

Date: July 09, 2015

URGENT – FIELD SAFETY NOTICE PIGF Kit Calibrator Stability Impaired

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT NUMBERS
DELFLA XPRESS PLGF KIT	6007-0010	1063814601
DELFLA XPRESS PLGF KIT	6007-0020	1063779001
DELFLA XPRESS PLGF KIT	6007-002C	1063825401, 1063782701

Dear Customer,

The purpose of this letter is to inform you that PerkinElmer is voluntarily recalling the lots of the DELFLA Xpress PIGF Kit (6007-0010, 6007-0020 and 6007-002C) listed above.

Reason for the Voluntary Recall:

We have become aware that the stability of the PIGF Calibrators lot 637341 is impaired. The stability issue is limited to one lot of PIGF Calibrators which is included in the PIGF kits lot shown above. Due to the impaired stability a decreasing trend in the signal level measured for the PIGF Calibrators occurs; the signal level of the PIGF Calibrators lot 637341 has decreased an average of 20% since release. The signal decrease results in the measured PIGF concentrations for the QC controls and patient samples will be falsely high, expected increase is approximately +20%.

Our investigations have identified the impaired stability of the PIGF Calibrators is due to an issue in the quality of a single batch of the raw material used in the manufacture of the PIGF Calibrators.

Risk to Health:

The risk to health was assessed to be low. The DELFLA Xpress PIGF kit instructions for use state that patient results should not be reported unless the values for the controls are within the defined acceptable range. Therefore no incorrect patient results should have been reported.

If control values were not within the defined acceptable range due to the stability issue of the PIGF Calibrators a delay in reporting patient risk screening results may have occurred for Pre-eclampsia and first trimester Downs Syndrome.

Actions to be taken:

Immediately discontinue use of the DELFLA Xpress PIGF kit lots listed in this Field Safety Notice. The remaining affected DELFLA Xpress PIGF kits in your inventory should be destroyed.

Review your PIGF control values for completed DELFLA Xpress PIGF runs with the above listed product lots. If the results for the QC controls have been within your established acceptance range, the patient sample results should be valid. If any deviation occurred in the measured PIGF control values, we recommend you to repeat the patient samples with another DELFLA Xpress PIGF kit lot.

R2015005

PerkinElmer will replace all DELFIA Xpress PIGF Kits of the designated lots in your inventory.

Please complete and return the attached **FSN Response Form** identifying the number of kits of the affected products in your inventory.

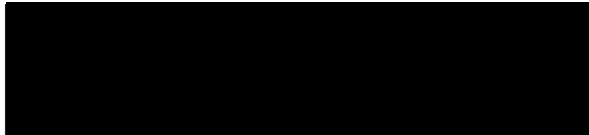
The completed response form should be returned for replacement DELFIA Xpress PIGF Kits by fax to + 358 2 2678 357 or by scanning and emailing to TurkuQMresponse@perkinelmer.com.

Please contact your local PerkinElmer representative for further information.

Other Information:

Please inform those affected in your organization accordingly.

We regret the inconvenience this recall causes and we appreciate your assistance.



Ann-Christine Fagerström
Quality Director
PerkinElmer Turku Site

Enclosure(s): Field Safety Notice Response Form

R2015005

Date: July 09, 2015

FSN 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(s) affected:

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT NUMBERS
DELFINA XPRESS PLGF KIT	6007-0010	1063814601
DELFINA XPRESS PLGF KIT	6007-0020	1063779001
DELFINA XPRESS PLGF KIT	6007-002C	1063825401, 1063782701

1. Have you read the letter accompanying this form? The letter provides information about the Field Safety Notice by PerkinElmer affecting the above listed products / lots.

Yes No

2. Please record the total number of defective DELFINA Xpress PIGF Kits in your inventory.

DELFINA XPRESS PLGF KIT LOT	NUMBER OF DEFECTIVE KITS IN INVENTORY
1063814601	
1063779001	
1063825401	
1063782701	

3. Please provide your contact name and shipping information. The replacement DELFINA Xpress PIGF Kits will be shipped to this address and to the attention of the individual named.

Ship to Name: _____

Ship to Address: _____

Signature _____ Date _____

Printed Name _____

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