

IMMULITE® IMMULITE® 1000

Thyroxine-Binding Globulin (TBG) Adjustment Slope Parameter Failure

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

Table 1. IMMULITE/IMMULITE 1000 Affected Product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Thyroxine-Binding Globulin	TBG	LKTB1	10381643	257

Reason for Correction

Siemens Healthcare Diagnostics has confirmed adjustment slope parameter failures for the IMMULITE®/IMMULITE® 1000 Thyroxine-Binding Globulin (LKTB1) kit lot listed in Table 1.

Siemens internal investigation has confirmed LKTB1 lot 257 may fail the adjustment slope parameter resulting in slopes of >1.8. Testing of kit lot 257 with an adjustment slope of >1.8 shows that patient samples may exhibit an average negative bias of approximately 20% (negative bias range 7% to 37% between 14 and 80 µg/mL (259 – 1480nmol/L)) when compared to kit lots with an acceptable adjustment slope parameter.

Controls may not detect the bias in patient results.

Extensive studies are being conducted to confirm the root cause. Preliminary investigation indicates the issue may be raw material related. An alternate lot is available (lot 259) which was manufactured with a combination of raw materials used in kit lots which have not previously exhibited the issue seen in kit lot 257. We continue to monitor the performance of lot 259.

Risk to Health

The risk to health when using the affected reagent lot listed in Table 1 is negligible and limited to a potential delay in TBG testing or further thyroid disorder investigations. Siemens is not recommending laboratory look back as a result of this issue.

Actions to be Taken by the Customer

- Discontinue use and discard kit lot listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within seven (7) days.

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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notification (UFSN) # 1114 dated April 2015 regarding Thyroxine-Binding Globulin (TBG) Adjustment Slope Parameter Failure. 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 UFSN 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
LKTB1 Lot 257 (SMN# 10381643)		

Name of person completing questionnaire: _____

Title: _____

Institution: Unilabs A/S Instrument Serial Number: F1222

Street: Nygårdsvej 32

City: København Ø

Phone: Country: Denmark

Please email this completed form to Soren.Ramso-Nielsen@Siemens.com at the Customer Care Center. If you have any questions, contact your local Siemens technical support representative.