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**Urgent Field Safety Notice:**

IMMULITE<sup>®</sup>  
 IMMULITE<sup>®</sup> 1000  
 IMMULITE<sup>®</sup> 2000  
 IMMULITE<sup>®</sup> 2000 XPi

**High Discordant Estradiol Results on Some Patient Samples**

Dear Sirs,

Our records indicate that you have received High Discordant Estradiol.

**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 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.

Letter of February 14, 2020  
to



We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

A handwritten signature in black ink, appearing to read "Franz Schwarz".

i.V. Dipl. Ing. Franz Schwarz  
Quality Management CEE

A handwritten signature in blue ink, appearing to read "Gernot Osterer".

i.A. Ing. Gernot Osterer  
Product Manager Austria & SEE