

Field Safety Notice
EliA CCP Assay
Field Safety Corrective Action

Date: June 9, 2016

Dear Customer

We are writing to inform you about the solution for the issue with affected EliA CCP assay results as described in FSN2016-02.

Description of the problem:

We informed you in FSN2016-02 that, when using EliA CCP Well in combination with EliA IgG Conjugate, anti-CCP-signals are elevated for new conjugate lots.

EliA CCP Well: (14-5515-01, 14-5515-41, 14-5515-03, 14-5515-10)
EliA IgG Conjugate: (83-1017-01, 83-1017-41, 83-1005-01, 83-1005-41,
83-1002-01, 83-1002-41 or 83-1018-01, 83-1018-41)

Solution of the problem:

We will release new lots of EliA CCP Well that are optimized to the performance of currently available and future lots of EliA IgG Conjugate. To ensure non-elevated assay performance these new EliA CCP Well lots must not be combined with old EliA IgG Conjugate lots and old EliA Positive Control lots, as illustrated below. Details on lot numbers can be found in Table 1 and 2 in this Field Safety Notice.

	new conjugate		old conjugate	
new CCP well	YES	new control old control	NO	new control old control
old CCP well	see FSN2016-02	new control old control	YES	new control old control



This information will also be distributed with each new EliA CCP Well lot as a package insert until October 31st 2017 (latest expiry date of old conjugate/control) to provide easy identification and direction for the user.



Actions to be taken by the customer/user:

- Do not use **new EliA CCP well** lots (14-5515-01 /-03 /-41 starting with kit lot 0200, 14-5515-10 starting with kit lot 0007) with **old EliA IgG Conjugates** listed in Table 1.
- Do not use **new EliA CCP well** lots (14-5515-01 /-03 /-41 starting with kit lot 0200, 14-5515-10 starting with kit lot 0007) with **old EliA CCP positive controls** listed in Table 2.
- Fill in the EliA CCP Positive Control Corrective Action notice on page 5 and return to the manufacturer.

Please do not use new EliA CCP well lots (14-5515-01 /-03 /-41 starting with kit lot 0200, 14-5515-10 starting with kit lot 0007) in combination **with old EliA IgG Conjugates** listed below. All other EliA IgG Conjugates can be used.




Table 1, Old EliA IgG Conjugates:

REF	LOT	LOT _{Box}		REF	LOT	LOT _{Box}	
EliA IgG Conjugate 50 83-1017-01 83-1017-41	BVCGK BVCGN BVCGR BVCGP BVCGS	H7Y1, HC45, HG55, HDKA, HHCD, HHOW	2016-06-30	EliA IgG Conjugate 200 83-1018-01 83-1018-41	BVFBY BVFC0	H9BB HECP	2016-06-30 2016-09-30
	BVCGT BVCGV BVCGU	HHR3 HLHY, HKUS	2016-10-31 2016-12-31		BVFC1 BVFC3 BVFC2	HH1S, HJPX HL9F, HNLS	2016-10-31 2016-12-31
	BVCGW BVCGZ BVCGY BVCGX BVCH0	HP03, HT1W, HR9H, HR58, HPND, HUS9, HWZP	2017-02-28		BVFC5 BVFC6	HSWH, HUS4, HXEJ	2017-03-31
	BVCH2 BVCH1 BVCH5 BVCH4 BVCH6	HYL1, HX65, HX36, HZ4B, JOF7, J1NE J4BZ, J49Y	2017-04-30 2017-06-30		BVFC7 BVFC8 BVFC9	HY6E, J06G, JOW5 J3NP	2017-04-30 2017-06-30

REF	LOT	LOT _{Box}		REF	LOT	LOT _{Box}	
EliA IgG Conjugate 83-1002-01 83-1002-41	BFVFF BFVFH BFVFG	HK45, HNRE HPK1, HZ07, HYD4, HZ09, JOZE, J86Y, J41U, J5WL	2016-10-31 2016-12-31	EliA IgG Conjugate 83-1005-01 83-1005-41	BFVFF BFVFH BFVFG BFVFK	HK6T, HPET, HJ6Y HXRL, HRHR, HTCT, HYD9, J3XW, J3FL, J5A5 JCDY, JDHH	2016-10-31 2016-12-31 2017-10-31

Please **do not use old EliA CCP positive control** lots listed below in combination with **new EliA CCP well** lots (14-5515-01 /-03 /-41 starting with kit lot 0200, 14-5515-10 starting with kit lot 0007).

Table 2, Old EliA CCP Positive Controls:

REF	83-1040-01	LOT Vial	LOT Box	
EliA CCP Positive Control 100	CA5BH, CA5BG	HNZW, HFFH, HR64, HMMC, HUAP	2016-06-30	
	CA5BL, CA5BK	J430, JB1N, J95D, J5YT, JATR, J9US, JB9C	2017-02-28	
REF	83-1035-01	LOT Vial	LOT Box	
EliA CCP Positive Control 250	C9VBH C9VBG	HSWF, HNZT, HR66, HMDS, HESH, HM8Z, HJPS	2016-06-30	
	C9VBJ	HTA0, HWLM, J01M	2016-12-31	
	C9VBL C9VBK	J5N5, JATS, J3FA, J4C9, J6T3, J4X1, JBLN, J8D4, JB9B, J8D6	2017-02-28	
REF	83-1076-01	LOT Vial	LOT Box	
EliA CCP Positive Control 2500/5000	CMLBH	HKET	2016-06-31	
	CMLBJ	HU5U	2016-12-31	
	CMLBK CMLBL	J5K5, JATT, JB4A, JCFG	2017-02-28	

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: UK: 01908 769111
IRL: 1800 625 167
Fax: UK: 0344 324 9495
IRL: 1800 625 169

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 'L West', with a horizontal line underneath.

Laura West - Application Specialist
Thermo Fisher Diagnostics Limited

EliA CCP Assay Corrective Action

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

I hereby acknowledge receipt of this notification: FSN 2016-02_2, EliA CCP Assay

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: UK: 01908 769111

IRL: 1800 625 167

Fax: UK: 0344 324 9495

IRL: 1800 625 169