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Our Reference FSN IMC 16-27
Date 24/11/2016
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URGENT FIELD SAFETY NOTICE

Please find attached an Urgent Field Safety Notice (UFSN). This is an important communication about medical safety issued by Siemens Healthcare Diagnostics.

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the UFSN.

Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the UFSN and the MHRA may need to issue a Medical Device Alert

Attachment:

FSN

If you have any questions or enquiries regarding this UFSN, please do not hesitate to contact the Siemens Healthcare Diagnostics Helpdesk:

Phone: 0845 600 1955

Email: Immunoassay.healthcare@siemens.com



Yours faithfully
Robert Davies
Regulatory Affairs Manager

**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 /1 st Distribution Date
IMMULITE® 2000/ IMMULITE® 2000 XPi Intact PTH	iPTH	L2KPP2 L2KPP6	10381441 10381442	320	2016/11/30	(L2KPP2) 2016-04-11 / 2016-04-14 (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.

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

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.

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 14 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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

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

Ref: IMC 16-27 [C/3765]

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. Please return this completed form to Siemens Healthcare Diagnostics.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Do you have any of the noted product on hand? Please check inventories before answering. 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.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 of person completing questionnaire:		
Title:		
Institution:	Instrument Serial Number:	
Street:		
City:	Post Code:	
Phone:	Email:	

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN with the MHRA.

Fax: 0845 605 6800

Email: robert.davies@siemens.com