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Date: October 18, 2013

URGENT – FIELD SAFETY NOTICE
High samarium background in Enhancement Solution

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT NUMBERS
DELFIA / AUTODELFIA ENHANCEMENT SOLUTION (8X250 ML)	**B118-100**	624854, 625522, 626050, 626298

Dear Customer,

The purpose of this letter is to inform you that **PerkinElmer Wallac Oy** is voluntarily recalling the above listed DELFIA / AutoDELFIA Enhancement Solution batches which are intended to be used in quantitative determination of the europium (Eu^{3+}) and samarium (Sm^{3+}) in dissociation-enhanced time-resolved DELFIA and AutoDELFIA fluoroimmunoassays.

Reason for the Voluntary Recall:
We have become aware through customer complaint investigation that some batches of Enhancement Solution show significantly higher samarium fluorescence background signal than typically measured in the DELFIA / AutoDELFIA assays using Sm-labeled antibodies as tracer. The high Sm- background **may affect the results only when two point calibration option is used.** The results measured against a whole calibration curve are not affected.
The affected assays are to measure Free hCGβ with AutoDELFIA AFP / Free hCGβ (B067-101) and AutoDELFIA Free hCGβ (B097-101) and to measure Total PSA with AutoDELFIA PSA Free / Total (B073-301).

The magnitude of the effect in measured concentrations depends on the reference calibration curve i.e. the Sm-signal of the Enhancements Solution used when reference curve was established
In the worst case the effect is seen as a decrease or increase in results at low Free hCGß concentration range and as an increase in the results at Total PSA concentration range. At the higher concentration levels the effect is minor and within the range of normal lot-to-lot variation.

The deficiency in Enhancement Solution does **not affect the results measured using Eu-labeled antibodies** as tracer.

The affected Enhancement Solution lots are listed in the table above.

Risk to Health:
In the worst case the high Sm- background may result in prenatal screening a false high risk for Trisomy 21 and in male population screening a false high risk for prostate cancer to be reported.

Actions to be taken:
All affected products in our inventory were placed on a shipping hold.
We have been able to identify a potential root cause in one of the raw materials of Enhancement Solution.
The investigation for the root cause is continued. Once we have completed our investigation the appropriate corrective action will be implemented.

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Corrective Action:
If you have been using the above listed, **defective Enhancement Solution lots and the two point calibration** in the AutoDELFIA assays for AFP / Free hCGβ, Free hCGβ or PSA Free / Total, as an immediate corrective action, we require that you **change to use another lot** of Enhancement Solution.
If you do not have another lot of Enhancement Solution (i.e. a lot not listed in the table of this FSCA letter) in your inventory, we recommend that you use whole calibration curve on each plate until you receive the replacement bottles of Enhancement Solution.

In the case of defective Enhancement Solution has been used with two point calibration, we recommend that you review the results for unexpectedly high signal level and assess the need and benefit of repeating the samples.

Customer Action:
We will replace your local Enhancement Solution inventory of the above listed lots with a new Enhancement Solution lot.

- Please complete and return the attached **FSCA response form** that identifies the current quantity of the defective lots of Enhancement Solution bottles in your inventory.
- Provide your shipping contact name and address in the **FSCA response form**.
- Once we have received the **returned FSCA response form**, a shipment of replacement Enhancement Solution will automatically be shipped to you.
- **It is essential that you destroy all remaining affected Enhancement Solution bottle inventory after receipt of the replacement shipment to ensure testing is not adversely impacted.**

Please contact your local PerkinElmer representative for further information.

Other Information:
Please inform those affected in your organization accordingly.

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 no later than November 08, 2013.

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

Ann-Christine Fagerström
Quality Director
PerkinElmer Turku Site

Enclosure(s): Recall Response Form

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Date: October 18, 2013

FSCA RESPONSE FORM

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

Product(s) affected:

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT NUMBERS
DELFIA / AUTODELFIA ENHANCEMENT SOLUTION (8X250 ML)	**B118-100**	624854, 625522, 626050, 626298

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

☐ Yes ☐ No

2. Please record the total number of Enhancement Solution bottles from affected lots that you have in inventory to be replaced

ENHANCEMENT SOLUTION LOT	PIECES IN INVENTORY

3. Please provide your contact name and shipping information. The replacement Enhancement Solution bottles 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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