SIEMENS

Urgent Field Safety Notice

IMC16-05.A.OUS

April, 2016

IMMULITE®
IMMULITE® 1000

Insulin-Like Growth Factor I (IGF-I) Patient Sample Pretreatment Activity Requires Increased Incubation Time

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

Table 1. IMMULITE/IMMULITE 1000 Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Assay
IGF-I	LKGF1	10381403	411	IGF-I

Reason for Correction

Siemens Healthcare Diagnostics has determined that it takes 24 minutes of incubation prior to processing the samples on the IMMULITE/IMMULITE 1000 system for the patient sample and the pretreatment solution to reach full equilibration when using pretreatment solution (LGFA) lot 055 contained in IGF-I Kit lot 411 (expiration 4/30/2016). If patient samples are run before reaching full equilibration an under-recovery of up to -36% may occur. If the sample is left to incubate for more than 24 minutes prior to testing, no under recovery is observed.

Quality Controls (QC) will not detect this issue.

No other IMMULITE/IMMULITE 1000 IGF-I kit lots are affected as lot 055 IGF-I pretreatment solution is only contained in IMMULITE/IMMULITE 1000 IGF-I kit lot 411.

Siemens is currently investigating the root cause of this issue.

Risk to Health

When this issue occurs, the potential exists for a falsely depressed IGF-I value to delay the diagnosis of acromegaly and/or delay potential pharmacologic treatment to normalize serum IGF-I. Potential clinical impact is mitigated by serial monitoring of serum IGF-I as well as correlation to serum growth hormone measurements and clinical presentation. Siemens is not recommending a review of previously generated results.

Actions to be taken by the Customer

Please perform the following steps:

511 Benedict Ave
Tarrytown, NY, 10591
www.siemens.com/diagnostics

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- To continue using IGF-I kit lot 411 and the associated pretreatment solution lot 055 to report patient results, ensure the IGF-I pretreatment solution is allowed to incubate with the patient sample for a minimum of 24 minutes prior to processing on the IMMULITE/IMMULITE 1000 systems.
- Complete and return the Effectiveness Check Form attached to this letter within 30 days.
- Please review this letter with your Medical Director.
- 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

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FIELD CORRECTION EFFECTIVENESS CHECK

Insulin-Like Growth Factor I (IGF-I) Patient Sample Pretreatment Activity Requires Increased Incubation Time

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC16-05.A.OUS dated April, 2016 regarding Insulin-Like Growth Factor I (IGF-I) Patient Sample Pretreatment Activity Requires Increased Incubation Time. 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 ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

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.

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