additional communication once a solution has been validated. Hologic is diligently working on assessing this issue and has identified multiple potential contributing factors. In instances where this issue occurred, Hologic identified multiple contributing factors were present suggesting a "stacked" effect of these factors. Investigation of this issue at Hologic is on-going.

Type of Action to mitigate the risk.

This notification is intended for Laboratory Managers, Site Administrators and Operators who have received the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay and is effective immediately upon receipt.

Action To Be Taken by the User

You may continue to test with the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay on the Panther Fusion System.

To ensure visibility of the issue, we recommend posting this notification on or near the Panther Fusion Systems that are running the Panther Fusion SARS-CoV-2/Flu A/B/RSV assay.

If you suspect a false Flu B positive result in combination with SARS-CoV-2 positive result (dual positive), please contact Hologic Technical Solutions using TSmolecular@hologic.com or using one of the local phone numbers which can be found on www.hologic.com/support/europe.

This Field Safety Notice is intended to be distributed to all those who need to be aware within your organization or to any organization where the potentially affected assays have been transferred.

Please maintain awareness of this notice and resulting action until further communication is received.

The Competent (Regulatory) Authority of your country has been informed of this Field Safety Notice distribution.

Hologic has partnered with IQVIA MedTech company to assist in this field action. Please acknowledge receipt of this notification by completing the Customer Acknowledgement Form (CAF).

Thank you for your compliance with this notification.

Respectfully yours,

Asad Amjad
Regulatory Affairs Officer, EMEA

Hologic BV

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Customer Acknowledgement Form Instructions

Please complete the Online Acknowledgement Form within **three (3) business days** upon receipt of this notification.

	STEP 1 – Scan the QR Code or visit the link below to access the response form https://iqvia-response.my.site.com/mt/fca?cid=HPAN24
	STEP 2 – Enter your Unique Identifier: Your Unique Identifier – XXXXX
	STEP 3 – Acknowledge the receipt of this notice & complete the form online *Call IQVIA MedTech for any questions/concerns with response form* Ph: +44 131 381 0956 E: hologicpantherfusionSARSassay@iqvia.com

Hologic has partnered with IQVIA MedTech to assist in this action. For any assistance regarding online response processing please contact IQVIA MedTech using the information above.