SIEMENS

Urgent Field Safety Notice

1103

April 2012

IMMULITE®

IMMULITE® 1000

Folic Acid Invalid Adjustments

Our records indicate that you may have received one or more of the following IMMULITE®/IMMULITE 1000 Folic Acid (LKFO1) kit lots: 324, 325, 326.

Siemens Healthcare Diagnostics has identified an accelerated decline in counts per second (CPS) for these kit lots. This decrease in CPS has produced adjustment slopes greater than 1.8, which results in a failure to give a valid adjustment slope during the shelf life of the kits.

In addition, for kit lots 325 and 326 positively biased or out-of-range control results may be observed in association with the elevated adjustment slopes. In line with good laboratory practice, patient results should not be reported when quality control results are out of range.

This issue is resolved for IMMULITE/IMMULITE 1000 Folic Acid kit lot 327 and above.

Siemens is conducting a voluntary corrective action for IMMULITE/IMMULITE 1000 Folic Acid (LKFO1), kit lots 324, 325, and 326. Immediately discontinue using and discard any inventory of affected kit lots.

Please complete and return the Field Correction Effectiveness Check attached to this letter to request your no-charge replacement kits.

If you have any questions or need additional information, please contact your Siemens Technical Solutions Center. Please forward this notification to whomever you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Folic Acid Invalid Adjustments

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice #1103 dated April 2012 regarding IMMULITE®/IMMULITE 1000 Folic Acid Invalid Adjustments. Please read each 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.

1. I have read and understood the Urgent Field Safety Notice instructions in the April 2012 letter. Yes ☐ No ☐

2. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

Folic Acid kit lots discarded:

Kit Lot	Quantity Discarded	Replacement Kits Required
LKFO1 324		
LKFO1 325		
LKFO1 326		

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

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