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Date August 26, 2020

Document Ref# VC-20-03.B.OUS

Urgent Field Safety Notice:

Dimension® EXL™ integrated chemistry system, LOCI Module

LOCI High-Sensitivity Troponin I (TNIH) Flex® reagent cartridge

Bias with Patient Samples

Dear Sirs,

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

Table 1. Dimension EXL affected product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Date of First Distribution	Expiration Date
LOCI High Sensitivity Troponin I	TNIH	RF627	10471068	EB0255	2020-01-29	2020-09-11

Reason for Notice

Siemens previously implemented a Field Correction for the Dimension Vista (VC-20-03.A.US) on July 2020. The purpose of this communication is to inform you that Siemens is expanding that Field Correction to include the Dimension EXL TNIH product listed in Table 1 due to a bias in patient sample results.

Siemens has observed a positive bias across the Analytical Measurement Range of the TNIH assay when lot EB0255 is compared to an unaffected control lot. The average bias observed for patient samples using the Dimension EXL Troponin lot EB0255 when compared with a control lot was +25% as shown in Figures 1 and 2. A maximum bias of +34% in patient samples around the 99th percentile was observed. Quality Control may not detect the patient bias.

All other Dimension EXL TNIH Lots in distribution do not exhibit this positive bias. Siemens is investigating the root cause of this issue. Future lots may contain an alert card in the carton containing lot specific correlation factors, if required.

Risk to Health

A rising or falling pattern in a troponin series for a patient would remain apparent to the clinician when all samples for a patient are tested within the same reagent lot, even if affected by this issue. There is negligible risk to health for this scenario.

For patients whose troponin series is tested across lots, a negative shift when using newer unaffected lots would reflect the true troponin result and would not lead to a missed or misdiagnosis of acute myocardial infarction. Initial treatment for suspected AMI would occur, along with consideration of serial troponin testing, electrocardiogram (ECG), clinical history, symptomology and risk factors, including further testing in the setting of an unstable angina diagnosis.

Figure 1. TNIH % Bias

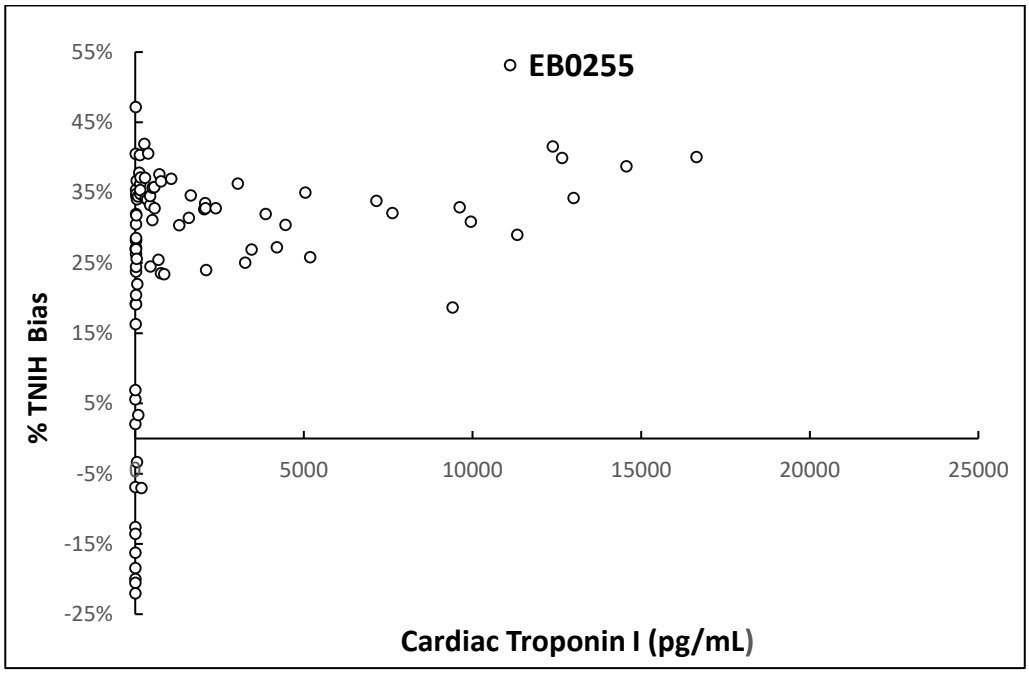
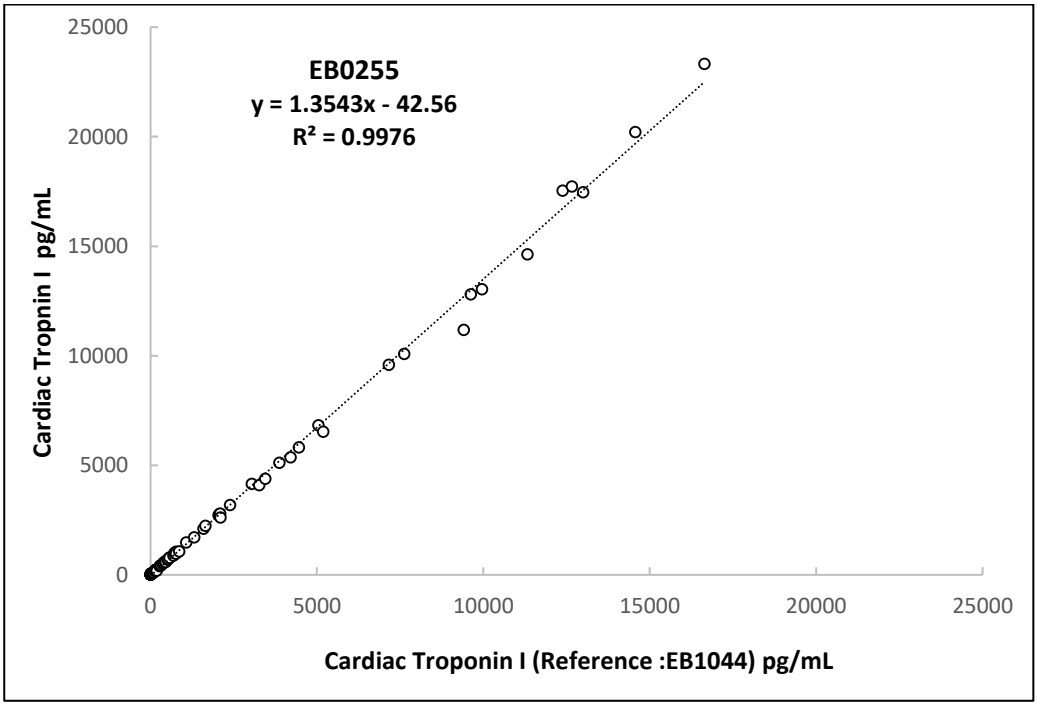


Figure 2. TNIH Recovery



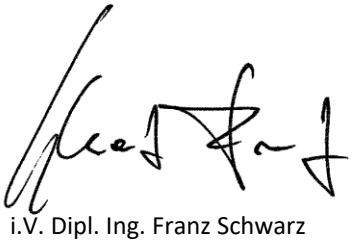
Actions to be Taken by the Customer:

- If you are using TNIH lot EB0255 DO NOT switch to another TNIH lot during serial measurements for a single patient sample.
- Discontinue use of and discard the TNIH reagent lot listed in Table 1 upon receipt of replacement product.
- Continue to use all other lots of TNIH.
- Review your inventory of these products to determine your laboratory's replacement needs. Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days to Siemens Healthineers for reporting to the authorities.
- Please review this letter with your Medical Director.
- If you received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Remote Services 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 Remote Services Center or your local Siemens Technical Support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



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SCF 02/2016 V16.05