Urgent Field Safety Notice
EliA SmD^{P} Well, Art.No. 14-5624-01, lot numbers 0018 and 0019
Field Safety Corrective Action

Date: December 28, 2015

The purpose of this letter is to inform you that Phadia AB, part of Thermo Fisher Scientific, is performing a field safety corrective action, which is more fully described below.

Upon conducting complaint investigations, we found unusually high number of positive results with EliA SmD^{P} Well lots, which are not due to anti-Sm antibodies. We are currently investigating the root cause of this issue.

Product affected:

All equivocal and positive patient sample results measured with the following lots are potentially incorrect and are thus considered to be invalid.

Product	EliA SmD^{P} Well	
REF	LOT	⌛
14-5624-01	0018	2016-11-30
	0019	2017-03-31

Description of the problem:

Analysis of patient samples received in complaint investigations showed that several of these samples caused unspecific signals up to 22 U/ml on EliA SmD^{P} well lots 0018 and 0019. The unspecific signals are neither caused by anti-Sm antibodies nor by anti-streptavidin antibodies (see limitation in Directions for Use), but are due to other unspecific signals with an as yet unknown cause.

All equivocal and positive results (≥ 7 EliA U/ml) on EliA SmD^{P} well lots 0018 and 0019 are potentially incorrect and must be considered invalid. All samples with a result ≥ 7 U/ml should be retested with an appropriate alternative assay for anti-Sm antibody detection. To our knowledge, there is no indication that negative results generated with EliA SmD^{P} well lots 0018 and 0019 are affected.

Actions to be taken by the customer/user:

1) Stop using EliA SmD^{P} Well, Art.No. 14-5624-01, lots 0018 and 0019.
2) Identify all patient results performed with EliA SmD^{P} Well, lots 0018 and 0019 (Code CTL0I = lot 0018, CTL0J = lot 0019) that are ≥7 EliA U/ml and inform the physicians that these equivocal or positive results are invalid.
3) Retest all samples with a result ≥7 EliA U/ml with an appropriate alternate assay for anti-Sm antibody detection, if possible.
4) Dispose of all remaining EliA SmDP Wells of lots 0018 and 0019 and request a refund or credit for tests affected. No return of product to the manufacturer is required.

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 needs your assistance with our efforts to process this product correction. 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,

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EliA SmD^{P} Well Product Correction Notice

The information in this Field Safety Notice was read and understood by all relevant personnel in our laboratory. We acknowledge that this information applies to the product EliA SmD^{P} Well (Art.No. 14-5624-01, lots 0018 and 0019) and the recommended actions described to be taken by the customer/user will be performed to the best of our ability.

I hereby acknowledge receipt of this notification:

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