SIEMENS

Urgent Field Safety Notice

10814910

May 2013

ADVIA Centaur® Systems
Dimension® Systems
Dimension Vista® Systems
IMMULITE® Systems

Undetectable Thyroid-Stimulating Hormone (TSH) Results Due to TSH Variant

Our records indicate that you have or may have received the following product:

Table 1.

Assay	Test Code	Catalog or Part Number	Siemens Material Number (SMN)	Lot Number
ADVIA Centaur® Systems TSH3 Ultra 100T, 500T, 2500T	TSH3-Ultra (TSH3-UL)	06491072 06491080 04862625	10282378 10282379 10361944	All
Dimension® Thyroid Stimulating Hormone	TSH	RF412	10444911	All
Dimension LOCI® Thyroid Stimulating Hormone	TSHL	RF612	10464524	All
Dimension Vista® LOCI Thyroid Stimulating Hormone	TSH	K6412	10445104	All
IMMULITE® Systems Third Generation TSH 100T, 500T	Third Generation TSH	LKTS1 LKTS5	10381620 10381627	All
IMMULITE® 2000/IMMULITE® 2000 XPi Third Generation TSH 200T, 600T	Third Generation TSH	L2KTS2 L2KTS6	10381665 10381667	All
IMMULITE Systems Rapid TSH 100T, 500T	Rapid TSH	LKRT1 LKRT5	10381637 10381628	All
IMMULITE 2000/IMMULITE 2000 XPi Rapid TSH 200T, 600T	Rapid TSH	L2KRT2 L2KRT6	10381651 10381652	All

Reason for Correction

Siemens Healthcare Diagnostics is informing customers that a rare variant of TSH, identified in a small cluster of patients, is not detected by the Siemens assays listed in Table 1.

As part of an investigation of unexplained discordant results, samples were identified in which the monoclonal antibody used in the reagent failed to detect the TSH molecule. These individuals may have a previously unrecognized, functionally normal TSH variant. The observed rate of occurrence during a 30-month time period was 0.6×10^{-7}.

The ADVIA Centaur Systems TSH assay (SMN 10309958, 10309959, and 10337442) recognizes the TSH variant in these individuals and therefore is not impacted by this notification.

Risk to Health

A falsely low TSH value may lead to inappropriate diagnosis or treatment of patients with or without thyroid disease if not interpreted with thyroid gland biomarker measurements. This risk is largely mitigated by co-interpretation of TSH results in conjunction with thyroxine and T3, patient history, and clinical signs and symptoms. In the monitoring of thyroid replacement therapy, the variant would be already known or would trigger further investigations prior to treatment modification.

Actions to be Taken by the Customer

- Siemens believes a look back is not required as the expected frequency of the variant is extremely rare and use of thyroxine measurements and FT3 are strong mitigating factors. However, this decision should be at the discretion of your Medical Director.

- Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

Additional Information

For diagnostic purposes, the results obtained from these assays should always be used in combination with the clinical examination, patient medical history, and other findings. See each product's Instructions For Use for further information.

Refer to the National Academy of Clinical Biochemistry: Laboratory Support for the Diagnosis and Monitoring of Thyroid Disease: Guideline #18 for additional information on investigating discordant TSH values.

We appreciate your time in reviewing this letter. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK

Undetectable Thyroid-Stimulating Hormone (TSH) Results Due to TSH Variant

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice #10814910 dated May 2013 regarding Undetectable Thyroid-Stimulating Hormone (TSH) Results Due to TSH Variant. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

Customer Sold To #: Customer Ship To #:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####.