Urgent Field Safety Notice

IMC26-03.A.OUS

IMMULITE 2000
IMMULITE 2000 XPi

Title EPO Adjustor and Control Module Open Vial Instability

Date Issued Feb-2026

Products

Product	Siemens Material Number/Catalog Number Unique Device Identification	Lot Number (adjustor lot)	Manufacturing Date	Expiration Date
IMMULITE 2000 EPO	10487628, 10487629 L2KEPN2, L2KEPN6 00630414989563 00630414986210	338 (125)	04-Mar-2025	04-Mar-2026
		339 (125)	03-Jun-2025	03-Jun-2026
		340 (126)	22-Jul-2025	22-Jul-2026
		341 (127)	19-Sep-2025	19-Sep-2026
IMMULITE EPO Control Module	10385384 LEPCM 0405686901425VE	0035	27-Jan-2025	27-Jan-2028
		035L		

Issue Description

Siemens Healthineers has confirmed, through the investigation of customer complaints that the adjustors kitted with the IMMULITE 2000 EPO kit lots and the controls in the IMMULITE EPO Control Module lots included in the Products table, do not meet the open vial stability at 2–8°C for 30 days after reconstitution, or for 6 months (aliquotted) at –20°C as published in the respective Instructions for Use for the products.

Following reconstitution, both the adjustor and Quality Control (QC) materials may exhibit instability depending on storage conditions. In certain scenarios, concurrent use of an unstable adjustor and QC material may result in QC results and adjustments appearing acceptable while potentially introducing a positive bias of up to 47% in patient results. The bias would affect patient results similarly across the measuring interval of the assay (1.0 – 750 mIU/mL).

See Appendix for additional data.

The investigation indicates the instability is due to a critical raw material shared in the manufacture of the specific adjustor lots and QC lots listed in the Products table.

Impact to Results

Erroneously elevated EPO patient results may occur as a result of this issue. The data from internal studies show a positive bias of up to 47% across the measuring range (see Appendix, Table 1-3), with bias increasing as storage times increases after reconstitution. Results of this assay should be used in conjunction with clinical findings and the results of other laboratory parameters.

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Customer Actions

Perform the instructions provided below:

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- To continue using the impacted lots listed in the Products table, follow steps below:
  - Adjust the assay using adjustors that have been freshly reconstituted within the past 8 hours
    - Discard adjustors after initial use
  - After reconstitution, aliquot and store QC material at –20°C for up to 30 days
    - Discard QC lots 0035 and 035L that were stored at 2–8°C after reconstitution
    - Discard all QC lots 0035 and 035L that were stored at -20°C after reconstitution for more than 30 days
  - If QC falls outside acceptable range, use freshly reconstituted QC
  - If freshly reconstituted QC is outside acceptable range, proceed with normal troubleshooting
- 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

The issue is limited to the lot numbers listed in the Products table and the customer actions are applicable only to these lot numbers. Future assay kit and control lots will not be impacted by this issue and are expected to be available in the March 2026 timeframe.

Single Registration Number (SRN)

GB-MF-000016339

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.

Appendix

The following tables show what may be observed for patient results and QC results when using different storage conditions of the adjustors and QC material. Depending on your usual storage conditions of the adjustors and QC material, QC results may or may not detect a bias with patient results.

The bias increases as storage times increase after reconstitution of adjustors.

“Fresh” indicates use of the respective material within 8 hours after reconstitution.

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Siemens Healthcare Diagnostics Inc.
333 Coney Street
East Walpole, Massachusetts 02032
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Table 1. Impact to results based on Adjustor material used Fresh (within 8 hours after reconstitution)

Adjustor Storage Condition	Impact to patient results	Control Storage Condition	Impact to QC Lot 0035 or 035L
Fresh	No bias	Fresh	In range
		2-8°C	Out of range negative
		-20°C	In range

Table 2. Impact to results based on Adjustor material stored at 2-8°C

Adjustor Storage Condition	Impact to patient results	Control Storage Condition	Impact to QC Lot 0035 or 035L
2-8°C	Positive bias up to 47%	Fresh	Out of range positive
		2-8°C	Falsely in range
		-20°C	Out of range positive

Table 3. Impact to results based on Adjustor material stored at -20°C

Adjustor Storage Condition	Impact to patient results	Control Storage Condition	Impact to QC Lot 0035 or 035L
-20°C	Positive bias up to 17%	Fresh	In range
		2-8°C	Out of range negative
		-20°C	In range

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice **IMC26-03.A.OUS** dated Feb-2026. 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:**	
Customer Sold To #	**Customer Ship To #**	

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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