

Field Safety Notice
EliA CCP Assay
Field Safety Corrective Action

Date: June 15, 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 CCP 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 Assay Control Corrective Action notice on page 4 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	H7Y1, HC45,	2016-06-30	EliA IgG Conjugate 200 83-1018-01 83-1018-41	BVFBY	H9BB	2016-06-30
	BVCGN	HG55, HDKA,			BVFC0	HECP	2016-09-30
	BVCGR	HHCD, HHOW			BVFC1	HH1S, HJPX	2016-10-31
	BVCGP		BVFC3		HL9F, HNLS	2016-12-31	
	BVCGS		BVFC2				
	BVCGT	HHR3	2016-10-31		BVFC5	HSWH, HUS4,	2017-03-31
	BVCGV	HLHY, HKUS	2016-12-31		BVFC6	HXEJ	
BVCGW	HP03, HT1W,	2017-02-28	BVFC7	HY6E, J06G,	2017-04-30		
BVCGZ	HR9H, HR58,		BVFC8	J0W5			
BVCGY	HPND, HUS9,	2017-04-30					
BVCGX	HWZP						
BVCHO							
BVCH2	HYL1, HX65,	2017-06-30					
BVCH1	HX36, HZ4B,						
BVCH5	J0F7, J1NE						
BVCH4							
BVCH6	J4BZ, J49Y						

REF	LOT	LOT _{Box}		REF	LOT	LOT _{Box}	
EliA IgG Conjugate 83-1002-01 83-1002-41	BFVFF	HK45, HNRE	2016-10-31	EliA IgG Conjugate 83-1005-01 83-1005-41	BFVFF	HK6T, HPET, HJ6Y	2016-10-31
	BFVFH	HPK1, HZ07,	2016-12-31		BFVFH	HXRL, HRHR,	2016-12-31
	BFVFG	HYD4, HZ09, JOZE, J86Y, J41U, J5WL			BFVFG	HTCT, HYD9, J3XW, J3FL, J5A5	
				BFVFK	JCDY, JDHH	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	J5K5, JATT, JB4A, JCFG		2017-02-28
	CMLBL			

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:

TBD, commercial Organizations contact person:

Name

Address

Telephone

E-mail

We apologize for any inconvenience this may cause.

If you have any questions, please contact us.

Sincerely,



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*):

Name
ImmunoDiagnostics
Thermo Fisher Scientific

Address

Office; Mobile; Fax

Email: xxxxxx@thermofisher.com



Document name FSN 2016-02_2 EliA CCP well factor - EU+restofworld Version Numbe
617121 Version 3.0

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