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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:

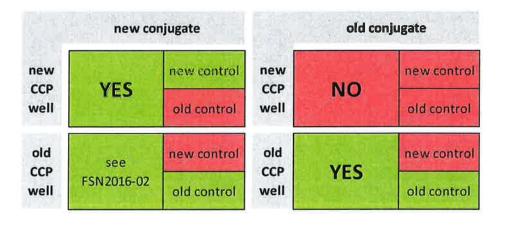
(14-5515-01, 14-5515-41, 14-5515-03, 14-5515-10) (83-1017-01, 83-1017-41, 83-1005-01, 83-1005-41,

EliA IgG Conjugate:

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.



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.





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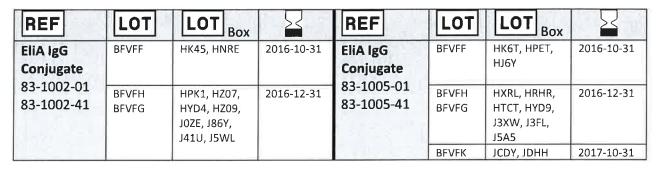
Actions to be taken by the customer/user:

- ➤ 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.

<u>Please do not use</u> 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 | <u>></u> | REF | LOT | LOT | <u> </u> |
|-------------------------------|----------------------------------|--|-------------|--------------------------------|----------------|---------------------|------------|
| EliA IgG | BVCGK | H7Y1, HC45, | 2016-06-30 | EliA IgG | BVFBY | Н9ВВ | 2016-06-30 |
| Conjugate 50 83-1017-01 | BVCGN BVCGR BVCGP BVCGS | HG55, HDKA, HHCD, HHOW | | Conjugate 200 83-1018-01 | BVFC0 | НЕСР | 2016-09-30 |
| 83-1017-41 | BVCGT | HHR3 | 2016-10-31 | 83-1018-41 | BVFC1 | HH1S, HJPX | 2016-10-31 |
| | BVCGV BVCGU | HLHY, HKUS | 2016-12-31 | | | | |
| | BVCGW BVCGZ | HP03, HT1W, HR9H, HR58, | 2017-02-28 | | BVFC3 BVFC2 | HL9F, HNLS | 2016-12-31 |
| | BVCGY BVCGX BVCH0 | HPND, HUS9, HWZP | | | BVFC5 BVFC6 | HSWH, HUS4, HXEJ | 2017-03-31 |
| | BVCH2 BVCH1 BVCH5 BVCH4 | HYL1, HX65, HX36, HZ4B, J0F7, J1NE | 2017-04-30 | | BVFC7 BVFC8 | HY6E, J06G, J0W5 | 2017-04-30 |
| | BVCH6 | J4BZ, J49Y | 2017-06-30 | | BVFC9 | J3NP | 2017-06-30 |







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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 | LOT | > |
|-------------------------------------|-----------------|--|------------|
| 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 | LOT | |
| EliA CCP Positive Control 250 | C9VBH C9VBG | HSWF, HNZT, HR66, HMDS, HESH, HM8Z, HJPS | 2016-06-30 |
| | C9VBJ | HTAO, HWLM, JO1M | 2016-12-31 |
| | C9VBL C9VBK | J5N5, JATS, J3FA, J4C9, J6T3, J4X1, JBLN, J8D4, JB9B, J8D6 | 2017-02-28 |
| REF 83-1076-01 | LOT | LOT | 2 |
| 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.

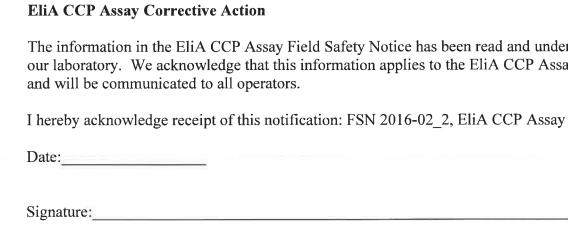
Please complete the last page of this letter and either scan/email or FAX it to:

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,





Approved by Fredrik Mirenborn 2016-Jun-15 14:55 CET Doc.no. 617121 Ver. 3.0 Page 4(5)



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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.

| 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

Issued by Wera Kleve 2016-Jun-15 12:40 CET

Approved by Fredrik Mirenborn 2016-Jun-15 14:55 CET Release Date 2016-Jun-15 14:55 CET