SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

IMC20-01.A.OUS

February 2020

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

High Discordant Estradiol Results on Some 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
Estradiol	E2	LKE21	10381132	All in date kit lots
Estradiol	E2	L2KE22 L2KE26	10381178 10381177	All in date kit lots

Reason for Communication

The purpose of this communication is to inform you of high discordant Estradiol results for some patient samples with the products indicated in Table 1.

Siemens Healthineers has determined kit lots 501 and above released in July 2018 for the IMMULITE systems are potentially affected.

Siemens Healthineers investigation indicates that some patient samples could potentially contain an unidentified interferent which is causing an increase in estradiol concentration in the IMMULITE Estradiol assay.

The majority of complaints received by Siemens Healthineers are from the United States. Based on available data the issue has been observed only with customer returned patient samples.

Quality control materials will not detect this issue.

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

Risk to Health

While this issue potentially affects all patient populations, worst case a falsely elevated estradiol level could lead a clinician to misinterpret a patient as pre-menopausal when truly post-menopausal. This may lead to delayed initiation of a potentially beneficial drug and/or

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administration of an unnecessary drug in the treatment for hormone receptor positive advanced or metastatic breast cancer.

Siemens is not recommending a review of previously generated results, except if the affected estradiol lots were used to assess the menopausal status of a female while determining therapy for hormone receptor positive advanced or metastatic breast cancer. If a patient in that population is currently undergoing a treatment based on an estradiol result above the post-menopausal reference limit (30 pg/mL for untreated patient), reassessing the menopausal status of the patient using an alternate estradiol assay should be considered.

Supply Disruption
Siemens Healthineers has currently suspended shipment of the IMMULITE Systems Estradiol assay and is diligently working towards restoring supply as soon as possible.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director, and consider if a retrospective review for your patients is appropriate

- If a patient sample will be used to assess menopausal status while determining therapy for hormone receptor positive advanced or metastatic breast cancer, please test the sample using an alternate methodology.
    - Please contact your local Siemens representative to discuss alternative Siemens Healthineers solutions.
- You may continue to use the IMMULITE systems Estradiol kits and report results on other patient populations than those listed in the bullet above.
- If a discordant high result for Estradiol is suspected, follow your established internal procedures to investigate the issue.
- 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.

Question and Answer

Question: How can I communicate this issue to healthcare providers?
Answer: Siemens Healthineers suggests the following wording:

Siemens Healthineers 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 have been complaints primarily from the US indicating discordant high Estradiol results on some patient samples.

Please consider reassessing the menopausal status in cases where all of the following events have occurred:

- Estradiol testing was performed on your patient during the dates listed above, and
- the result was used to assess the menopausal status of a female while determining therapy for hormone receptor positive advanced or metastatic breast cancer, and
- the patient is currently undergoing a treatment based on an estradiol result above the post-menopausal reference limit *[insert your institution's post-menopausal female reference range]*.

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FIELD CORRECTION EFFECTIVENESS CHECK

High Discordant Estradiol results on some patient samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, IMC20-01.A.OUS dated February 2020 regarding High Discordant Estradiol 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 XXXX@XXXX

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

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

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