

**IMMULITE®**  
**IMMULITE® 1000**

**Lipopolysaccharide Binding Protein (LBP) elevated slopes and adjustor open vial stability at room temperature**

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	Manufacturing /1 <sup>st</sup> Distribution Date
IMMULITE/IMMULITE 1000 LBP	LBP	LKLB1	10381395	330	2017-06-30	2016-07-21 2016-08-05

### Reason for Recall

Siemens Healthcare Diagnostics has confirmed that the IMMULITE®/IMMULITE® 1000 Lipopolysaccharide Binding Protein (LBP) Kit Lot 330 listed in Table 1 shows elevated adjustment slopes and Quality Control (QC) samples recovering outside of published  $\pm 2SD$  range. If your lab is using QC ranges  $> \pm 2SD$ , the potential exists to pass QC and to report patient samples with an average positive patient bias of 29% (ranging from 21% at 12  $\mu\text{g/mL}$  to 77% at 112  $\mu\text{g/mL}$ ).

In addition Adjustor Lot 134 packed with Kit Lot 330 listed in Table 1 does not meet the four hour open vial stability claim at room temperature as published in the Instructions for Use (IFU). The investigation has confirmed a decrease in counts per second (CPS) of the adjustor after reconstitution; this could potentially lead to failed adjustment slopes as well as quality control samples recovering outside of the published  $\pm 2SD$  range.

Siemens is currently investigating the root cause of the issues.

Adjustor Lots 135 and above included in LBP Kit Lots 331 and above, are not affected by this issue.

### Risk to Health

The overall risk to health as a result of this issue is negligible, as LBP would not be used in isolation but would be correlated with clinical symptomology as well as with other laboratory testing during investigations for and monitoring of endotoxin exposure. Siemens is not recommending a review of previously generated results.

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### **Actions to be Taken by the Customer**

- Please review this letter with your Medical Director.
- Discontinue use of and discard the kit lot 330 listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 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 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.

IMMULITE is a trademark of Siemens Healthcare Diagnostics.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

**Lipopolysaccharide Binding Protein (LBP) elevated slopes and adjustor open vial stability at room temperature**

This response form is to confirm receipt of the enclosed Siemens Healthcare Urgent Field Safety Notice IMC17-13.A.OUS dated March 2017 regarding IMMULITE /IMMULITE 1000 Systems Lipopolysaccharide Binding Protein elevated slopes and adjustor open vial stability at room temperature. 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 UFSN 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 LBP LKLB1/ SMN 10381395/Lot 330		

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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.