Field Safety Notice (FSN)

Hologic Aptima CMV Quant assay ML2 Errors with plasma samples on the Panther Instrument

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Hologic Ref.: FA-00234

Information on Affected Devices.

The Aptima CMV Quant Assay is an *in vitro* nucleic acid amplification test for the quantitation of human cytomegalovirus DNA in human EDTA plasma and whole blood on the fully automated Panther system. The Aptima CMV Quant Assay is intended for use to aid in the diagnosis and to aid in the management of solid-organ transplant patients and hematopoietic stem cell transplant patients.

Reason for Field Safety Corrective Action.

Description of the product problem.

When plasma specimens from specific patients are tested with the Aptima CMV Quant assay, there is a potential for the sample result to be invalidated with an ML2 error flag. The ML2 error flag occurs when the Magnetic Wash Station reports high liquid level, which is caused by clogging of the Magnetic Wash Station's aspirators after the initial aspiration of a MTU tube containing the sample. Importantly, this issue has not been observed when running whole blood samples with the Aptima CMV Quant assay.

Hologic has observed cases in which repeat testing on the Panther instrument of plasma samples that generated invalid results due to ML2 error flags, may lead to the Magnetic Wash Station going out of service. This may require a field service visit to restore functionality of the Magnetic Wash Station. With the Aptima CMV Quant assay, it is not recommended to retest a plasma sample that was previously invalidated due to an ML2 error on the Panther instrument.

This Field Safety Notice is **not applicable** when the the Aptima CMV Quant Assays is used on whole blood samples since these samples are processed differently as per the product package instruction. Additionally, all the other Hologic Aptima Assays and Panther Fusion assays that use plasma as sample matrix are unaffected by this issue and Field Safety Notice.

Hazard giving rise to the FSCA.

When the Panther reports an ML2 error due to clogging of the tubing in the Magnetic Wash Station, the instrument may need to be serviced, which could lead to a delay in CMV assay quantitative

results. Based on the low level of occurrence of these errors there is a remote risk of a multiple day delay in CMV assay results which may lead to omission of or a delay of therapy.

Background on Issue.

Hologic has investigated this phenomenon and has identified that only specific plasma samples with an abnormally high concentration of globulin proteins may result in coagulation during assay processing, which can clog the Magnetic Wash Station during aspiration.

We are currently in the process of evaluating solutions to mitigate the protein coagulation that occurs in some plasma samples during assay processing and will provide additional communication once a solution has been validated.

Type of Action to mitigate the risk.

Action To Be Taken by the User

You may continue to use the Aptima CMV Quant assay on plasma and whole blood samples. Whenever obtaining an ML2 error, please run the Mag Wash Clean Procedure and Contact Hologic Technical Support as described in the Assay Processing Flags section of the Panther/Panther Fusion Operator's Manual.

With the Aptima CMV Quant assay, it is not recommended to retest a plasma sample that was previously invalidated due to an ML2 error on the Panther instrument.

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 devices have been transferred. Please maintain awareness of this notice and resulting action until additional further communication is received.

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

Thank you for your compliance with this notification. If you have any questions or concerns about this notification, 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.

Respectfully yours,

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Hologic BV