SIEMENS

Urgent Field Safety Notice

4007

August 2013

IMMULITE®
IMMULITE® 1000
IMMULITE® 2000
IMMULITE® 2000 XPi

IMMULITE Systems Free T3 Assays

Reason for Correction

Siemens Healthcare Diagnostics has confirmed customer complaints regarding an increase in the number of euthyroid patients (those with normal function of the thyroid) demonstrating values above the recommended normal range as published in the Instructions For Use (IFU) for the IMMULITE®/IMMULITE® 1000 and/or IMMULITE® 2000/IMMULITE® 2000 XPi Free T3 kit lots listed in Table 1. A positive bias in quality control results was also observed, but the values may remain within the established ranges.

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

Table 1.

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE/IMMULITE 1000 FT3	FT3	LKF31	10381626	353, 354
IMMULITE 2000/IMMULITE 2000 XPi FT3	FT3	L2KF32	10381675	737, 738, 739, 740, 741, 742, 743
IMMULITE 2000/IMMULITE 2000 XPi FT3	FT3	L2KF36	10381682	

The root cause of this issue is related to adjustor (LF3L/H) lot 135, which is included in the assay kit lots listed in Table 1.

Siemens has confirmed that kit lots containing adjustor lot 136 or higher align with the expected values published in the IFU. Refer to Table 2 for additional information.

Siemens Healthcare Diagnostics

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Table 2. IMMULITE Systems Free T3 Adjustor Lot 135 vs.136

	IFU Upper 95% Limit (pg/mL)	Adjustor Lot	Upper 95% Limit Observed (pg/mL)	Percentage Difference Compared to IFU
IMMULITE/IMMULITE 1000	4.1	135	4.9	20%
		136	4.3	5%
IMMULITE 2000/IMMULITE 2000 XPi	4.2	135	5.1	22%
		136	4.4	4%

Risk to Health

The observed bias due to adjustor (LF3L/H) lot 135 may result in a slightly elevated Free T3 result in euthyroid patients or a low but within reference interval result for hypothyroid patients. In these cases, results would not correlate with the TSH thyroxine results and/or Free T4 results. Because assessment of thyroid function is based on multiple analytes, a T3 result that is inconsistent with other thyroid markers would be questioned by a clinician and precludes clinical intervention based on a single result. Siemens does not recommend a look back of previously generated results. Siemens recommends that you review this letter with your Medical Director.

Actions to be Taken by the Customer

Discontinue use of and discard the kit lots listed in Table 1.

In addition, please perform the following:

- Review your inventory of these reagents to determine your laboratory's replacement needs.
- Keep this letter with your laboratory records.
- Forward this letter to whomever you may have distributed these products.

We apologize for the inconvenience this situation has caused. If you have any questions or need additional information, please contact your local Siemens representative.