SIEMENS

Urgent Field Safety Notice

1111

February 2014

IMMULITE®
IMMULITE® 1000

Osteocalcin Under Recovery of Patient Values

Our records indicate that your facility has received the following product:

Table 1. IMMULITE/IMMULITE 1000 Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE/IMMULITE 1000 Osteocalcin	OCN	LKON1	10381396	316, 317, 318, 319, 320

NOTE: Your facility may have received Urgent Field Safety Notice #3019 dated December 2013 if you received IMMULITE® 2000/IMMULITE® 2000 XPi Osteocalcin kit lots 218 and above. Siemens Healthcare Diagnostics is expanding the scope of the field action to include the IMMULITE®/IMMULITE® 1000 Osteocalcin assay.

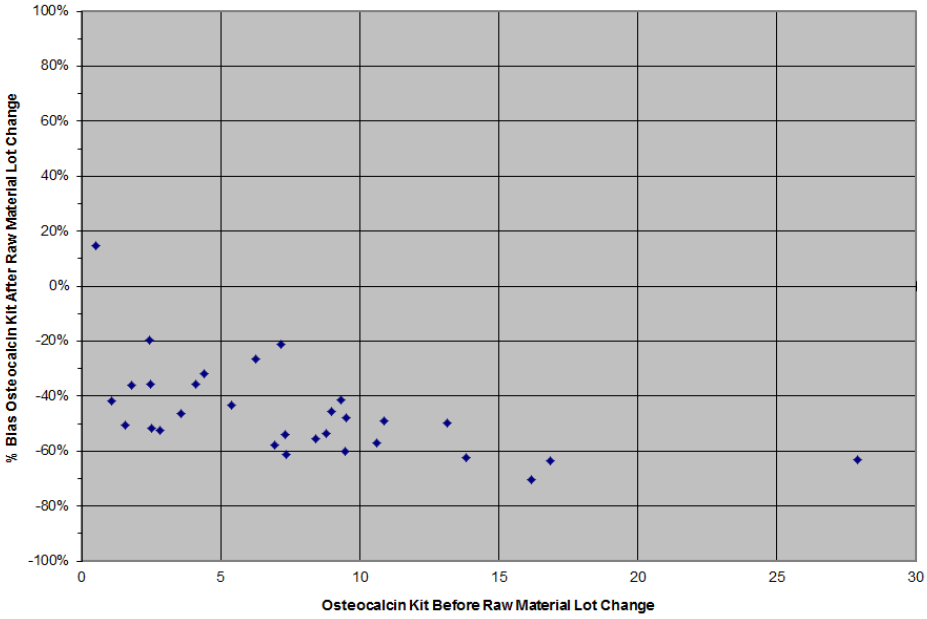
Reason for Correction

Siemens has confirmed an average under recovery of 50% in patient values across the assays reportable range with the IMMULITE/IMMULITE 1000 Osteocalcin (LKON1) 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.

Refer to Figure 1 for an example of the bias observed between an Osteocalcin kit lot before and after the raw material lot change.

Figure 1. Bias Plot



Risk to Health

Osteocalcin can serve as a measure of increased bone resorption in some patients. Depending on 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.

Siemens recommends discussing the content of this field action 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/IMMULITE 1000 Osteocalcin kit lots 316, 317, 318, 319 and 320 (which began shipping in February 2013).

Actions to be Taken by the Customer

Siemens does not currently have a replacement for this product. Please contact your Siemens Customer Care Center to discuss alternate solutions that meet your testing needs.

- Discontinue use of and discard the kit lots listed in Table 1.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within thirty (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 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.

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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE/IMMULITE 1000 Osteocalcin Under Recovery of Patient Values

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice #1111 dated February 2014 regarding IMMULITE/IMMULITE 1000 Osteocalcin Under Recovery of Patient Values. 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.

Product Description Product Catalog #/SMN #/Lot #	**Quantity of Affected Product in inventory that has been discarded**
LKON1 lots 316, 317, 318, 319, 320	

Name of person completing questionnaire:

Title:

Institution:

Street:

City: State:

Phone: Country

Customer Sold To #: Customer Ship To #:

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.