Urgent Field Safety Notice

AIMC 22-03.A.OUS

March 2022

Atellica® Solution
ADVIA Centaur® CP
ADVIA Centaur® XP
ADVIA Centaur® XPT

Enhanced Estradiol (eE2) – Falsely Elevated Results Observed with Plasma Specimens

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

Table 1. Atellica® Solution and ADVIA Centaur® Systems Affected Product(s)

Assay	Siemens Material Number (SMN)	Lot Number
Atellica IM Enhanced Estradiol (eE2) 100T	10995561	All Lots
Atellica IM Enhanced Estradiol (eE2) 500T	10995562	All Lots
ADVIA Centaur Enhanced Estradiol (eE2) 100T	10490889	All Lots
ADVIA Centaur Enhanced Estradiol (eE2) 500T	10491445	All Lots

Reason for Correction

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 customer observations of falsely elevated results when using plasma specimens across the entire Analytical Measuring Range (AMR) with the Atellica IM Enhanced Estradiol (eE2) assay. Results demonstrate that plasma specimens are not meeting claims as defined in the Instructions for Use (IFU). Limited data is available at this time as the investigation for this issue is on-going.

In the interim, Siemens requires that customers discontinue use of plasma tubes for specimen collection and testing with the Atellica IM eE2 and ADVIA Centaur eE2 assays until further notice.

Customers can continue to use the Atellica IM eE2 and ADVIA Centaur eE2 assays for testing serum specimens.

333 Coney Street
East Walpole, MA 02032

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 in cases where plasma samples were used to assess the menopausal status of a female for the purpose of determining therapy for hormone receptor positive advanced or metastatic breast cancer. If a patient in this population is currently undergoing a therapeutic treatment based on a plasma estradiol result above the post-menopausal reference limit (32.2 pg/mL or 118.2 pmol/L) for untreated patient), then a reassessment of the patient's menopausal status using a serum sample should be considered. Based on the maximum bias observed due to this issue, only patients with plasma estradiol values between 32.2 pg/mL (118.2 pmol/L) and 100.0 pg/mL (367.0 pmol/L) are recommended for reassessment with a serum sample. When serial monitoring has occurred in this clinical context, only the most recent plasma estradiol result needs to be considered.

Actions to be Taken by the Customer

- Customers must discontinue use of plasma specimens for testing with the Atellica IM and ADVIA Centaur eE2 assays until further notice.
- Customers may continue to use the Atellica IM eE2 and ADVIA Centaur eE2 assays with serum specimens.
- Please review this letter with your Medical Director.
- 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.

Atellica Solution and ADVIA Centaur Systems are trademarks of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Enhanced Estradiol (eE2) – Falsely Elevated Results Observed with Plasma Specimens

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice AIMC 22-03.A.OUS dated March 2022 regarding Enhanced Estradiol (eE2) – Falsely Elevated Results Observed with Plasma Specimens. Please read the question below and indicate the appropriate answer.

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

1. I have read and understood the Urgent Field Safety Notice 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 CruinnFSNGroup@cruinn.ie.

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

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

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