

Urgent Field Safety Notice

3001-0902

September 2009

IMMULITE[®], IMMULITE 1000, IMMULITE 2000, IMMULITE 2500

Instability of High Sensitivity C-Reactive Protein Adjusters and Controls

Our records indicate that as an IMMULITE[®] High Sensitivity CRP (hsCRP) customer (IMMULITE, IMMULITE 1000, IMMULITE 2000, IMMULITE 2500), you may have received hsCRP Adjusters (LCRL and LCRH) lot 120 contained in:

- IMMULITE / IMMULITE 1000 hsCRP LKCRP Kit Lot 302
- IMMULITE 2000 hsCRP L2KCRP Kit Lot 243
- IMMULITE 2500 hsCRP L5KCRP Kit Lot 233

Or you may have received IMMULITE C-Reactive Protein Control Module (LCRCM) Lots 021, 022, 022L, or 025L contained in:

- Control lot LCRC1-3 0014
- Control lot LCRC1-3 0015

Internal testing conducted by Siemens Healthcare Diagnostics indicates instability of these lots of hsCRP Adjusters and Controls, which are prepared with the same formulations and critical raw materials.

Siemens Healthcare Diagnostics is conducting a voluntary corrective action for these products. Immediately discontinue use of, and discard, IMMULITE / IMMULITE 1000 LKCRP Kit Lot 302, IMMULITE 2000 L2KCRP Kit Lot 243, IMMULITE 2500 L5KCRP Kit Lot 233, and the IMMULITE C-Reactive Protein Control LCRC1-3 Lots 0014 and 0015.

Patient sample results obtained with the impacted kits may have an average positive bias of 20% compared with results obtained with previous kit lots. The control lots listed above tend to yield variable results that can exceed the established +/- 2SD control ranges. Control results from IMMULITE C-Reactive Protein Controls lots 0014 and 0015 may not provide an alert to a high bias in patient results; however, control results from Bio-Rad Liquichek[™] Cardiac Marker Plus Control LT should reflect any bias in patient results.

A look-back on patient results obtained with the affected products is not required. The observed bias would not lead to a different clinical interpretation in the acute inflammatory response application. In the use of the assay as a risk stratification marker, the bias could lead to follow-up testing or a treatment with aspirin.

Siemens Healthcare Diagnostics Inc.

62 Flanders-Bartley Road
Flanders, NJ 07836

973.927.2828
www.siemens.com/diagnostics

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Information About High Sensitivity C-Reactive Protein Adjusters and Controls

Availability of the next kit lots of IMMULITE / IMMULITE 1000 LKCRP, IMMULITE 2000 L2KCRP, and IMMULITE 2500 L5KCRP is anticipated near the end of September 2009. Availability of the next lot of IMMULITE C-Reactive Protein LCRC1-3 has not been determined. Bio-Rad Liquichek™ Cardiac Marker Plus Control LT can be used as an alternative to the IMMULITE CRP controls. The Bio-Rad controls can be purchased directly from Bio-Rad.

Please complete and return the Field Correction Effectiveness Check form attached to this bulletin within 7 days. Once received, credit or replacement will be processed for the discarded product.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

Please forward this letter to anyone you may have distributed this product to.

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

FIELD CORRECTION EFFECTIVENESS CHECK

Information About High Sensitivity C-Reactive Protein Adjusters and Controls.

Dear Customer:

This response form (continued on the next page) is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 3001-0902 dated 2009-09 regarding:

- IMMULITE / IMMULITE 1000 LKCRP Kit Lot 302,
- IMMULITE 2000 L2KCRP Kit Lot 243,
- IMMULITE 2500 L5KCRP Kit Lot 233, and
- IMMULITE C-Reactive Protein Tri-level Control Modules: LCRCM Control Module Lots 021, 022, 022L, and 025L containing controls LCRC1-3 lots 0014 and 0015.

Please read each question and answer appropriately. Fax the completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of the next page.

Submitting this form indicates you have received this information and discarded all of the lots of IMMULITE / IMMULITE 1000 LKCRP Kit Lot 302, IMMULITE 2000 L2KCRP Kit Lot 243, IMMULITE 2500 L5KCRP Kit Lot 233, and IMMULITE C-Reactive Protein Tri-level Control Modules: LCRCM Control Module Lots 021, 022, 022L, and 025L containing controls LCRC1-3 lots 0014 and 0015.

The form is continued on the next page.

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FIELD CORRECTION EFFECTIVENESS CHECK (Continued)

1. Did we effectively communicate all necessary information? 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:

No charge replacement Kits will be provided when available

Number of IMMULITE/IMMULITE 1000
LKCRP Kits Lot 302 and date discarded: _____

Number of IMMULITE 2000 L2KCRP Kits
Lot 243 and date discarded: _____

Number of IMMULITE 2500 L5KCRP Kits
Lot 233 and date discarded: _____

Credit will be issued for discarded Control Modules

Number of IMMULITE C-Reactive Protein
Control Module Lot 021 and date
discarded: _____

Number of IMMULITE C-Reactive Protein
Control Modules Lot 022 and date
discarded: _____

Number of IMMULITE C-Reactive Protein
Control Modules Lot 22L and date
discarded: _____

Number of IMMULITE C-Reactive Protein
Control Modules Lot 025L and date
discarded: _____

Signature: _____

Date: _____

Printed Name & Title: _____

PLEASE COMPLETE THIS FORM AND FAX TO XXXXXXXXXX.