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**Urgent Field Safety Notice:**

**IMMULITE 2000**

**IMMULITE 2000 XPi**

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

To whom it may concern,

Our records indicate that you have received:

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

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.

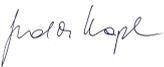
**Resolution**

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

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: Dec 18, 2025 12:53:45 GMT+1*

i.V. Dipl.-Ing. Gudrun Kapl



*Electronically signed by: Michael  
Edetsberger  
Reason: I have reviewed this document  
Date: Dec 18, 2025 12:33:10 GMT+1*

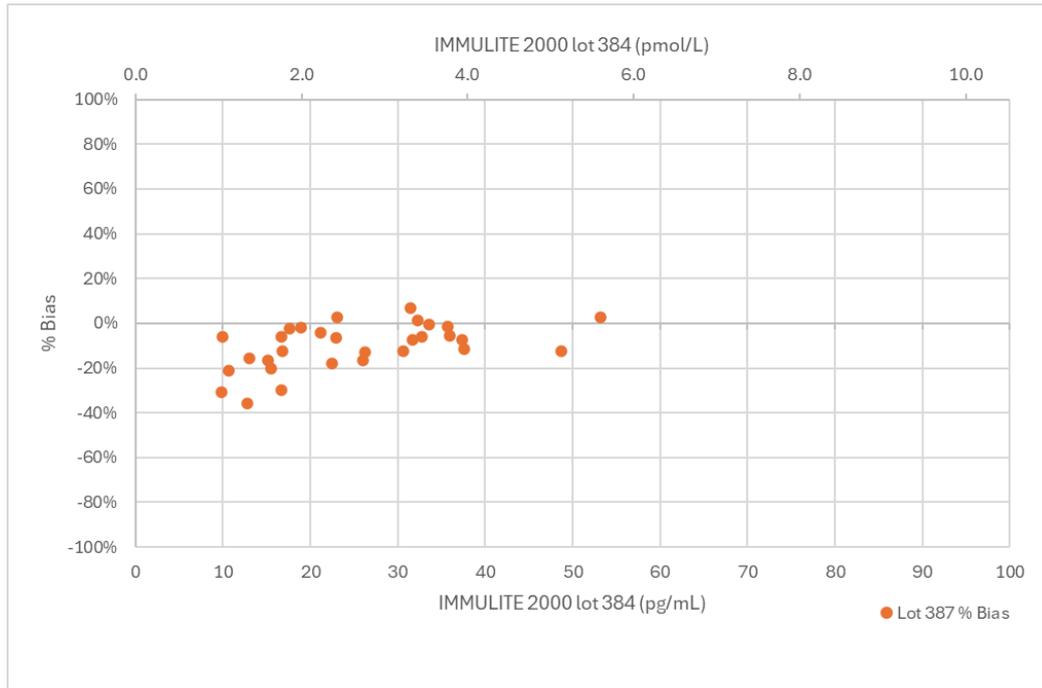
i.V. Dr. Michael Edetsberger

**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)**



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