diagenode
diagnostics

Urgent Field Safety Notice

Notification of a Field Safety Corrective Action (FSCA) for Panther Fusion® EBV Quant Assay – EBV Reagent Cartridge

Catalog number: PRD-07157

Seraing, January 11th, 2023

Dear Customer,

The purpose of the notification is to inform you a voluntary recall of the of Panther Fusion EBV Quant Assay - EBV Reagent Cartridges (PRD-07157).

The Panther Fusion EBV quant assay has recently reported systematic quantitation discrepancies in natural whole blood specimens when compared to some other commercial molecular assays. Even through Product's Quality specifications are met and the assay performs as claimed in its Instructions for Use, this quantitation discrepancy regarding other assays may lead to a systematic underestimation of EBV viral load in patient's whole blood samples.

The Panther Fusion EBV Quant assay is intended to aid in the diagnosis and management of solid-organ transplant patients and hematopoietic stem cell transplant patients. It is not intended for use as a screening assay for the presence of EBV in blood and blood products.

Quantitation of EBV DNA load in plasma or whole blood is generally used to identify patients at risk of post-transplant lymphoproliferative disorder (PTLD). Clear increase in EBV DNA level in a patient who was seronegative for EBV at the time of the transplantation is a candidate for preemptive therapy such as lowering immunosuppressants or administering treatment with therapeutic monoclonal anti-CD20 antibody. EBV DNA load quantitation by real-time polymerase chain reaction (qPCR) of blood specimens is often used as a means of screening for these diseases or assessing treatment response.

Hazards Giving Rise to the FSCA:

The first hazard of the under-quantitation of the EBV viral load from whole blood specimens may occur if a decision of initiating pre-emptive EBV therapy is based on quantitation result reaching a fixed threshold. In that case, the initiation of treatment could be delayed leading potentially to somewhat increased PTLD risk.

The second hazard is based on situation where a clinical set-point for terminating the pre-emptive therapy is a fixed threshold. In this case, the under-quantitation may result in premature termination of the therapy leading potentially to somewhat increased PTLD risk.

Probability of Problem Arising:

The probability that a patient at risk for EBV-related incurable PTLD gets the disease due to undetected EBV infection because of the under-quantitation (hazard 1) has been estimated to be occasional (less than 1 in 10,000 but more than 1 in 100,000).

The probability that a patient at risk for EBV-related incurable PTLD gets the disease due to under-quantitation of EBV viral load resulting in premature termination of the therapy (hazard 2) has been estimated to be improbable (less than 1 in 1,000,000).

Probability of problems arising from the hazards is relatively low since the decision of initiation or termination of the chosen pre-emptive therapy is based on repetitive samples in which a considerable increase or decrease in the viral load is more important than the absolute value of the quantitation itself.

Predicted Risk to Patient:

The predicted risk to patient could occur only if the assay was used in clinical decision making and a fixed set-point for preemptive therapy was used. In that case the predicted risk to patient was delayed preemptive therapy or premature termination of EBV therapy, both resulting in an increased risk for PTLD.

Scope of the Notification:

This notification is intended for Laboratory Managers, Site Administrators and Operators, and is effective immediately upon receipt.

This recall only concerns Panther Fusion EBV Quant assay cartridges. Other Panther Fusion assays and reagents manufactured by Diagenode are not impacted by this FSCA.

Field Safety Notice (FSN) Details:

Manufacturer:	Diagenode S.A. Rue du Bois Saint-Jean 3 4102 Seraing BELGIUM
Manufacturer's SRN:	BE-MF-000015361
Manufacturer's FSN reference number:	2023-CN-001
FSN date:	11-Jan-2023
Required action type:	Destroy Device

Product Details:

Catalogue number:	PRD-07157
Name:	Panther Fusion EBV Quant Assay- EBV Reagent Cartridges
Affected lot(s)/ serial number(s):	000234BDGN (exp. 2023-11-15) 000235BDGN (exp. 2023-11-15) 000258BDGN (exp. 2024-02-15) 000257BDGN (exp. 2024-02-15) 000259BDGN (exp. 2024-02-15)

This product is distributed by Hologic.

Requested actions:

- Please **immediately** discontinue use of the Panther Fusion EBV Quant assay Cartridges.
- Please **immediately** check your inventory and segregate the Panther Fusion EBV Quant assay Cartridges lots listed in Table 2.
- Please fill out the document completely, including the number of boxes of the specified lots remaining in inventory (whether unopened or partial boxes).
- After completing the document, destroy the segregated inventory.
- Complete the customer acknowledge form on page 5 and return it to the specified recipient no later than one week after receipt of this notice.
- If the assay has been used for diagnostic purposes from whole blood, the clinicians who have requested the analysis must be contacted immediately.
    - The clinician needs to be informed that the results of the Panther Fusion EBV Quant assay from whole blood are lower than those obtained with some other commercial IVD assays (quantity approx. 30% of the comparators across the whole quantitation range of the Panther Fusion EBV Quant assay).

- If the clinician considers that the above-mentioned under-quantification may have affected the treatment or management decisions for a patient, a new plasma or whole blood sample from the patient needs to be taken without an unnecessary delay. Plasma samples may be analyzed with the Panther Fusion EBV Quant assay but whole blood samples only with another quantitative EBV assay validated for whole blood samples.
- Treatment decisions should be revisited based on the results from the new sample.

Please contact Hologic's representative for further information.

This notice needs to be passed on 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 on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Thank you for your compliance with this notification. If you have any questions or concerns about this notification or about the replacement product, please contact Hologic Technical Solutions using TSmolecular@hologic.com or local phone numbers can be found on https://www.hologic.com/support/europe.

Sincerely Yours,

Géraldine Poncin,

Diagenode S.A., Person Responsible for Regulatory Compliance

diagenode
diagnostics

Urgent Field Safety Notice (January 11,2023)

Panther Fusion® EBV Quant Assay- EBV Reagent Cartridges

ACKNOWLEDGEMENT

We kindly ask you to confirm receipt of this Field Safety Notice by filling and returning this form in any of the following methods:

- by mail to: Diagenode S.A.,
  to Romy Zaletelj
  Rue du Bois Saint Jean 3
  4102 Seraing
  BELGIUM
- by email to: QA-Diagenode@hologic.com

Manufacturer's FSN reference number:	2023-CN-001
Catalogue number:	PRD-07157
Affected lot(s) / serial number(s):	000234BDGN (exp. 2023-11-15) 000235BDGN (exp. 2023-11-15) 000258BDGN (exp. 2024-02-15) 000257BDGN (exp. 2024-02-15) 000259BDGN (exp. 2024-02-15)
Company/laboratory:	
Address:	
Contact person:	
Direct phone number:	
Email address:	
Acknowledgement:	I acknowledge receipt of this Field Safety Notice and that I have understood the information provided in it.
Date:	
Signature:	