

**Dimension Vista® Systems
LOCI Thyroid Stimulating Hormone (K6412 SMN 10445104)
Lot 14237AA, Falsely low results near the end of a well set**

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

Table 1. Dimension Vista® TSH

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
TSH	K6412	10445104	14237AA

Reason for Field Action

Siemens Healthcare Diagnostics has determined that Dimension Vista® LOCI Thyroid Stimulating Hormone (TSH) Lot 14237AA may produce falsely depressed results ranging from -23% to -96% near the end of the well set due to inadequate reagent volume in a Flex® well. The occurrence of this issue is low. Quality Control will detect the issue if it is run near the end of an affected well set. Siemens is instructing customers to discontinue use of TSH lot 14237AA as a result of this issue.

Risk to Health

The potential for clinical impact as a result of this issue is limited to a delay in hypothyroidism investigations. When this issue occurs, it is likely the falsely depressed TSH values will not correlate reciprocally with free or total thyroid hormone values. In cases of monitoring TSH suppression for thyroid cancer, the potential for misinterpretation of a patient's response to thyroid hormone replacement therapy exists.

Siemens is recommending a laboratory look back for previously generated results using the lot listed in Table 1 provided the sample is within the specified storage conditions and time, and where a TSH value within or below the reference interval did not reciprocally correlate with free or total thyroid hormone values.

Actions to be taken by Customer

Please do the following:

- Review this letter with your Medical Director.
- Discontinue use and discard your remaining inventory of the reagent lot listed in Table 1.
- Indicate your replacement product needs on the attached Field Correction Effectiveness Check Form and fax the form your local Siemens technical support representative within 30 days. Siemens will replace any unused inventory of the affected lot at no charge.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact 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.

Dimension Vista® TSH, Falsely low results near the end of a well set

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK
Dimension Vista® Systems
Thyroid Stimulating Hormone (TSH) (K6412 SMN 10445104)
Lot 14237AA, Falsely low results near the end of a well set

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Letter Number 15-25 dated April 2015 regarding TSH, Falsely low results near the end of a well set. 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 Medical Device Recall 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.

Dimension Vista® TSH (K6412, SMN 10445104)	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Lot # 14237AA		

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.