

17 December 2021

URGENT: FIELD SAFETY NOTICE

Potential for decreased analyte measurement with DELFIA[®] Xpress hAFP, Free hCG β , PAPP-A, and hCG kits

Dear Customer,

The purpose of the letter is to inform you that PerkinElmer is voluntarily initiating a field safety corrective action of PerkinElmer DELFIA[®] Xpress hAFP, Free hCG β , PAPP-A, and hCG kit lots identified in the enclosed response form.

Reason for the Voluntary Field Safety Corrective Action:

We have become aware that the measured analyte concentrations in occasional patient samples may be decreased with DELFIA[®] Xpress kit lots identified in the enclosed response form. The issue may also cause failed results. Based on investigation the antifoam concentration of the tracers is incorrect at the end of the manufacturing series and therefore only certain tracer vials are affected by the issue. The issue may lead to occasional pipetting failures of the tracer during the assay procedure.

Risk to Health:

The risk to health is dependent on the analyte. For hAFP and PAPP-A the risk to health has been assessed to be moderate. The decreased hAFP or PAPP-A analyte concentrations may cause an increase in false high risk results in Down's syndrome screening. The proportion of false high risk results depends on your local risk calculation protocol. A false positive screening result may cause indirect harm due to possibility for unnecessary confirmatory testing and/or medical intervention.

The decreased AFP concentration may cause an increase in false negative results in Neural Tube Defect screening which may cause delay in diagnosis and subsequent clinical decisions.

For Free hCG β and hCG the risk to health has been assessed to be low. The decreased Free hCG β and hCG analyte concentrations may cause an increase in false low risk results in Down's syndrome screening.

The failed results may cause minor delay in reporting.

Actions to be taken by the customer:

- Inspect the inventory for the affected DELFIA[®] Xpress kit lots
- If you have affected DELFIA[®] Xpress kit lots, confirm whether the tracers included in kits lots are affected by inspecting the tracer vial numbers from the tracer barcodes on the tracer labels visually or with the help of a barcode reader. Figure 1 is an example tracer label for Free hCG β Tracer lot 690880. The barcode format is 0AAAAAABBBBC. Only 11 digits are printed below the barcode i.e. 0AAAAAABBBB excluding the check digit C. The check digit is visible, when the barcode is read with hand held barcode reader to Notepad.
 - The first digit is always zero

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- **AAAAAA is the tracer lot number** (Figure 1 – the tracer lot is 690880, Figure 2 – the tracer lots are 688007 and 690231)
- **BBBB is the sequential number of the vial in the manufacturing series** (Figure 1 – vial number is 0000, Figure 2 – the vial numbers are 1160 and 0394)
- C is the check digit. **The check digit is not printed below the barcode** (see the example, Figure 1) The check digit is shown when the barcode is read with a hand-held barcode reader to Notepad. (see Figure 2)

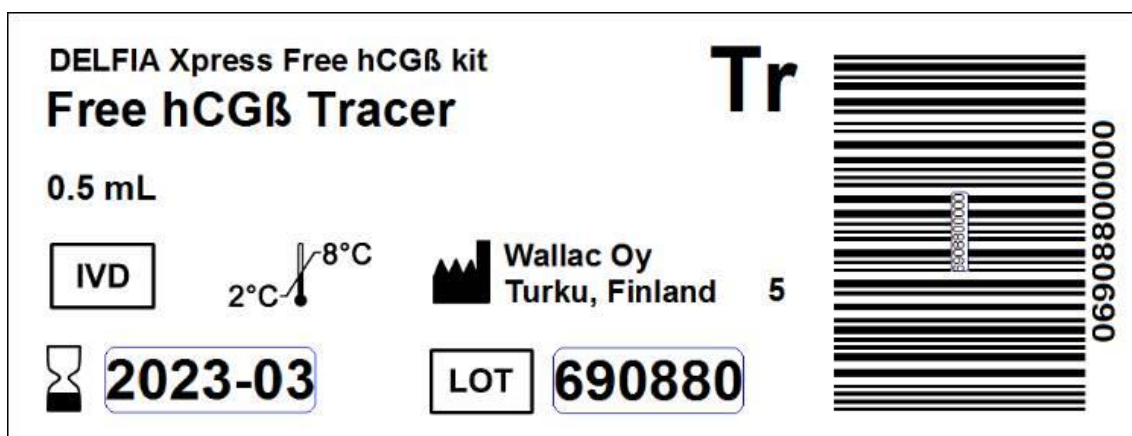


Figure 1. Example of printed barcode excluding check digit, four last numbers equal vial number 0000

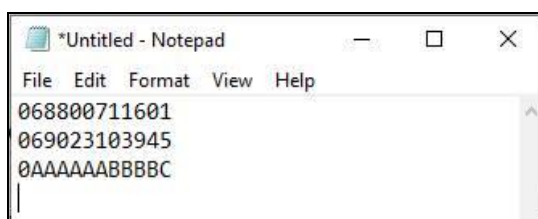


Figure 2. Example barcodes read with barcode reader including the check digit as the last digit, vial numbers are 1160 and 0394

- Confirm from the table below if the sequential number of the vial (BBBB) is affected by the issue.
- If the tracer vial is not affected by the issue, the use of the kit can continue
- If the tracer vial is affected by the issue and another vial or kit lot is not available, the screening for Down's syndrome and/or Neural Tube Defect may be continued, with caution on the falsely low analyte results.
- Dispose the affected DELFIA® Xpress kit lots according to your local requirements.
- Complete the Response Form with the quantity of affected DELFIA® Xpress kit lots you have disposed from your inventory and return the Response Form to PerkinElmer and replacement kits will be shipped to you upon its receipt.

Please contact your local PerkinElmer representative for further information.

Tracer	Tracer lot number	Sequential number of the affected vials
Free hCGβ Tracer	689004	0373 – 0778
Free hCGβ Tracer	689679	4078 – 4622
Free hCGβ Tracer	690880	0298 – 0699
Free hCGβ Tracer	691528	4254 – 4887
hAFP Tracer	688913	0507 - 1612
hAFP Tracer	690343	0381 – 0783
hCG Tracer	690632	0261 – 0461
PAPP-A Tracer	688463	0376 – 0783

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PAPP-A Tracer	689131	0461 – 0865
PAPP-A Tracer	689733	0186 – 0591
PAPP-A Tracer	690733	0676 – 1084
PAPP-A Tracer	691418	0247 – 0674

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 31 January 2022.

We regret the inconvenience this is causing and we appreciate all your assistance.

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

Mikaela Toivonen
Quality Director
Wallac Oy

Enclosure(s): Response Form

RESPONSE FORM

17 December 2021

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:

Kit no.	Kit name	Kit lot	Tracer lot	UDI
6001-0010	DELFLIA Xpress hAFP kit	1068903501	688913	(01)06438147178131(17)220228(10)689035
6001-0010	DELFLIA Xpress hAFP kit	1068922301	688913	(01)06438147178131(17)220228(10)689223
6001-0010	DELFLIA Xpress hAFP kit	1068977901	688913	(01)06438147178131(17)220228(10)689779
6001-0010	DELFLIA Xpress hAFP kit	1069054502	690343	(01)06438147178131(17)220228(10)690545
6001-0010	DELFLIA Xpress hAFP kit	1069071801	690343	(01)06438147178131(17)220531(10)690718
6001-0010	DELFLIA Xpress hAFP kit	1069094901	690343	(01)06438147178131(17)220531(10)690949
6001-001C	DELFLIA Xpress hAFP kit	1068991101	688913	(01)06438147252381(17)220228(10)689911
6001-001C	DELFLIA Xpress hAFP kit	1069071701	690343	(01)06438147252381(17)220531(10)690717
6002-0010	DELFLIA Xpress Free hCG β kit	1068952002	689004	(01)06438147178148(17)221031(10)689520
6002-0010	DELFLIA Xpress Free hCG β kit	1068967401	689004	(01)06438147178148(17)221130(10)689674
6002-0010	DELFLIA Xpress Free hCG β kit	1069019302	689679	(01)06438147178148(17)221130(10)690193
6002-0010	DELFLIA Xpress Free hCG β kit	1069090301	689679	(01)06438147178148(17)230131(10)690903
6002-0010	DELFLIA Xpress Free hCG β kit	1069097501	690880	(01)06438147178148(17)230131(10)690975
6002-0010	DELFLIA Xpress Free hCG β kit	1069101301	690880	(01)06438147178148(17)230228(10)691013
6002-0010	DELFLIA Xpress Free hCG β kit	1069184501	691528	(01)06438147178148(17)230228(10)691845
6002-001C	DELFLIA Xpress Free hCGB kit	1069008101	689679	(01)06438147252398(17)221130(10)690081
6002-001C	DELFLIA Xpress Free hCGB kit	1069180401	691528	(01)06438147252398(17)230228(10)691804
6003-0020	DELFLIA Xpress PAPP-A kit	1068868301	688463	(01)06438147244904(17)220228(10)688683
6003-0020	DELFLIA Xpress PAPP-A kit	1068893801	688463	(01)06438147244904(17)220228(10)688938
6003-0020	DELFLIA Xpress PAPP-A kit	1068946901	689131	(01)06438147244904(17)220430(10)689469
6003-0020	DELFLIA Xpress PAPP-A kit	1068949101	689131	(01)06438147244904(17)220430(10)689491
6003-0020	DELFLIA Xpress PAPP-A kit	1068997401	689733	(01)06438147244904(17)220430(10)689974
6003-0020	DELFLIA Xpress PAPP-A kit	1069064901	689733	(01)06438147244904(17)220531(10)690649
6003-0020	DELFLIA Xpress PAPP-A kit	1069077201	689733	(01)06438147244904(17)220531(10)690772
6003-0020	DELFLIA Xpress PAPP-A kit	1069081601	690733	(01)06438147244904(17)220531(10)690816
6003-0020	DELFLIA Xpress PAPP-A kit	1069109501	690733	(01)06438147244904(17)220531(10)691095
6003-0020	DELFLIA Xpress PAPP-A kit	1069155501	691418	(01)06438147244904(17)220531(10)691555
6003-0020	DELFLIA Xpress PAPP-A kit	1069187501	691418	(01)06438147244904(17)220731(10)691875
6003-0020	DELFLIA Xpress PAPP-A kit	1069187701	691418	(01)06438147244904(17)220731(10)691877
6003-0020	DELFLIA Xpress PAPP-A kit	1069201701	691418	(01)06438147244904(17)220731(10)692017
6003-002C	DELFLIA Xpress PAPP-A kit	1068985101	688463	(01)06438147253890(17)220430(10)689851
6003-002C	DELFLIA Xpress PAPP-A kit	1069077101	689733	(01)06438147253890(17)220531(10)690771
6003-002C	DELFLIA Xpress PAPP-A kit	1069190001	691418	(01)06438147253890(17)220630(10)691900
6003-0050	DELFLIA Xpress PAPP-A	1068908301	688463	(01)06438147348565(17)220228(10)689083
6003-0050	DELFLIA Xpress PAPP-A	1069120701	690733	(01)06438147348565(17)220531(10)691207
6003-0050	DELFLIA Xpress PAPP-A	1069180501	691418	(01)06438147348565(17)220531(10)691805
6003-005C	DELFLIA Xpress PAPP-A	1069171401	691418	(01)06438147348572(17)220531(10)691714

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6004-0010	DELFLIA Xpress hCG kit	1069123001	690632	(01)06438147295593(17)220131(10)691230
6004-0010	DELFLIA Xpress hCG kit	1069220501	690632	(01)06438147295593(17)220331(10)692205
6004-0010	DELFLIA Xpress hCG kit	1069310201	690632	(01)06438147295593(17)220531(10)693102
6004-001C	DELFLIA Xpress hCG kit	1069327001	690632	(01)06438147295630(17)220531(10)693270
6004-001C	DELFLIA Xpress hCG kit	1069397101	690632	(01)06438147295630(17)220531(10)693971

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 lots that you have in inventory:

Kit Name	Kit lot

3. Did you inspect all items of the affected lots 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:

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

Yes No

If No, please explain:

Tracer lot	Pieces of defective tracer vials in your inventory	Vial sequential numbers	Quantity destroyed	Date destroyed

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 disposed kits 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 _____