

HAEMONETICS®

Urgent Field Safety Notice (FSN)

TEG® 5000 - Functional Fibrinogen Reagent

May 2, 2022

To the attention of: **Materiovigilance correspondent**, Risk Management and Material Management

Please forward this communication to all potential users of the products.

Dear Customer,

The purpose of this FSN is to advise you that Haemonetics Corporation is conducting a voluntary correction related to the TEG 5000 - Functional Fibrinogen Reagent (Item Number 07-034). The product instructions for use (118474-MULTI) is being updated to revise the Citrated Blood Reference Range for the maximum amplitude (CFF-MA) and the functional fibrinogen level (FLEV).

Reason for the Field Notice:

Haemonetics has identified a shift in the citrated blood reference range for a normal population. Due to this shift, the ranges stated in TEG® Hemostasis System Functional Fibrinogen Reagent IFU (118474-MULTI (AA)) are changing. The CFF-MA range is changing from 11.0 – 24.4 mm to 11.5 – 31.6 mm and the FLEV range is changing from 200 - 444.9 mg/dL to 210.6 - 576.4 mg/dL.

The MEAN and SD values are also being updated for both MA and FLEV, please see the table below.

Citrated Blood Reference Ranges

Parameter	Mean	SD	Range (95% Confidence Interval)
MA	21.6	5.1	11.5 - 31.6
FLEV	393.5	93.3	210.6 - 576.4

These TEG 5000 reference ranges are established according to CLSI EP28-A3 using samples from a heterogeneous population of healthy donors. Since patient populations may differ due to geography, age, diet, etc., customers should verify the manufacturer's ranges or establish their own reference ranges to enter into the software, as stated in the TEG 5000 System User Manual (113146-IE(AD)).

Product & Distribution Information:

This FSN and correction is applicable to TEG 5000 - Functional Fibrinogen Reagent (Item Number 07-034).

Risk to Health:

TEG 5000 Functional Fibrinogen users may experience CFF-MA readings above 24.4 mm, but below 31.6 mm, and FLEV results above 444.9 mg/dL, but below 576.4 mg/dL. Based on reference ranges in the current instructions for use, the high MA (above 24.4 but below 31.6) test result could be interpreted as hypercoagulable and the high FLEV (above 444.9 mg/dL but below 576.4 mg/dL) test result could be interpreted as increased fibrinogen contribution to clot strength. If the clinician relies solely on these TEG 5000 results in comparison to the normal donor reference range, it could lead to misdiagnosis and incorrect treatment or failure to treat. Haemonetics has not received any reports of adverse events associated with this issue.

Actions to be taken by the Customer/User:

Customers may continue to use the TEG 5000 Functional Fibrinogen reagent with the current instructions for use (118474-MULTI(AA)) in conjunction with this letter reflecting the updated ranges. Please assess your verified reference ranges for any impact related to this notification. The TEG 5000 user manual (113146-IE(AD)) will remain unchanged due to these reference range updates. When you receive the updated IFU for the TEG 5000 Functional Fibrinogen reagent (Item Number 07-034), follow your institutional protocol regarding manufacturer labeling changes.

As a reminder,

- Results from the TEG analyzer should not be the sole basis for a patient diagnosis.
- TEG analyzer results should be considered along with a clinical assessment of the patient's condition and other coagulation laboratory tests.

We ask that **all recipients of this notice complete the attached acknowledgement form in its entirety**. Once complete, please return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this FSN.

Haemonetics is actively revising the Functional Fibrinogen Reagent Instructions for Use (IFU, 118474-MULTI) for TEG 5000 with revised reference range values for CFF-MA from 11.0 – 24.4 mm to 11.5 – 31.6 mm and for FLEV from 200 - 444.9 mg/dL to 210.6 - 576.4 mg/dL.

We apologize for any disruption this situation may cause your organization and we thank you for your business and continued support. Haemonetics is committed to continually improving its products and services, with safety and quality as our top priority. This action is being performed by Haemonetics in full transparency with regulatory authorities. Please contact your Haemonetics representative or customer support if you have any questions.

Sincerely,

Andrew Sette

VP International Regulatory & Government Affairs

QSELA@haemonetics.com

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ACKNOWLEDGEMENT and RECEIPT FORM

TEG® 5000 - Functional Fibrinogen Reagent

Please complete this form in its entirety and return to Haemonetics within 7 days.

- I have read and understand this FSN regarding correction of the TEG Hemostasis System Functional Fibrinogen reagent (07-034).
- I do not have TEG Hemostasis System Functional Fibrinogen Reagent (07-034).

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

Institution city: _____

Institution Country: _____

SIGNATURE _____ DATE: _____

PLEASE RETURN BY FAX TO +41 22 594 8558 OR SCAN AND E-MAIL TO QSELA@HAEMONETICS.COM