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☐ PRODUCT RECALL ☐ MARKET WITHDRAWAL ☒ FIELD CORRECTIVE ACTION ☐ NOTIFICATION

TO: **TCAutomation / enGen Users**

FROM: **Thermo Fisher Scientific Oy, Clinical Diagnostics Finland**

DATE: **October 5th, 2009**

SUBJECT: **URGENT PRODUCT CORRECTION FOR TCAutomation™ / enGen™ Laboratory Automation Systems**

Issue Description:

This notification is to inform you, that Thermo Fisher Scientific recently became aware of one confirmed report of misreported patient results on an enGen™ Laboratory Automation System. We have determined after investigations that, for TCAutomation™ / enGen™ Laboratory Automation Systems with TCAutomation™ Software Versions 2.9 and below, incorrect sample IDs may be electronically written to the Radio Frequency ID (RFID) tags on the sample carriers, potentially leading to misreported patient results.

When each sample exits the automation system, the TCAutomation™ / enGen™ System performs an RFID tag cross check operation in the exit module. This operation verifies, that the sample ID on the sample barcode label matches the sample ID carried in the RFID tag of the sample carrier. A cross check error message is an indicator that the sample ID on the barcode label does not match the sample ID in the RFID tag. When cross check error occurs, it is possible that a sample ID may be associated to an incorrect sample and its corresponding assay results.

Description of Cross Check Error:

Description of Cross check error according to the TCAutomation Operator Manual (Cross check error message is shown on TCA Controller's Messages screen):

Error ID: 521

Text: Cross check failure: <Main Module Name>

The sample's barcode and the carrier's ID are not identical. Check the results of samples existing in the Exit module.

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Immediate Actions after Cross Check Error:

Each cross check error message has message details containing information of BCR SID and TAG SID, that shows mismatched information. Immediate actions are required, if valid ID is shown in both BCR SID and TAG SID. Both sample IDs involved must be retested, and if results have been already reported they must be rejected.

Products In Concern:

All TCAutomation™ / enGen™ laboratory automation systems

Further Actions:

1) Advice your customers to use a risk assessment approach to define and implement a process for their laboratory that will prevent the release of patient results prior to the completion of the cross check operation on each sample.

   Note: In case of cross check error, both sample IDs contained in the error message must be retested before releasing the results. Initial results for both samples must be rejected.

2) Based on your risk assessment, if no appropriate interventions are identified for your laboratory, Thermo Fisher Scientific recommends your customer to discontinue the use of TCAutomation™ / enGen™ laboratory automation system.

3) Our Marketing Support will answer any questions you or your customers may have and help you identify a process and a timeline for implementing a suitable solution for your customer's laboratory.

4) After informing this notification to the customers, please fill in the attached acknowledgement form with each customer and deliver it to the provided address.

Informing the Local Authorities (Competent Authority): Yes. Thermo Fisher Scientific will inform the issue to the National Agency for Medicines in Finland (Competent Authority in Finland).

We are continuing to actively investigate the root cause of this issue. We apologize for the inconvenience that this issue has caused your customer's laboratory.

If you have any additional questions regarding this notification, please contact:

Janne Järvinen, Product Marketing Manager, Laboratory Automation

janne.jarvinen@thermofisher.com or tel +358 9 329 10 759

Yours Sincerely,

[redacted] Quality Manager
Clinical Diagnostics Finland
Thermo Fisher Scientific Oy

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ACKNOWLEDGEMENT OF RECEIPT

I have received information of the URGENT CORRECTION regarding the TCAutomation™ / enGen™ Laboratory Automation System of October 5th, 2009, and I understand that I must implement a process for my laboratory that will prevent the release of patient results prior to the completion of the cross check operation on each sample.

If no appropriate interventions are identified for my laboratory, I must discontinue the use of TCAutomation™ / enGen™ Laboratory Automation System.

Date: _____

Institution name: _____

_____

Institution address: _____

_____

Institution phone number and fax: _____

_____

Responsible person: _____

_____

Responsible person's signature: _____

Please sign and fax to +358-9-32910300 by October 14th, 2009 or send the scanned fullfilled document to Info.cdx.fi@thermofisher.com