

# Urgent Field Safety Notice

IMC24-04.A.OUS

## IMMULITE Analyzer

## IMMULITE 1000 Analyzer

<b>Title</b>	IMMULITE and IMMULITE 1000 TNF $\alpha$ Positive Shift in the Lower End of the Analytical Measuring Range								
<b>Date Issued</b>	Jun-2024								
<b>Issue Description</b>	<p>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<sup>®</sup> and IMMULITE 1000<sup>®</sup> TNF<math>\alpha</math>. 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.</p> <p>All in-date lots are impacted until further notice.</p> <p>The IMMULITE 2000/IMMULITE 2000 XPi TNF<math>\alpha</math> assay is not impacted.</p> <p>Siemens is currently investigating the root cause of this issue.</p>								
<b>Products</b>	<table border="1"><thead><tr><th>Assay</th><th>Catalog # Siemens Material Number/Unique Device Identification</th><th>Lot Number</th></tr></thead><tbody><tr><td>IMMULITE/IMMULITE 1000 TNF<math>\alpha</math></td><td>LKNF1/10381417/ 00630414964294</td><td>In-date kit lots</td></tr></tbody></table>	Assay	Catalog # Siemens Material Number/Unique Device Identification	Lot Number	IMMULITE/IMMULITE 1000 TNF $\alpha$	LKNF1/10381417/ 00630414964294	In-date kit lots		
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IMMULITE/IMMULITE 1000 TNF $\alpha$	LKNF1/10381417/ 00630414964294	In-date kit lots							
<b>Impact to Results</b>	<ul style="list-style-type: none"><li>Falsely elevated TNF<math>\alpha</math> results may occur in the lower end of the measuring range. A patient result below the upper limit of normal (ULN; <math>\leq 8.1</math> 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.</li></ul>								
<b>Customer Actions</b>	<ul style="list-style-type: none"><li>Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.</li><li>Perform the instructions provided below:<ul style="list-style-type: none"><li>Consider establishing a reference range per your laboratory's procedure for the IMMULITE/IMMULITE 1000 TNF<math>\alpha</math> assay.</li></ul></li><li>Complete and return the Field Correction Effectiveness Check Form attached to this letter within (10) days.</li><li>Please retain this letter with your laboratory records and forward this letter to those who may have received this product.</li></ul>								
<b>Resolution</b>	<p>A follow up communication will be provided when Siemens has identified a resolution.</p> <p>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.</p>								

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**FIELD CORRECTION EFFECTIVENESS CHECK**

This response form is to confirm receipt of the enclosed Siemens Healthineers [Urgent Field Safety Notice IMC24-04.A.OUS](#) dated [Jun-2024](#). Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. Have you read and understood the instructions provided in this letter? Yes  No
- 2. Were affected Site Personnel notified? Yes  No
- 3. Was a copy of the letter retained and posted with the current product labeling? Yes  No

<b>Name of person completing questionnaire:</b>			
<b>Title:</b>			
<b>Institution:</b>			
<b>Street:</b>			
<b>City:</b>		<b>State:</b>	<b>Zip Code:</b>
<b>Phone:</b>		<b>Country:</b>	

Please send a scanned copy of the completed form via email to [fscareportingunit.my@siemens-healthineers.com](mailto:fscareportingunit.my@siemens-healthineers.com)

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