

Date: October 31, 2018

MEDICAL DEVICE CORRECTION

DELFIA Xpress Sample Tube Rack Deficiency

PRODUCT NAME	PRODUCT NUMBER	SERIAL NUMBERS
DELFIA® XPRESS	6000-0010	See separate list
DELFIA® XPRESS SAMPLE TUBE RACK (50-75 MM)	6000-2010	n/a
DELFIA® XPRESS SAMPLE TUBE RACK (75-100 MM)	6000-2020	n/a
DELFIA® XPRESS CALIBRATOR RACK	6000-2030	n/a
SAMPLE TUBE RACK WITH DILUTION (50-75 MM)	6000-2060	n/a
SAMPLE TUBE RACK WITH DILUTION (75-100 MM)	6000-2070	n/a
SAMPLE CAROUSELS MULTIPROCESS TOOL PACKAGE	61005006	n/a

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is conducting a voluntary medical device correction concerning sample and calibrator racks as listed in the table above. The affected sample and calibrator racks have been delivered as spare parts or together with the DELFIA Xpress instruments as listed in the table above.

Reason for the Medical Device Correction:

PerkinElmer has become aware that some DELFIA Xpress sample or calibrator racks delivered with the instruments or as spare parts are deficient, causing the tube holders to position tubes in a nonvertical alignment. The accuracy of aspirated sample / calibrator volume is not affected. However, in some instances where the probe does not detect the tube due to nonvertical alignment, instrument will give a no result flagging. This may result a short delay in reporting the results due to the need to retest the samples.

The root cause for the deficiency was a supplier manufacturing error in the production of the bushing that holds the tubes in a vertical position. The plastic compound of the bushing component omitted a required ingredient.

The deficiency may affect the sample and calibrator racks delivered on or after 8 December 2016.

Risk to Health:

The risk to health was assessed to be low. The potential tilting of sample tubes or calibrator vials in the racks may cause a situation where no sample / calibrator can be aspirated that causes a no-result situation or in the worst case stop the assay run. This may cause a short delay in reporting the results due to the need to retest the samples.

R2018005

Actions to be taken:

PerkinElmer will replace all affected sample and calibrator racks manufactured on or after 08 October 2016. Until the replacement racks are received it is safe to continue to use the sample and calibrator racks already delivered. After receiving the replacement racks please remove the defective sample and calibrator racks from use.

To comply with regulatory requirements we require that you complete the enclosed Response Form and return it by fax to +358 2 2678 357 or as scanned document by e-mail to TurkuQMresponse@perkinelmer.com as soon as possible.

Please contact your local Perkin Elmer contact for more information.

Other Information:

Please inform those affected in your organization accordingly.

We regret the inconvenience the issue may have caused to you and we appreciate your understanding.



Rina Wahlroos Quality Director
PerkinElmer Turku Site

Enclosure(s): List of the serial numbers of the affected DELFIA Xpress Instruments
Response Form

Date: October 31, 2018

RESPONSE FORM

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

Product(s) affected:

PRODUCT NAME	PRODUCT NUMBER	SERIAL NUMBERS
DELFLIA® XPRESS	6000-0010	See separate list
DELFLIA® XPRESS SAMPLE TUBE RACK (50-75 MM)	6000-2010	n/a
DELFLIA® XPRESS SAMPLE TUBE RACK (75-100 MM)	6000-2020	n/a
DELFLIA® XPRESS CALIBRATOR RACK	6000-2030	n/a
SAMPLE TUBE RACK WITH DILUTION (50-75 MM)	6000-2060	n/a
SAMPLE TUBE RACK WITH DILUTION (75-100 MM)	6000-2070	n/a
SAMPLE CAROUSELS MULTIPROCESS TOOL PACKAGE	61005006	n/a

1. Have you read and understood the letter accompanying this form? The letter provides information about the medical device correction by PerkinElmer affecting the above listed product serial numbers/ products.

Yes

No

2. Please record the total number of defective sample and / or calibrator racks in your inventory.

AFFECTED RACKS	NUMBER OF DEFECTIVE RACKS IN INVENTORY
DELFLIA® XPRESS SAMPLE TUBE RACK (50-75 MM)	
DELFLIA® XPRESS SAMPLE TUBE RACK (75-100 MM)	
DELFLIA® XPRESS CALIBRATOR RACK	
SAMPLE TUBE RACK WITH DILUTION (50-75 MM)	
SAMPLE TUBE RACK WITH DILUTION (75-100 MM)	
SAMPLE CAROUSELS MULTIPROCESS TOOL PACKAGE	

Signature _____ Date _____

Printed Name _____

Laboratory / Clinic _____

State / Country _____

R2018005: List of DELFIA Xpress Instruments serial numbers shipped with defective tube racks.

