

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)

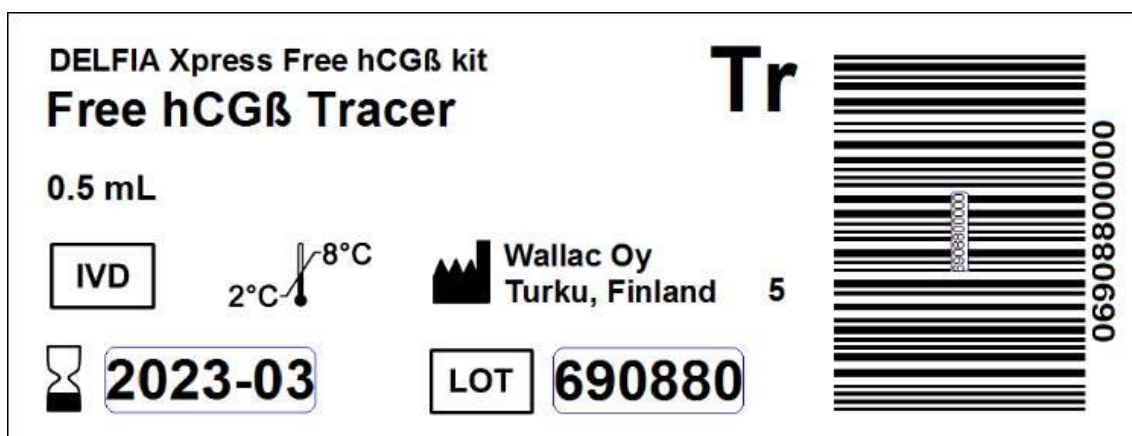


Figure 1. Example of printed barcode excluding check digit, four last numbers equal vial number 0000

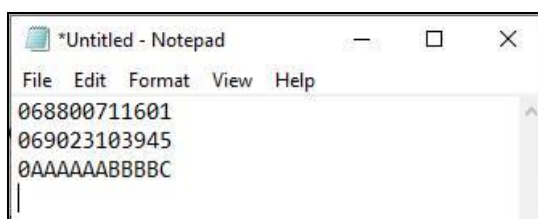


Figure 2. Example barcodes read with barcode reader including the check digit as the last digit, vial numbers are 1160 and 0394

- 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.

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 _____