SIEMENS

Urgent Field Safety Notice

IMC16-20.A.OUS

August 2016

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

Rubella 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 Rubella IgM	RUM	LKRM1	10381282	0333 0334	2016/08/31 2016/11/30	2015/10/06 2016/03/01
IMMULITE 2000/ IMMULITE 2000 XPi Rubella IgM	RUM	L2KRM2	10381327	236M 237 238 239 239L	2016/04/30 2016/08/31 2016/10/31 2017/03/31 2017/03/31	2015/09/17 2015/10/09 2016/02/02 2016/04/12 2016/06/09

Reason for Recall

Siemens Healthcare Diagnostics has confirmed increased imprecision on some patient samples with the Rubella IgM reagent lots listed in Table 1 on the IMMULITE®/IMMULITE® 1000 and 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.

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

Siemens continues to investigate the cause of the imprecision. Siemens recommends transitioning to IMMULITE/IMMULITE1000 Rubella IgM kit lot 0337 and above or to IMMULITE 2000/IMMULITE 2000 XPi Rubella IgM kit lot 240 and above.

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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 Rubella 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 Rubella IgG titers or viral culture.

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 ≥0.47 but <0.9. Retesting using Rubella IgM or another appropriate Rubella 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.

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Question and Answer:

Question: Why are only nonreactive results of ≥0.47 and <0.9 included in the lookback for kit lots listed in Table 1?

Answer: Statistical analysis demonstrates that a sample result of <0.47 is highly improbable to be a true indeterminate or reactive sample. Based on the observed magnitude of the within-run imprecision, ratios between ≥0.47 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 patient samples for the Rubella IgM assay on the IMMULITE/IMMULITE 1000 and 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 Rubella IgM or another appropriate Rubella test in cases where all of the following events have occurred:

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

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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE/IMMULITE 1000 and IMMULITE 2000/IMMULITE 2000 XPi Systems Rubella IgM Imprecision on Patient Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice IMC16-20.A.OUS dated August 2016 regarding IMMULITE/ IMMULITE 1000 and IMMULITE 2000/IMMULITE 2000 XPi Systems Rubella 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 Rubella IgM LKRM1 / SMN 10381282 / Lot 0333		
IMMULITE/IMMULITE 1000 Rubella IgM LKRM1 / SMN 10381282 / Lot 0334		
IMMULITE 2000/IMMULITE 2000 XPi Rubella IgM L2KRM2 / SMN 10381327 / Lot 237		
IMMULITE 2000/IMMULITE 2000 XPi Rubella IgM L2KRM2 / SMN 10381327 / Lot 238		
IMMULITE 2000/IMMULITE 2000 XPi Rubella IgM L2KRM2 / SMN 10381327 / Lot 239		
IMMULITE 2000/IMMULITE 2000 XPi Rubella IgM L2KRM2 / SMN 10381327 / Lot 239L		

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 64907374. If you have any questions, contact your local Siemens technical support representative.

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Signature	
Date	
Company Stamp	

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