

Field Safety Notice
EliA CCP Positive Control
Field Safety Corrective Action

Date: April 21, 2016

Dear Customer,

We are writing to you concerning an issue affecting the EliA CCP assay and to inform you of the mitigating measures to be taken.

Description of the problem:

Investigation of complaints received has concluded that when using EliA CCP Well (14-5515-01) in combination with EliA IgG Conjugate (83-1017-01, 83-1005-01, 83-1002-01 or 83-1018-01), anti-CCP-signals can be elevated for the conjugate lots listed below.

The positive bias of the EliA CCP test will change a small percentage of test results from negative to equivocal and equivocal or high negative to low positive.

Testing on clinical samples of both confirmed Rheumatoid Arthritis (RA) patient sera, healthy blood donors and other disease controls resulted in < 1% of the samples changing from negative to positive, according to current cut-off ranges (total study includes 472 samples). The results of the assay evaluation studies performed confirm the variance to be within current clinical performance, and it is concluded that the clinical impact of the observed bias is negligible.

Products being affected

Although the clinical performance of the assay is not affected by this issue, the shift in specific anti-CCP signals causes the EliA CCP Positive Control samples to fail. Therefore, we are adjusting the ranges for EliA CCP Positive Control (83-1040-01, 83-1076-01 and 83-1035-01), when used in combination with EliA IgG Conjugate (83-1017-01, 83-1005-01, 83-1002-01 or 83-1018-01) lots listed below, including the new recommended ranges:

Product	Lot	New QC range (EliAU/ml)
EliA CCP Positive Control 2500/5000 83-1076-01	CMLBE	37,7-88,0
	CMLBF	
	CMLBH	
	CMLBJ	38,7-90,2
	CMLBK	

Product	Lot	New QC range (EliAU/ml)
EliA CCP Positive Control 250 83-1035-01	C9VBE	36,3-84,6
	C9VBF	
	C9VBG	
	C9VBH	
	C9VBJ	37,2-86,8
	C9VBK	
	C9VBL	
EliA CCP Positive Control 100 83-1040-01	CA5BE	38.8 - 90.6
	CA5BF	
	CA5BG	
	CA5BH	
	CA5BL	39.8 – 92.8
	CA5BK	

As described above, the following EliA IgG Conjugates are affected:

Product REF	LOT
EliA IgG Conjugate 50 83-1017-01	BVCH7
	BVCH8
	BVCH9
	BVCHA
	BVCHB
	BVCHC
	BVCHD
	BVCHE
EliA IgG Conjugate 200 83-1018-01	BVFCA
	BVFCE
	BVFCC
	BVFCD

Product REF	LOT
EliA IgG Conjugate 83-1005-01	BFVFJ
	BFVFK
	BFVFL
EliA IgG Conjugate 83-1002-01	BFVFJ
	BFVFK
	BFVFL

The current problem affects EliA CCP. No other EliA assays using the EliA IgG Conjugates listed above are affected.

Actions to be taken by the customer/user:

- Use the above stated measuring ranges for EliA CCP Positive Control (83-1040-01, 83-1076-01 and 83-1035-01), when used in combination with EliA IgG Conjugate (83-1017-01, 83-1005-01, 83-1002-01 or 83-1018-01) of lots stated above.
- Fill in the EliA CCP Positive Control Corrective Action notice on page 3 and return to the manufacturer.

Transmission of this Notification:

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact.

Phadia AB needs your assistance with our efforts to process this Field Safety Corrective Action. We are requesting that a responsible member of your laboratory sign and return a copy of the attached Acknowledgement Form to verify receipt of this letter. Please complete the last page of this letter and either scan/email or FAX it to:

Laura West - Application Specialist
Thermo Fisher Diagnostics Limited
16 Shenley Pavilions,
Chalkdell Drive,
Shenley Wood
Milton Keynes, MK5 6LB

Email: laura.west1@thermofisher.com

Phone: +44 (0)1908 769111 or 1800 625 169. Fax: 0344 324 9495 or 1800 625 168

We apologize for any inconvenience this may cause. If you have any questions, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Laura West', written over a horizontal line.

Laura West - Application Specialist
Thermo Fisher Diagnostics Limited

EliA CCP Positive Control Corrective Action

The information in the EliA CCP Positive Control Field Safety Notice has been read and understood by our laboratory. We acknowledge that this information applies to the EliA CCP Positive Control products and will be communicated to all operators.

I hereby acknowledge receipt of this notification: FSN 2016-02, EliA CCP Positive Control

Date: _____

Signature: _____

(Please print name): _____

Name of
laboratory: _____

E-mail a signed, scanned copy or fax to (*to be defined by Commercial Organizations*):

Laura West - Application Specialist
Thermo Fisher Diagnostics Limited
16 Shenley Pavilions,
Chalkdell Drive,
Shenley Wood
Milton Keynes, MK5 6LB

Email: laura.west1@thermofisher.com

Phone: +44 (0)1908 769111 or 1800 625 169
Fax: 0344 324 9495 or 1800 625 168