SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Follow up Urgent Field Safety Notice

Follow up IMC19-07.B.OUS

January 2020

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(s):

Table 1. IMMULITE Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
PRG	PRG	LKPW1	10381128	All in date kit lots
PRG	PRG	L2KPW2 L2KPW6	10381181 10381170	All in date kit lots

Reason for Communication

Siemens Healthcare Diagnostics Inc. issued Urgent Field Safety Notice IMC19-07.A.OUS in July 2019 to inform you of a potential for low discordant progesterone results on some patient samples.

As a follow up to IMC19-07.A.OUS, this communication expands on the actions to be taken at the laboratory level. Because the specific interference is still unknown and may not be readily identifiable Siemens recommends an option for a short-term approach in the “Actions for Customer” section to manage the potential interference.

Siemens understands the urgency of this situation and is actively working to determine the root cause.

Risk to Health

Progesterone measurements are used in a variety of endocrine clinical scenarios, including fertility assessment, as an aid in diagnosis and treatment. The risk exists that an undetected falsely low progesterone result may lead to inappropriate treatment decisions, such as administration of progesterone supplementation. Progesterone results would be used in conjunction with the patient’s medical history, clinical examination and other findings including but not limited to serial

hCG measurements, FSH, LH and ultrasound. Siemens is not recommending a review of previously generated patient results.

Actions to be Taken by the Customer

Note: Interference will not be detected by quality control and the presence of the interference may not be readily identifiable.

- Follow your established internal procedures to determine if additional testing is needed to identify samples with suspected interference and to determine if the patient sample result is accurate.
- A potential approach to identify interference is to dilute the sample.
- In-house studies have shown that a 1:5 dilution of the sample is effective in diluting out the potential interferant.
- Please note that for samples with an undiluted result of ≤ 1 ng/mL, greater variability could potentially be observed after dilution due to assay precision in this region.

Instructions

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Please contact your local Siemens representative with any questions or concerns.
- 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.

511 Benedict Avenue
Tarrytown, NY 10591

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 Follow-up IMC19-07.B.OUS dated January 2020 regarding Low Discordant Progesterone Results on some 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(s):

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to **CruinnFSNgroup@cruinn.ie**

Or to fax this completed form to the Cruinn Customer Care Center at **01-6297401.**

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

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