Urgent Field Safety Notice

IMC19-07.A.OUS

July 2019

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

Low Discordant Progesterone results on a Subset of 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	Manufacturing date
PRG	PRG	LKPW1	10381128	Kit lots 0259 and above	2018-10-19
PRG	PRG	L2KPW2 L2KPW6	10381181 10381170	Kit lots 510 and above	2018-10-01 2018-09-28

Reason for Communication

The purpose of this communication is to inform you of a potential issue with the performance of the products indicated in Table 1.

Siemens Healthcare Diagnostics Inc. has determined that there is a potential for low discordant progesterone results on a subset of patient samples. Our investigation of customer complaints suggests the presence of a potential interferent with the assay. Based on available data, it is estimated the occurrence is <1%.

Due to the nature of initial complaints received, the investigation to date has focused on In Vitro Fertilization (IVF) patient sample performance. Siemens is actively working to investigate the root cause.

Risk to Health

A falsely low progesterone result may lead to the consideration for additional progesterone supplementation. Progesterone results would be used in conjunction with the patient's medical history, clinical examination and other findings such as serial hCG measurements and ultrasound. Siemens is not recommending a review of previously generated patient results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If interference is suspected, follow your established internal laboratory procedures to investigate the interference.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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.

511 Benedict Avenue
Tarrytown, NY 10591

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FIELD CORRECTION EFFECTIVENESS CHECK

Low Discordant Progesterone results on a Subset of Patient Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, IMC19-07.A.OUS dated July 2019 regarding Low discordant Progesterone results on a Subset of Patient Samples. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

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

511 Benedict Avenue
Tarrytown, NY 10591