

# Follow-up Urgent Field Safety Notice

IMC25-05.B.OUS-1

## IMMULITE 2000 IMMULITE 2000 XPi

---

**Title** Resolution: Intact PTH Potential Negative Bias with Patient Results at the Low End of the Assay Range

---

**Date Issued** Dec-2025

---

**Products**

Assay	Test Code	Siemens Material Number/Catalog Number/Unique Device Identification	Lot Number(s)
IMMULITE 2000 Intact PTH	iPT	10381441, 10381442 L2KPP2, L2KPP6 00630414961910 00630414961927	387 and above

---

**Issue Description**

Siemens Healthineers is communicating the resolution to Urgent Field Safety Notice (UFSN) IMC25-05.A.OUS-1, released Sep-2025, regarding the potential for negative bias with patient results at the low end of the assay range when using lots 385 or 386 on IMMULITE 2000 and IMMULITE 2000 XPi systems. Siemens Healthineers is pleased to inform you that beginning with lot 387 and above, Intact PTH assay performance has been restored on IMMULITE 2000 and IMMULITE 2000 XPi systems. See Appendix A for supporting data.

---

**Customer Actions**

- Please review this letter with your Medical Director.
- 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**

Beginning with lot 387 and above, Intact PTH assay performance has been restored for IMMULITE 2000 and IMMULITE 2000 XPi systems.

---

**Single Registration Number (SRN)**

GB-MF-000016339

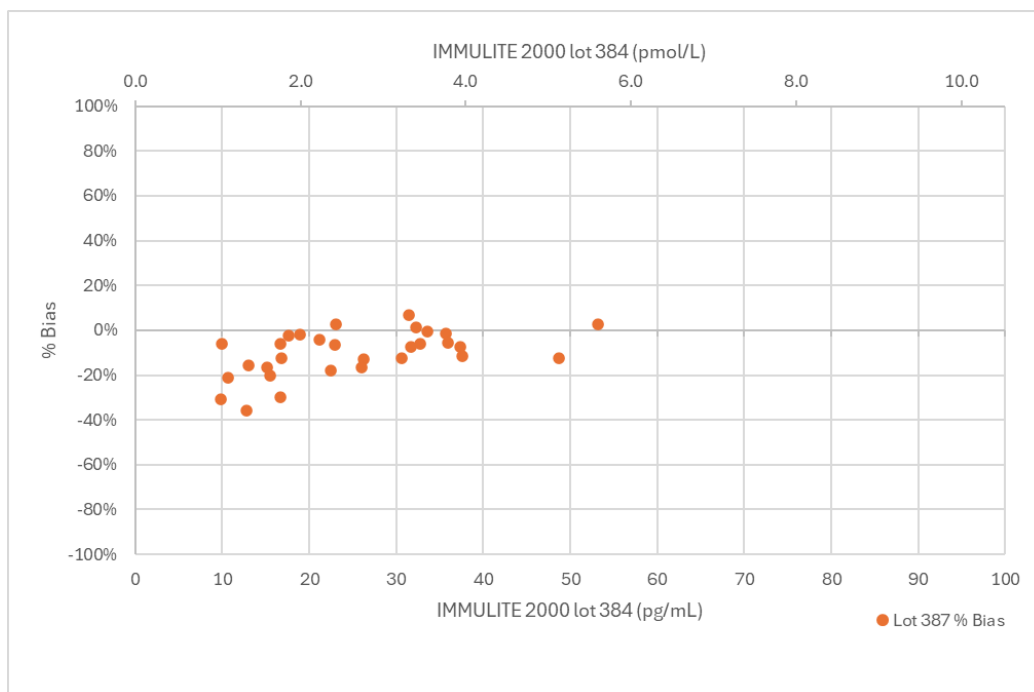
---

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 A** Twenty-nine patient samples with results  $\leq 50$  pg/mL ( $\leq 5.3$  pmol/L) were tested using Intact PTH lot 384 and 387 and showed an average percent bias of -11% and a reference interval verification study showed equivalent performance between the lots. No patient samples that read  $> 3$  pg/mL (0.3 pmol/L) using lot 384 read  $< 3$  pg/mL ( $< 0.3$  pmol/L) when tested with lot 387. Assay performance from 51 – 2500 pg/mL (5.4 – 263 pmol/L) remains acceptable showing an average percent bias of 5%.

**Figure 1. Bias Plot: IMMULITE 2000 Intact PTH Lot 384 vs Lot 387 (3 - 100 pg/mL, 0.3 – 10.5 pmol/L)**



All trademarks are property of their respective owners.

**FIELD CORRECTION EFFECTIVENESS CHECK**

This response form is to confirm receipt of the enclosed Siemens Healthineers **Follow-up Urgent Field Safety Notice IMC25.05.B.OUS-1** dated **Dec-2025**. 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>	
<b>Customer Sold To #</b>	<b>Customer Ship To #</b>	

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**

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.