SIEMENS

Urgent Field Safety Notice

1110

November 2013

IMMULITE®
IMMULITE® 1000

Folic Acid Failed Adjustments

Our records indicate that you have received the following product:

Table 1. IMMULITE/IMMULITE 1000 Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Folic Acid	FOL	LKFO1	10380902	335, 336, and 337

Reason for Correction

Siemens Healthcare Diagnostics identified the potential for an accelerated decline in counts per second (CPS) for the IMMULITE®/IMMULITE® 1000 Folic Acid (LKFO1) kit lots listed in Table 1. This may lead to a failed adjustment before the expiration date, which is indicated on the kit label, is reached.

Siemens performed internal testing using one of the affected IMMULITE/IMMULITE 1000 Folic Acid (LKFO1) kit lots; this testing showed that patient samples may exhibit an approximate negative bias of as much as 24% for results less than 4 ng/mL and a positive bias of as much as 22% for results above 20 ng/mL when adjustments slopes are greater than 1.8. Controls may not detect the bias in patient results at these levels.

Results between 4 ng/mL and 20 ng/mL exhibit normal variability of the method (± 10%).

Siemens continues to investigate the root cause of this issue.

As a proactive measure, Siemens will temporarily reduce IMMULITE/IMMULITE 1000 Folic Acid shelf life from 12 months to 6 months.

Risk to Health

When adjustment slopes are elevated greater than 1.8, patient sample results may exhibit an approximate negative bias ranging from -9 to -24% for results less than 4 ng/mL. Controls may not detect the bias in patient results at concentrations less than 4 ng/mL. A negatively biased folate value below the 4 ng/mL cutoff will lead to dietary counseling, folate supplementation, and repeat testing during follow-up visits during routine patient management for folate deficiency; therefore look back is not recommended.

Siemens Healthcare Diagnostics

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

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Folate concentrations above 20 ng/mL may exhibit an approximate positive bias as much as 22%, which would not impact dietary counseling or supplementation. Folate concentrations 4 ng/mL to 20 ng/mL exhibit normal variability of the method (± 10%).

Actions to be Taken by the Customer

If the adjustment slope is less than or equal to 1.8 and quality control results are within the established ranges, the kit may be used to generate patient results.

If the adjustment slope is greater than 1.8, please perform the following:

- Discontinue use and discard the kit lots listed in Table 1.
- Review your inventory of the affected reagent lots to determine your laboratory's replacement needs.

Additionally, for all customers receiving this Urgent Field Safety Notice, please perform the following:

- Review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check form attached to this letter within thirty (30) days.

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

We apologize for any inconvenience this situation may have caused. If you have any questions or need additional information, please contact your Siemens Customer Care Center or your local technical support representative.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.