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Urgent Field Safety Notice:

**IMMULITE Analyzer
IMMULITE 1000 Analyzer**

IMMULITE and IMMULITE 1000 TNF α Positive Shift in the Lower End of the Analytical Measuring Range

To whom it may concern,

Siemens Healthineers has confirmed, through the investigation of customer complaints, a positive shift in the lower end of the Analytical Measuring Range when using IMMULITE[®] and IMMULITE 1000[®] TNF α . The positive shift began with kit lot 416 and has not been observed at higher levels of the assay range. A difference of up to approximately 5 pg/mL may be observed.

All in-date lots are impacted until further notice.

The IMMULITE 2000/IMMULITE 2000 XPi TNF α assay is not impacted.

Siemens is currently investigating the root cause of this issue.

Assay	Catalog # Siemens Material Number/Unique Device Identification	Lot Number
IMMULITE/IMMULITE 1000 TNF α	LKNF1/10381417/ 00630414964294	In-date kit lots

Impact to Results

Falsely elevated TNF α results may occur in the lower end of the measuring range. A patient result below the upper limit of normal (ULN; ≤ 8.1 pg/mL) may be mildly elevated above the ULN. A difference of up to approximately 5 pg/mL may be observed. The results obtained from this assay would be used in combination with the clinical examination, patient medical history, and other findings.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided below:
 - Consider establishing a reference range per your laboratory's procedure for the IMMULITE/IMMULTE 1000 TNF α assay.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within (30) days.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

– Resolution

A follow up communication will be provided when Siemens has identified a resolution.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature:



*Electronically signed by: Roland Ertl
Reason: I am approving this document
Date: Jun 24, 2024 13:55 GMT+2*

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