PerkinElmer
Wallac Oy
Mustionkatu 6
FI-20750 Turku, Finland

Phone +358 - (0)2 – 267 8111
Fax +358 - (0)2 – 267 8357
www.perkinelmer.com

Date 1 July 2014

URGENT: FIELD SAFETY NOTICE

Potential mismatch of patient demographics with test results within Specimen Gate Screening Center software

Product Code	Product Name	Product Version(s)
5002-0500	Specimen Gate Screening Center™	Versions 1.4 and 1.6

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is voluntarily recalling the PerkinElmer Specimen Gate Screening Center™ software, versions 1.4 and 1.6.

Reason for the Voluntary Recall:
We have become aware that an anomaly in Specimen Gate Screening Center™ software may cause incorrect test results to be reported for patients. Our investigation has shown that simultaneous entries or entries entered within milliseconds of another into the Specimen Gate database through the Screening Center module may create conditions where patient demographic information could become mismatched. This may result in one patient results being reported with another patient's demographic results.

Risk to Health: Potential False Negative and Positive Results
The software anomaly has the potential to mismatch demographic information and test results between patients. The mismatch of data could lead to the reporting of false negative or false positive screening results for the patient. Based on the low incidence of the diseases tested for in newborn screening and the low frequency (0.02%) with which the software anomaly has been observed to occur; the probability of an injury occurring has been assessed to be remote.

Actions to be taken by the Customer:
Until PerkinElmer corrective measures are available, we request you;

- Immediately limit the entry of patient demographics and test results into Screening Center to a single workstation / point of entry. Do not simultaneously attempt to input data into Screening Center from multiple points of entry.
- Prior to releasing a patient report, locate the specimen collection card human readable barcode number from the patient report.
- Retrieve the specimen collection card with the matching barcode number.
- Compare the demographic information of specimen collection card with that of the patient report to ensure the information on the report is accurate.
- If the demographic information is accurate; the patient report may be released.
- If the demographic information is not accurate, do not release the results and contact PerkinElmer Software Services for further support at +358 40 552 9938.

Actions to be taken by PerkinElmer:

- PerkinElmer is developing a software tool (Database Investigation Script) that PerkinElmer Health Informatics Software Services will run daily on your database, remotely, to determine if any anomalies have occurred. We will identify and communicate to you which demographic records need to be reviewed and corrected prior to patient reports being released.
- Once this first software tool corrective measure is available from PerkinElmer, you may discontinue the actions outlined in "Actions to be taken by the Customer" and resume normal sample entry and processing

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- PerkinElmer is developing a second software tool (Exception Script) that will be installed to Screening Center at your site that enables the identification of anomalies within 60 minutes of occurrence and notifies you of the affected specimen collection card barcode number and/or patient-identifying demographics so errors can be corrected prior to patient reports being released.
- As each software tool becomes available, you will be notified by your local PerkinElmer representative to arrange for deployment of the tools.
- You should continue to use both software tools, until the final corrective measures are available.

Final Corrective Action:
As a final corrective measure, a mandatory software update of Specimen Gate Screening Center will be developed once the root cause has been isolated. You will be notified when the software update is available and it will be provided to you free of charge.

Other Information:
Please distribute this information immediately to any staff that may be impacted by this Screening Center™ issue.

To comply with regulatory requirements we request that you complete the enclosed response form and return it by fax to number +358 2 2678 357 or scan and e-mail to TurkuQMresponse@perkinelmer.com as soon as possible, but not later than July 15, 2014.

We regret any inconvenience this product issue may cause and we appreciate your assistance. For further information, please contact your local PerkinElmer representative or SpecimenGateSupportFI@perkinelmer.com.

Sincerely,

Ann-Christine Fagerström
Quality Director
Wallac Oy

R2014004/EN

Date: 1 July 2014

RESPONSE FORM

Please complete this response form and send it by fax to +358 2 2678 357 or scan and e-mail to TurkuQMresponse@perkinelmer.com.

Product / versions affected:

Product Code	Product Name	Software Version
5002-0500	Screening Center™	Versions 1.4 and 1.6

1. Have you read the letter accompanying this form? The letter provides information of the medical device recall corrective action by PerkinElmer of the above listed device.

☐ Yes ☐ No

Signature / Date _____ / _____

Printed Name _____

Laboratory / Clinic _____

State / Country _____

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