

**Urgent Field Safety Notice
Follow Up**

**VC17-04.B.OUS
October 2017**

**Dimension[®] and Dimension Vista[®] Assays
Biotin Interference - Instructions for Use (IFU) Information**

Our records indicate that your facility may have received the products listed in Table 1 below.

Table 1. Dimension[®] and Dimension Vista[®] LOCI[®] Assays

<u>Assay</u>	<u>Catalog Number</u>	<u>Siemens Material Number (SMN)</u>	<u>Lot Numbers</u>
Thyroid Stimulating Hormone (TSHL)	RF612	10464524	All lots (including all future lots until Instructions For Use is updated)
LOCI Free Thyroxine (FT4L)	RF610	10464523	All lots (including all future lots until Instructions For Use is updated)
Thyroid Stimulating Hormone (TSH)	K6412	10445104	All lots (including all future lots until Instructions For Use is updated)
Cardiac Troponin I (CTNI)	K6421	10445098	All lots (including all future lots until Instructions For Use is updated)
Mass creatine kinase MB isoenzyme (MMB)	K6420	10445097	All lots (including all future lots until Instructions For Use is updated)
Sirolimus (SIRO)	DF306	10464331	All lots (including all future lots until Instructions For Use is updated)

Reason for Follow Up Correction

In March 2017, Siemens Healthcare Diagnostics issued Urgent Field Safety Notice VC17-04.A.OUS regarding incorrect units for biotin listed in the Non-Interfering Substances section of select Instructions for Use in Dimension[®] and Dimension Vista[®] assays.

Siemens ongoing investigation has identified the following new information regarding biotin interference:

1. Biotin interference limits are incorrectly listed in the Instructions for Use (IFU) for the following assays: Dimension TSHL, Dimension FT4L and Dimension Vista TSH.

Dimension and Dimension Vista Assays
 Biotin Interference - Instructions for Use (IFU) Information

Concentrations of biotin above the concentration listed in Table 2 in the Revised Biotin Non-Interference column can potentially result in interference >10%.

2. The Dimension Vista CTNI, MMB, and Dimension SIRO method IFUs do not contain biotin interference information. Concentrations of biotin above the concentration listed in Table 2 in the Revised Biotin Non-Interference column can potentially result in interference >10%.

Table 2. Revised Dimension and Dimension Vista Assay IFU Biotin Non-Interference Information (Amount of biotin that causes ≤10% interference)

Assay	Catalog Number [SMN Number]	Current Biotin Non-Interference IFU Information ng/mL [nmol/L]	Revised Biotin Non-Interference IFU Information ng/mL [nmol/L]
Thyroid Stimulating Hormone (TSHL)	RF612 [10464524]	250 [1025]	100 [409]
LOCI Free Thyroxine (FT4L)	RF610 [10464523]	100 [409]	50 [205]
Thyroid Stimulating Hormone (TSH)	K6412 [10445104]	500 [2050]	100 [409]
Cardiac Troponin I (CTNI)	K6421 [10445098]	No Information in IFU	100 [409]
Mass creatine kinase MB isoenzyme (MMB)	K6420 [10445097]	No Information in IFU	250 [1025]
Sirolimus (SIRO)	DF306 [10464331]	No Information in IFU	250 [1025]

Please refer to the information provided in Table 2 above until the appropriate IFU updates regarding biotin interference are completed. Siemens continues to investigate biotin interference with our assays and more information will be forthcoming.

Risk to Health

The probability of misinterpretation of results for FT4L, TSH, CTNI, MMB, and SIRO due to this issue is remote, and would be limited to specimens containing high levels of biotin. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing, serial testing, and/or concomitant imaging studies depending on the analyte. Siemens is not recommending a lookback as a result of this issue.

The difference between the interference observed for TSHL at the biotin concentration listed in the current IFU compared to the interference observed at the revised biotin concentration in Table 2 would not impact the clinical interpretation of TSHL results.

Actions to be Taken by the Customer

- Review the information contained in this letter.

Dimension and Dimension Vista Assays
Biotin Interference - Instructions for Use (IFU) Information

- Review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form 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 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.

Dimension, Dimension Vista, and LOCI are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK
Dimension and Dimension Vista Assay
Biotin Interference - Instructions for Use (IFU) Information

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Follow Up VC17-04.B.OUS dated October 2017 regarding Dimension and Dimension Vista Assays Biotin Interference - Instructions for Use (IFU) Information. Please read the question below and indicate the appropriate answer. Send 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 your local Siemens Technical Support Representative. If you have any questions, contact your local Siemens Technical Support Representative.