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www.revvity.com

Date 03 August 2023

URGENT: FIELD SAFETY NOTICE

Defective Vanadis Extract® Reaction Plates
Product number 4306-0010

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT	REACTION PLATE LOT	LOT NUMBER ON THE BARCODE
Vanadis Extract® Reaction Plates	4306-0010	742254	741096	505XXX741096XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	744491	743926	505XXX743926XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	744811	744481	505XXX744481XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	745232	744592	505XXX744592XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	745619	745136	505XXX745136XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	746077	745859	505XXX745859XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	746522	746100	505XXX746100XXXXXX

Dear Customer,

The purpose of the letter is to inform you that Revvity, formerly PerkinElmer, is initiating a Field Safety Corrective Action of Vanadis Extract® Reaction Plates product, of the lots listed above.

Reason for the Voluntary Recall/ Reason for the Voluntary Field Safety Corrective Action:

We have become aware that the above lots of the Vanadis Extract® Reaction Plates can include plates, which are not acceptable to be used in Vanadis system. These plates have been manufactured by our supplier using a different mold and can be identified based on the number 2 or 3 in the corner of the reaction plate (picture below). They are slightly higher and have 8 additional bars at the rim of the plate which causes the plate to rest 1-2 mm higher on the instrument adapter, which may result in run failure due to issues with moving the plate within the instrument or, due to suboptimal temperature during extraction of cell-free DNA, (cfDNA) can cause insufficient protein degradation, which can potentially affect performance of the Vanadis Core® T21/T18/T13 Reagent Cartridge.

Reaction Plates with no marking are manufactured using the correct mold and can continue to be used. Vanadis Extract® Reaction Plates with later lot numbers have been inspected and are not affected by this issue.

Wallac Oy Business Identity Code: 0937168-4 Registered office: Turku

Risk to Health:
Insufficient protein degradation during extraction of cfDNA can potentially affect performance of the Vanadis Core® T21/T18/T13 Reagent Cartridge assay and may cause failed results or an increase in false positive rate in prenatal screening of trisomy 21, 18, and/or 13. A false positive screening result may cause indirect harm due to the possibility for unnecessary confirmatory testing and/or medical intervention. The risk to health has been assessed to be moderate.

The failed results may cause minor delay in reporting.

Actions to be taken by the customer:

- Inspect the Reaction Plates prior to use in the Vanadis Extract® instrument, **do not use plates with number 2 or 3 in the corner of the reaction plate.**
- **Plates with no marking can continue to be used.**
- Destroy the defective Reaction Plates according to your local requirements.
- Complete the Response Form with the quantity of Reaction Plates you have disposed of from your inventory and return the Response Form to Revvity. Replacements will be shipped to you free of charge upon its receipt.

Please contact your local Revvity 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 +1 330 -825-8520 / +358 2 2678 357 or as scanned by e-mail to TurkuQMresponse@perkinelmer.com as soon as possible, but not later than 04 September 2023.
We regret the inconvenience this is causing and we appreciate all your assistance.

[redacted]
Quality Director
Wallac Oy

Enclosure(s): Response Form

R2023003

RESPONSE FORM

Date 03 August 2023

Please complete this response form and send it by fax to number +1 330 -825-8520 /+ 358 2 2678 357 or as scanned by e-mail to TurkuQMresponse@perkinelmer.com.

Product(s) affected:

PRODUCT NAME	PRODUCT NUMBER	PRODUCT LOT	REACTION PLATE LOT	LOT NUMBER ON THE BARCODE
Vanadis Extract® Reaction Plates	4306-0010	742254	741096	505XXX741096XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	744491	743926	505XXX743926XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	744811	744481	505XXX744481XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	745232	744592	505XXX744592XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	745619	745136	505XXX745136XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	746077	745859	505XXX745859XXXXXX
Vanadis Extract® Reaction Plates	4306-0010	746522	746100	505XXX746100XXXXXX

1. I acknowledge that I have read and understood the letter accompanying this form.

☐ Yes ☐ No

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

PRODUCT LOT	REACTION PLATE LOT	PIECES OF DEFECTIVE PRODUCT IN YOUR INVENTORY
742254	741096	
744491	743926	
744811	744481	
745232	744592	
745619	745136	
746077	745859	
746522	746100	

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

☐ Yes ☐ No

If No, please explain:

_____

_____

_____

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I have destroyed all affected products (please enter the number destroyed and date completed in the table below)

☐ Yes ☐ No

If No, please explain:

PRODUCT LOT	REACTION PLATE LOT	QUANTITY OF REACTION PLATES DESTROYED	DATE DESTROYED
742254	741096		
744491	743926		
744811	744481		
745232	744592		
745619	745136		
746077	745859		
746522	746100		

4. Have you identified or received information on potential incidents* associated with the issue described in the letter accompanying this form?

☐ Yes ☐ No

*Incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, *might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health*. Incomplete or inaccurate results may indirectly lead to an incident as a consequence of the medical decision, action taken/not taken on the basis of the information or result(s) provided by the device.

If Yes, please explain:

5. Please provide your contact and shipping information. The replacement of Vanadis Extract® Reaction Plates will be shipped to this address and to the attention of the individual named.

Health Care Organisation Name	
Organisation Address	

Department/Unit	
Shipping address if different to the above	
Contact Name	
Title or Function	
Email	
Shipping contact name if different	

Signature _____ Date _____

Printed Name _____

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