URGENT MEDICAL DEVICE RECALL LETTER/FIELD SAFETY NOTICE- IMMEDIATE ACTION REQUIRED

EliA RF IgM Well

[Insert date]

[Insert Customer or Distributor name
Attn:
Customer / Distributor address]

Dear <insert Customer or Distributor name or> Thermo Fisher Scientific Dealer Partner:

The purpose of this letter is to advise you that Phadia AB, part of Thermo Fisher Scientific, is voluntarily performing a Field Safety Corrective Action for lot 0085 of EliA RF IgM Well, Article number 14-5600-01.

PRODUCT INFORMATION:

Product	Article Number	Lot Number	Barcode
EliA RF IgM Well	14-5600-01	0085	CJY2D

REASON FOR THIS RECALL LETTER/FIELD SAFETY NOTICE:
An issue with EliA RF IgM Well lot 0085 has been identified.
Low results have been reported for EliA RF IgM Well lot 0085 used with different lots of EliA RF Positive Control. Internal investigations have confirmed an issue with individual carriers of this Well lot. When a carrier of EliA RF IgM Well lot 0085 is affected, all Wells from this specific carrier are affected.

The issue may have caused erroneous RF IgM test results:

- For affected carriers, the reported concentration of RF IgM will be approximately 60% lower than the real concentration.
- Due to the lower concentration, false negative test results may be reported.

RISK TO HEALTH:
False negative results may lead to a delay of diagnosis. In a worst-case, a delay in diagnosis may lead to a delay in appropriate treatment. This may lead to reversible injury from which the patient is expected to completely recover. There have been no serious injuries reported.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

- Please review patient results obtained with the lot 0085 (barcode CJY2D). The following criteria shall be applied:
    - All samples reported as positive, > 5 IU/ml, are positive, but the true concentration could be higher than reported.
    - The true concentration of a sample reported as equivocal, 3.5 – 5 IU/ml, could be higher, i.e. it could potentially be a positive sample.
    - Negative results between 2 IU/ml and 3.5 IU/ml are potentially false negative.
    - Negative results < 2 IU/ml could be higher, but would still be reported as negative results with a 60% higher concentration.
    - If EliA RF Positive Control was performed and found to be within the expected range, all results and reported RF IgM concentrations for patient samples analyzed with Wells from the same carrier are not affected by the described issue.
    - If EliA RF Positive Control was performed and found to be below the expected range, all results and reported RF IgM concentrations for patient samples analyzed with Wells from the same carrier may be affected by the described issue and should be reviewed.
    - A logfile analysis is able to identify if EliA RF Positive Control and patient samples were measured with Wells from the same carrier. Please contact the local representative of Thermo Fisher Scientific in case you need further support.
- Please scrap or return any unused EliA RF IgM Well, Article number 14-5600-01 of lot 0085 to the contact person listed below and order the replacement products free of charge.
- Please fill out the Recall Letter/Field Safety Notice return response (see below) and return it to Phadia AB (Thermo Fisher Scientific) by email.
- We recommend that internal operating procedures are applied to determine if further actions are needed.

ACTIONS UNDERTAKEN BY PHADIA AB:

- Corrective and preventive actions (CAPA) have been initiated to prevent this issue from recurring.

We appreciate your immediate attention to this Field Safety Corrective Action. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the Competent Authorities.
We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any questions, please contact <name, department, etc.> at <email address, phone number, fax number, etc.>.

Sincerely,

Name
Title

MEDICAL DEVICE RECALL LETTER/FIELD SAFETY NOTICE RETURN RESPONSE

Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:
[Customer name
Attn:
Address]

EliA RF IgM Well lot 0085

I have read and understood the attached
Recall Letter2019-03/Field Safety Notice2019-03 _____ (initials)

Responsible members of the laboratory staff and instrument operators have been informed of the need to discontinue the use of EliA RF IgM Well lot 0085:

Yes ☐

Have any adverse events associated with the product been reported?

Yes ☐ No ☐

If yes, please explain: _____

AFFECTED PRODUCT INFORMATION:

Product	Material Number	Lot Number	Quantity Ordered	Quantity Used	Quantity Destroyed/Returned
EliA RF IgM Well	14-5600-01	0085			

RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL < > OR FAX NUMBER < >, ATTN: < >

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
E-mail:	