

Siemens Healthcare Diagnostics GmbH, SHS EMEA CEECA QT, Siemensstrasse 90,  
1210 Vienna

Name: Florian Nemestothy, BSc  
 Department: SHS EMEA CEECA QT  
 Mobile: +43 (664) 8855 8770  
 E-mail: florian.nemestothy@siemens-healthineers.com  
 Date: 13.02.2026  
 Document Ref#: IMC26-03.B.OUS

**Urgent Field Safety Notice:**

**— IMMULITE 2000 / IMMULITE 2000 XPI  
 EPO Adjustor and Control Module Open Vial Instability**

To whom it may concern,

Our records indicate that you have received:

| 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 00630414953175                                       | 0035                      | 27-Jan-2025        | 27-Jan-2028     |
|                             |   | 035L                      |                    |                 |

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.

## 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  $-20^{\circ}\text{C}$  for up to 30 days
    - Discard QC lots 0035 and 035L that were stored at  $2-8^{\circ}\text{C}$  after reconstitution
    - Discard all QC lots 0035 and 035L that were stored at  $-20^{\circ}\text{C}$  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.

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



*Electronically signed by: Gudrun Kapl  
Reason: I have reviewed this document  
Date: Feb 12, 2026 13:41:51 GMT+1*

i.V. Dipl.-Ing. Gudrun Kapl



*Electronically signed by: Michael  
Edetsberger  
Reason: I have reviewed this document  
Date: Feb 12, 2026 13:30:05 GMT+1*

i.V. Dr. Michael Edetsberger

## 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.

**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                      |

All trademarks are property of their respective owners.