SIEMENS

**Urgent Field Safety Notice**

**IMC16-27.A.OUS**

**November 2016**

**IMMULITE® 2000**

**IMMULITE® 2000 XPi**

## Intact PTH (Intact Parathyroid Hormone) Lower Recovery at the Low End of the Assay Range

Our records indicate that your facility may have received the following product:

**Table 1. IMMULITE® Systems Affected Product(s)**

| Assay | Test Code | Catalog Number | Siemens Material Number (SMN) | Lot Number | Expiration Date | Manufacturing /1st Distribution Date |
|---|---|---|---|---|---|---|
| IMMULITE® 2000/ IMMULITE® 2000 XPi Intact PTH | iPTH | L2KPP2<br>L2KPP6 | 10381441<br>10381442 | 320 | 2016/11/30 | (L2KPP2) 2016-04-11 / 2016-04-14<br>(L2KPP6) 2016-04-12 / 2016-04-20 |

**Reason for Recall**

Siemens Healthcare Diagnostics is conducting a recall for the IMMULITE® 2000/IMMULITE® 2000 XPi Intact PTH (Intact Parathyroid Hormone) (iPTH) assay kit lot 320. Siemens has confirmed that IMMULITE® 2000/IMMULITE® 2000XPi Intact PTH kit lot 320 listed in Table 1 can exhibit an average negative bias of up to -39% at iPTH concentrations <20 pg/mL with serum and EDTA patient samples vs. a reference kit lot. The average bias and range of bias observed across different iPTH concentrations is shown in Table 2.

**Table 2. Bias observed with kit lot 320**

| iPTH Concentration (pg/mL) | Average % Bias compared to a reference kit lot | Range of Bias Observed (%) |
|---|---|---|
| <20 | -39% | -29% to -55% |
| 20 to <50 | -22% | 0% to -49% |
| 50 to <100 | -18% | 1% to -44% |
| ≥100 | -5% | 4% to -25% |

Depending upon the quality control ranges used by your laboratory, this issue may not be detected by quality controls.

Siemens continues to investigate the root cause of the low bias. Siemens recommends transitioning to IMMULITE 2000/IMMULITE 2000 XPi Intact PTH kit lots 321 and above which show acceptable performance across the assay range.

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## Risk to Health

When this issue occurs, the potential exists for misinterpretation of iPTH levels which may delay determination of the etiology of hypercalcemia or hypocalcemia. Clinical impact would be mitigated by correlation to clinical symptomology and additional diagnostic laboratory testing. Siemens is not recommending a review of previously generated results.

## Actions to be taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard IMMULITE® 2000/IMMULITE® 2000 XPi Intact PTH kit lot 320.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

## IMMULITE 2000/ IMMULITE 2000 XPi Intact PTH (Intact Parathyroid Hormone) Lower Recovery at the Low End of the Assay Range

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated November 2016 regarding IMMULITE 2000/IMMULITE 2000 XPi Intact PTH lower recovery at low end of the assay range with kit lot 320. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

| **Product Description Product Catalog #/SMN #/Lot #** | **Quantity of Affected Product in inventory that has been discarded** | **Replacement Quantity Required** |
|---|---|---|
| IMMULITE® 2000/2000 XPi Intact PTH /L2KPP2/ SMN/ 10381441 | | |
| IMMULITE® 2000/ 2000 XPi Intact PTH /L2KPP6/ SMN/10381442 | | |

**Name:**

**Date:**

**Facility:**

**Signature:**

**Company stamp:**

To fax this completed form please send it to the Customer Care Center at (65) 6466-3376. If you have any questions, contact your local Siemens technical support representative.

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