Urgent Field Safety Notice

IMC20-03.A.OUS

January, 2020

IMMULITE® 2000
IMMULITE® 2000 XPi

EBV-VCA IgM Imprecision

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

Table 1. IMMULITE® 2000 Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing (YYYY-MM-DD)
EBV-VCA IgM	ECM	L2KEM2	10488005	355	2020-01-31	2019-08-21

Reason for Field Action

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for an increase in within run and within laboratory imprecision on Siemens' EBV-VCA IgM Control Module quality control material and patient samples with EBV-VCA IgM on 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 across nonreactive, indeterminate and reactive S/CO ratios. The imprecision is especially evident on quality control material and samples that are close to the indeterminate range (0.9 to 1.0 S/CO ratio) of the assay. The imprecision may cause the interpretation of a sample that is nonreactive to be indeterminate or reactive and a sample that is reactive to be nonreactive or indeterminate.

Siemens continues to investigate the cause of the imprecision. Siemens recommends transitioning to IMMULITE 2000/IMMULITE 2000 XPi EBV-VCA IgM kit lots 356 and above.

Risk to Health

A false nonreactive result may lead to delayed detection of EBV infection. Results would be correlated to clinical signs and symptoms of EBV infection and other laboratory testing such as EBV heterophile antibody, EBV-VCA IgG antibodies, EBV antibodies to nuclear antigen, EBV DNA quantification, complete blood count and liver function tests. Siemens is not recommending a review of previously generated results.

511 Benedict Avenue
Tarrytown, NY 10591

Actions to be Taken by the Customer

- 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 Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

IMMULITE is a trademark of Siemens Healthcare Diagnostics Inc.

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