

**URGENT – FIELD SAFETY NOTICE**  
**Potential for decreased analyte measurements with**  
**DELFLA /AutoDELFLA hCG kit**

Product Code	Product Name	Kit Lot Number	Pack Lot Number	UDI
A007-101	DELFLA® hCG Kit	664891 666471 666604	1066489101, 1066647101, 1066660401	(01)06438147009176(17)190430(10)664891 (01)06438147009176(17)190430(10)666471 (01)06438147009176(17)190430(10)666604
B007-101	AutoDELFLA® hCG Kit	664670 666553	1066467001 1066467002 1066655301	(01)06438147009336(17)190430(10)664670 (01)06438147009336(17)190430(10)666553
B007-112	AutoDELFLA® hCG Kit	664303	1066430301 1066430302	(01)06438147009343(17)190430(10)664303
A082-101	DELFLA® hCG Kit	667233	1066723301	(01)06438147121533(17)191231(10)667233
B082-101	AutoDELFLA® hCG Kit	667140	1066714001	(01)06438147121540(17)191231(10)667140

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is voluntarily initiating a field safety corrective action (FSCA) of PerkinElmer DELFLA® / AutoDELFLA® hCG kit lots identified above.

**Reason for the Correction:**

We have become aware that hCG analyte concentrations may be decreased up to 15- 20% at the lower measuring range of hCG concentrations. A decrease with higher concentrations (i.e.  $\geq 1000$  IU/L) is approximately 2%. The root cause investigation is ongoing.

**Risk to Health:**

The risk to health has been assessed to be low. The potential consequence of the decrease in hCG measurements is a delay in reporting the patient sample results. When the hCG assay results are rejected due to the control values being outside laboratory's established acceptance range, the samples must be retested.

**Actions to be taken:**

PerkinElmer requires customers to:

- Inspect DELFLA / AutoDELFLA hCG kit inventory for the affected lots.
- Review your QC follow-up of the AutoDELFLA hCG assay for potential decrease in the control concentrations.
- If the control values are within your established acceptance range it is safe to report the results
- To avoid unnecessary repeat testing of samples, if the control values are out of the acceptance range discontinue use of the DELFLA / AutoDELFLA hCG kit lot and dispose the remaining kits of the lot.
- Complete the Response Form with the quantity of affected DELFLA / AutoDELFLA hCG kits you have disposed from your inventory.
- Return the Response Form to PerkinElmer and replacement kits will be shipped to you upon its receipt.

R2018006

**Other Information:**

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

To comply with regulatory requirements we require that you complete the enclosed Response Form and return it to fax number 1-330-825-8520 (North America) / +358 2 2678 357 (all other regions) or as scanned document by e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com) as soon as possible, but not later than 31 January, 2019.

We regret the inconvenience this issue may cause to you and we appreciate your understanding. For further information, please contact your local PerkinElmer representative.



Rina Wahlroos  
Quality Director  
PerkinElmer Turku Site

Attachment: Response Form R2018006

R2018006

Date: January 08, 2019

**RESPONSE FORM**

Please complete this response form and return it by fax to phone number 1-330-825-8520 (for North America) / +358 2 2678 357 (for all other regions) or as scanned document by e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com).

Product(s) affected:

Product Code	Product Name	Kit Lot Number	Pack Lot Number	UDI
A007-101	DELFI <sup>®</sup> hCG Kit	664891 666471 666604	1066489101, 1066647101, 1066660401	(01)06438147009176(17)190430(10)664891 (01)06438147009176(17)190430(10)666471 (01)06438147009176(17)190430(10)666604
B007-101	AutoDELFI <sup>®</sup> hCG Kit	664670 666553	1066467001 1066467002 1066655301	(01)06438147009336(17)190430(10)664670 (01)06438147009336(17)190430(10)666553
B007-112	AutoDELFI <sup>®</sup> hCG Kit	664303	1066430301 1066430302	(01)06438147009343(17)190430(10)664303
A082-101	DELFI <sup>®</sup> hCG Kit	667233	1066723301	(01)06438147121533(17)191231(10)667233
B082-101	AutoDELFI <sup>®</sup> hCG Kit	667140	1066714001	(01)06438147121540(17)191231(10)667140

1. Have you read the letter accompanying this form? The letter provides information about the Medical Device Correction by PerkinElmer affecting the above listed product and lots.

Yes

No

2. Please record the total number defective DELFIA / AutoDELFI<sup>®</sup> hCG kits disposed.

KIT LOT	PRODUCT PACK LOT	NUMBER OF KITS DISPOSED
664891	1066489101	
666471	1066647101	
666604	1066660401	
664670	1066467001	
664670	1066467002	
666553	1066655301	
664303	1066430301	
664303	1066430302	
667233	1066723301	
667140	1066714001	

4. Please provide your contact name and shipping information. The replacement DELFIA / AutoDELFI<sup>®</sup> hCG 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 \_\_\_\_\_

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