Completion of the signature block below signifies the review and approval of this document.

Signed by:	Reason:	Date / Time (UTC):
Robles Chantale	QA Approval	10-Apr-2019 16:52:22
Lee Rino	Business Owner Approval	10-Apr-2019 16:59:39

Urgent Field Safety Notice
Procleix HEV Assay
Additional Limit of Detection Data for the HEV WHO International Standard (PEI 6329/10) Diluted in K_2EDTA plasma

Date: 10 April 2019

Attention: *Procleix HEV Customer*

Information on Affected Devices
Device Type
Nucleic Acid Test for the detection of Hepatitis E virus (HEV). Test kit supplied in a 1000 or 5000 test configuration that includes multiple boxes with various reagents which are loaded onto an analyzer and used to screen human plasma and serum samples for HEV.
Commercial name
Procleix HEV Assay
Intended Use
The Procleix HEV Assay is a qualitative in vitro nucleic acid amplification test for the detection of hepatitis E virus (HEV) RNA in plasma and serum specimens from human donors, tested individually or in pools. It is also intended for use in testing plasma and serum to screen organ and tissue donors, including cadaveric (non-heart-beating) donors. It is not intended for use on samples of cord blood. This assay is not intended for use as an aid in diagnosis.
Catalogue Numbers
PRD-02789 (1000 Test Kit) and PRD-03042 (5000 Test Kit)
Field Service Corrective Action Number
Vk_20190408_04

Reason for Field Safety Corrective Action (FSCA)
Description of the product problem
The "Analytical Sensitivity" section of the instructions for use has been updated to include additional limit of detection (LOD) data for the HEV WHO International Standard (PEI 6329/10) when diluted in K_2EDTA and processed plasma (defibrinated, delipidated sodium citrate plasma). The analytical sensitivity data in the current revision of the HEV package insert (504513EN, rev. 002) was generated with panels that used processed plasma as sample matrix. The data generated with Lot 1 of reagent showed a 95% detection probability of 10.37 IU/mL with 95% fiducial limits (FL) of 7.58 - 16.77 IU/mL in processed plasma. Additional testing comparing detection of HEV WHO International Standard (PEI 6329/10) in K_2EDTA and processed plasma was completed. In this additional testing, the data generated with Lot 5 showed a 95% detection probability of 12.61 IU/mL with 95% FL (9.09 – 21.39 IU/mL) for K_2EDTA plasma as the matrix, and a 95% detection probability of 8.03 IU/mL

with 95% FL (5.64 – 14.72 IU/mL) for processed plasma as the matrix. Lots 1 and 5 were the lots with the highest 95% detection probability in the original package insert and updated testing, respectively. The testing comparing detection of HEV WHO International Standard (PEI 6329/10) in K_2EDTA and processed plasma was completed to provide further characterization of the assay and is being added to the 'Analytical Sensitivity' section of the package insert. This testing does not replace the data currently found in the instructions for use. The additional LOD data using panels diluted in K_2EDTA is different than panels diluted in processed plasma, but the difference is not statistically significant. The additional LOD data does not indicate an additional risk related to the performance of the assay and does not impact the determination of pool sizes for testing with the Procleix HEV Assay or any previous results generated using the assay.

Background on Issue

Grifols became aware of the issue following customer complaints of inability to confirm LOD of the assay with dilutions of the HEV WHO International Standard. Further characterization of the assay of the WHO International Standard (PEI 6329/10) diluted in K2EDTA and processed plasma was completed and the additional data is being added to the instructions for use.

Advice on action to be taken by user

Download and review updated instruction for use (504513EN, rev. 003) from https://grifols.force.com/DxNet.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact Information

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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency. Refer to attached electronic signature.