

Date 04 October 2021

## INFORMATION - RECOMMENDATION

### Potential for decreased analyte measurement with DELFIA<sup>®</sup> Xpress Free hCG $\beta$ kits

Product Code	Product Name	Kit Lot Number	UDI
6002-0010	DELFIA <sup>®</sup> Xpress Free hCG $\beta$ kit	1068884601	(01)06438147178148(17)221031(10)688846

Dear Customer,

The purpose of the letter is to inform you that PerkinElmer is voluntarily initiating a field correction of PerkinElmer DELFIA<sup>®</sup> Xpress Free hCG $\beta$  kit lots identified above.

#### Reason for Correction:

We have become aware that the measured free hCG $\beta$  analyte concentrations in occasional patient samples may be decreased with DELFIA<sup>®</sup> Xpress Free hCG $\beta$  kit lots identified above. The issue may also cause failed results. Based on investigation the antifoam concentration of the Free hCG $\beta$  tracer is incorrect. The issue may lead to occasional pipetting failures of the Free hCG $\beta$  Tracer during the assay procedure.

#### Risk to Health:

The risk to health has been assessed to be low. The decreased free hCG $\beta$  analyte concentrations may cause an increase in false low risk results in Down's syndrome screening by 0,0065%. The proportion of false low risk results depends on your local risk calculation protocol. The failed results may cause minor delay in reporting.

#### Actions to be taken:

- Inspect the inventory for the affected DELFIA<sup>®</sup> Xpress Free hCG $\beta$  lots
- If another DELFIA<sup>®</sup> Xpress Free hCG $\beta$  lot is not available, the screening for Down's syndrome may be continued, with caution on the falsely low free hCG $\beta$  results.
- Dispose the affected DELFIA<sup>®</sup> Xpress Free hCG $\beta$  lot according to your local requirements.
- Complete the Response Form with the quantity of affected DELFIA<sup>®</sup> Xpress Free hCG $\beta$  lot you have used/disposed from your inventory and return the Response Form to PerkinElmer and replacement kits will be shipped to you upon its receipt.

#### Other Information:

Please distribute this information to any staff that may be impacted by this issue.

To comply with regulatory requirements, we request that you complete the enclosed Response Form and return it to fax number +358 2 2678 357 or as scanned document by e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com) as soon as possible, but not later than 29 October 2021.

We regret the inconvenience this is causing and we appreciate your understanding. For further information, please contact your local PerkinElmer representative.

R2021003

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Mikaela Toivonen  
Quality Director  
Wallac Oy

Date 04 October 2021

## RESPONSE FORM

Please complete this response form and send it by fax to number + 358 2 2678 357 or as scanned by e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com).

Product(s) affected:

Product Code	Product Name	Kit Lot Number	UDI
6002-0010	DELFI <sup>®</sup> A Xpress Free hCG $\beta$ kit	1068884601	(01)06438147178148(17)221031(10)688846

1. Have you read the letter accompanying this form? The letter provides information of the field correction by Wallac Oy of the above listed products / lots.

Yes       No

2. Please record the total number of items of each of the affected lot(s) that you have disposed from your inventory:

Product lot / serial / version number	Pieces of defective product in your inventory

3. Did you check all items of the affected lot(s) that you have in inventory for defective products as described in the letter that accompanies this form?

Yes       No

4. Please provide your contact name and shipping information. The replacement of DELFI<sup>®</sup>A Xpress Free hCG $\beta$  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 \_\_\_\_\_