SIEMENS

Urgent Field Safety Notice

3019

January 2014

IMMULITE® 2000
IMMULITE® 2000 XPi

Osteocalcin Under Recovery of Patient Values

Our records indicate that you have or may have received the following product:

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Lots

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE 2000/IMMULITE 2000 XPi	OCN	L2KON2	10381477	218, 219, 220, 221

Reason for Correction

Siemens Healthcare Diagnostics has confirmed under recovery up to 50% in patient values across the assays reportable range with the IMMULITE 2000/IMMULITE 2000 XPi Osteocalcin (L2KON2) kit lots listed in Table 1. Quality Control materials will not detect the bias.

The root cause has been attributed to a raw material lot change in the reagent wedge. Siemens is actively working to resolve this issue.

Siemens Healthcare Diagnostics

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

Risk to Health

Osteocalcin can serve as a measure of increased bone resorption in some patients. Depending upon the treatment approach, the measurement of osteocalcin may correlate to therapy. In some patients risk of osteoporosis correlates to increasing values of Osteocalcin. This issue is not expected to impact treatment.

Look Back
We recommend discussing the content of this letter with your medical director regarding the need to review previous test results, conduct patient follow-up, and/or repeat testing for any patients tested with IMMULITE 2000/IMMULITE 2000XPi Osteocalcin kit lots 218 through 221 (which began shipping in May 2013).

Actions to be Taken by the Customer:

- Discontinue use and discard kit lots listed in Table 1.
- Siemens does not currently have a replacement for this product. Please contact your local sales representative to discuss alternate solutions that meet your testing needs.
- Please share this communication with you laboratory director.

In addition, please perform the following:

- Complete and return the Field Correction Effectiveness Check form attached to this letter within thirty (30) days.
- Keep this letter with your laboratory records.
- Forward this letter to whomever you may have distributed these products.
- 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.

We apologize for the inconvenience this situation has caused. 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 Osteocalcin Under Recovery with Patient Values

REF: IMC 14-07

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # 3019 dated January 2014 regarding IMMULITE 2000/ 2000 XPi Osteocalcin. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in the January 2014 letter.	Yes ☐	No ☐

Product Description Product Catalog# / Lot #	Quantity Discarded	Replacement Kits Required

Name of person completing questionnaire: Block Capitals		Date:	
Title:		Account Number:	
Hospital:		Instrument Serial Number:	
Street:			
City:		Post Code:	
Phone:		Email:	

Please complete and fax/email to:

FAX 0845-605-6800

Email: robert.davies@siemens.com

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