SIEMENS

Urgent Field Safety Notice

1112

October 2014

IMMULITE®
IMMULITE® 1000

Turbo Troponin I Falsely Elevated Results

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

Table 1. IMMULITE/IMMULITE 1000 Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Turbo Troponin I	RTI	LSKTI1	10381014	319, 321, 322, 323

Reason for Recall

Siemens Healthcare Diagnostics is conducting a recall for IMMULITE®/IMMULITE® 1000 *Turbo* Troponin I (LSKTI1) assay, kit lots listed in Table 1. Siemens has confirmed that the IMMULITE/IMMULITE 1000 *Turbo* Troponin I reagent kit lots 319, 321, 322, and 323 demonstrate an increased frequency of 2–7% in the number of falsely elevated troponin values in patient samples above the 99th percentile claim of >0.30 ng/mL (µg/L), as published in the Instructions For Use (IFU). Quality control is unlikely to detect this issue.

This issue only impacts the IMMULITE/IMMULITE 1000 *Turbo* Troponin I assay. Siemens is investigating the root cause of the falsely elevated troponin values.

Supply Disruption

Siemens has suspended shipment of the IMMULITE/IMMULITE 1000 *Turbo* Troponin I assay while conducting the investigation. As a result, Siemens is recommending that customers transition to an alternate Troponin assay. Siemens offers alternate Troponin I assays on the following systems: IMMULITE/IMMULITE 1000, IMMULITE 2000/IMMULITE 2000 XPi, ADVIA Centaur® Systems, Dimension® EXL™, Dimension Vista®, and the Stratus® systems.

Risk to Health

Use of the affected reagent lots may lead to an increased frequency of falsely elevated troponin values. It is unlikely that quality control will detect this issue. A falsely elevated troponin value may lead to unnecessary additional treatment or diagnostic procedures. Siemens is recommending a laboratory look back for any existing troponin sample(s) during the period of time within sample stability labeling, and, with troponin values greater than the laboratory's established cutoff, or 99th percentile, that were not also confirmed by another method.

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Tarrytown, NY 10591
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Actions to be Taken by the Customer

- 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 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 contact your local Siemens technical support representative to discuss alternative Siemens solutions.

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.

ADVIA Centaur, Dimension, Dimension Vista, IMMULITE, and Stratus are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Turbo Troponin I Falsely Elevated Results

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice #1112 dated October 2014 regarding *Turbo* Troponin I Falsely Elevated Results. 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 Credit**
LSKTl1 / 10381014 / 319		
LSKTl1 / 10381014 / 321		
LSKTl1 / 10381014 / 322		
LSKTl1 / 10381014 / 323		

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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