SIEMENS

Urgent Field Safety Notice

IMC16-22.A.OUS

August 2016

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

CMV IgM Imprecision on Patient Samples

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

Table 1. IMMULITE® Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	1st Distribution Date
IMMULITE/ IMMULITE 1000 CMV IgM	CMM	LKCM1	10381296	0330 0331	2016-11-30 2017-02-28	2016-02-02 2016-05-27
IMMULITE 2000/ IMMULITE 2000 XPi CMV IgM	CMM	L2KCM2	10381320	255 256 257 258 259 260 261 262 263 264 266 267	2016-02-29 2016-03-31 2016-07-31 2016-08-31 2016-08-31 2016-09-30 2016-09-30 2016-11-30 2016-12-31 2017-01-31 2017-02-28 2017-05-31	2015-04-09 2015-06-18 2015-08-20 2015-08-31 2015-10-09 2015-11-19 2015-12-29 2015-12-11 2016-03-02 2016-03-25 2016-05-13 2016-06-28

Reason for Recall

Siemens Healthcare Diagnostics has confirmed increased imprecision on some patient samples with the CMV IgM reagent lots listed in Table 1 on the IMMULITE®/IMMULITE® 1000 and the IMMULITE® 2000/IMMULITE® 2000 XPi Systems. These samples may exhibit higher percent coefficient of variation (% CV) than the precision performance data published in the Instructions For Use (IFU) across nonreactive, indeterminate, and reactive ratios.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

IMMULITE® Systems

CMV IgM Imprecision on Patient Samples

Quality controls provided in the CMV IgM kit may not detect the imprecision with patient results.

Siemens continues to investigate the cause of the imprecision. Siemens recommends transitioning to IMMULITE/IMMULITE 1000 kit lot 0332 and above and IMMULITE 2000/2000 XPi CMV IgM kit lots 268 and above.

Risk to Health

When this issue occurs, the risk to health is remote and limited to a falsely nonreactive result when truly indeterminate or reactive, which may lead to delayed investigation of acute CMV infection. The risk to health is reduced by correlation with clinical presentation and clinical history of exposure, as well as concurrent or consequent testing such as with CMV IgG titers, IgG avidity or PCR.

A lookback, including retesting of existing samples provided specimens meet time and storage conditions specified in the Instructions for Use, is recommended for previously generated nonreactive results of ≥0.40 and <0.9. Retesting using CMV IgM or another appropriate CMV test, depending on the clinical context and timing of the initial test, may be considered (refer to Question and Answer below for suggested criteria).

Actions to be Taken by the Customer
For the product lot numbers listed above in Table 1, please perform the following steps:

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Discontinue use of and discard the kit lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

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.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

Questions and Answers:

Question: Why are only nonreactive results of ≥0.40 and <0.9 included in the lookback for kit lots listed in Table 1?

Answer: Statistical analysis demonstrates that a sample result of <0.40 is highly improbable to be a true indeterminate or reactive sample. Based on the observed magnitude of the within-run imprecision, ratios between ≥0.40 and <0.9 could potentially be true indeterminate or reactive samples.

Question: How can I communicate this issue to healthcare providers?

Answer: Siemens suggests the following wording:

Siemens Healthcare Diagnostics has confirmed through internal investigation that between [date when your laboratory began using the affected products in this recall through the date your laboratory discontinued using the affected products in this recall], there was an increase in imprecision for some patients samples for the CMV IgM assay on the IMMULITE/ IMMULITE 1000 and the IMMULITE 2000/IMMULITE 2000 XPi Systems. Results may have been reported as nonreactive when truly reactive, though the risk to health is remote.

Please consider retesting using CMV IgM or another appropriate CMV test in cases where all of the following events have occurred:

1. You have had CMV IgM testing performed on your patient(s) during the dates listed above,
2. Your patient's CMV IgM result was nonreactive,
3. Your patient is currently pregnant or is a child,
4. Repeat or additional CMV testing was not performed, and
5. There is high clinical suspicion for disease.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE/IMMULITE 1000 and IMMULITE 2000/IMMULITE 2000 XPi CMV IgM Imprecision on Patient Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated August 2016 regarding IMMULITE/ IMMULITE 1000 and the IMMULITE 2000/IMMULITE 2000 XPi CMV IgM Imprecision on Patient Samples. 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 Urgent Field Safety Notice 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**
IMMULITE/IMMULITE 1000 CMV IgM LKCM1 / SMN 10381296 / lot 330		
IMMULITE/IMMULITE 1000 CMV IgM LKCM1 / SMN 10381296 / lot 331		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 258		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 259		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 260		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 261		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 262		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 263		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 264		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 266		
IMMULITE 2000/IMMULITE 2000 XPi L2KCM2 / SMN 10381320 / lot 267		

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

IMMULITE® Systems

CMV IgM Imprecision on Patient Samples

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

To fax this completed form please send it to the Customer Care Center at (65) 6266-3376. If you have any questions, contact your local Siemens technical support representative.

Signature	
Date	
Company Stamp	

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics