

Urgent Field Safety Notice

IMC24-03.A.OUS

IMMULITE 2000 Analyzer

IMMULITE 2000 XPi Analyzer

Title	IMMULITE 2000 and IMMULITE 2000 XPi PSA High-dose Hook Effect
Date Issued	Sep-2024
Issue Description	<p>Siemens Healthineers has confirmed, through the investigation of customer complaints, that the IMMULITE® 2000 PSA assay for use on the IMMULITE 2000 and IMMULITE 2000 XPi analyzers did not meet the High-dose Hook Effect claim as stated in the Instructions for Use (IFU) for the lots listed below.</p> <p>The IMMULITE 2000 PSA assay measuring range (working range per IFU) upper limit is 150 ng/mL. The IFU states “High-dose Hook Effect: None up to 4277 ng/mL”.</p> <p>For the lots listed in the ‘Products’ table below, the High-dose Hook Effect claim begins to fail at concentrations below 4277 ng/mL.</p> <p>Note that impacted lots have all reached expiration.</p> <p>Samples with IMMULITE 2000 PSA results within the measuring range of the assay (0.04 – 150 ng/mL) perform as intended.</p> <p>IMMULITE and IMMULITE 1000 PSA assays are not impacted.</p>

Products	Assay	Catalog # Siemens Material Number Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
	PSA	L2KPS2, L2KPS6 10380986, 10380996 00630414961958, 00630414961965	438	23-Jan-2023	30-Nov-2023
			439	21-Feb-2023	31-Jan-2024
			440	04-Jul-2023	30-Jun-2024

Impact to Results	<p>Data from an internal study demonstrated that, when affected lots were used, samples with true PSA results above the upper limit of the measuring range (150 ng/mL) may recover erroneously depressed.</p> <p>Depending on the affected kit lot used, samples with true PSA concentrations between 513 and 4277 ng/mL recovered erroneously between 60 and 150 ng/mL.</p> <p>As stated in the Limitations section of the IFU: “Prediction of malignant prostatic disease recurrence should be based on a complete clinical evaluation of the patient, which may also include serial serum PSA determinations.”</p>
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- Customer Actions**
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, that may have been affected.
 - 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 IMMULITE 2000 and IMMULITE 2000 XPi PSA kit lots 441 and above meet the IFU High-dose Hook Effect claim.

Siemens continues to investigate root cause of the issue observed with the impacted kit lots.

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.

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Siemens Healthineers

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice IMC24-03.A.OUS dated Sep-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

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	Zip Code:
Phone:		Country:	

Please send a scanned copy of the completed form via email to **XXXX@XXXX**

Or to fax this completed form to the Customer Care Center at **XXXXXX**

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