# Urgent Field Safety Notice

**AIMC 23-08.A-2.OUS**

**August 2023**

**ADVIA Centaur® XP**
**ADVIA Centaur® XPT**
**ADVIA Centaur® CP**

## Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Detection Capability

Our records indicate that your facility has received the following product:

**Table 1. ADVIA Centaur® Systems Affected Product(s)**

| Assay | Siemens Material Number (SMN) | Unique Device Identification (UDI) | Lot Number | Expiration Date (YYYY-MM-DD) | Manufacturing Date (YYYY-MM-DD) |
|---|---|---|---|---|---|
| ADVIA Centaur FBHCG | 10994996 | 00630414010410522120352023092 9 | 52212035 | 2023-09-29 | 2022-10-11 |
| ADVIA Centaur FBHCG | 10994996 | 00630414010410542650362024041 9 | 54265036 | 2024-04-19 | 2023-05-10 |

## 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 through internal investigation that the Free Beta Human Chorionic Gonadotropin (FBHCG) assay does not meet the Limit of Quantitation (LOQ), Limit of Blank (LoB), and Limit of Detection (LoD) as stated in the Instructions for Use (IFU) for the ADVIA Centaur Systems.

Siemens has defined an interim LOQ for the FBHCG assays for customers to utilize for the lots listed in Table 1 and future lots. Furthermore, future lots will be aligned to these interim values. Refer to Table 2 for the interim LOQ values.

Since the LoB and LoD fall below the assay measuring interval as defined by the LOQ, the establishment of an interim LoB and LoD was not conducted nor indicated.

**Table 2: FBHCG Current IFU and Interim LOQ (IU/L (ng/mL))**

| Platform | Current IFU LOQ | Interim LOQ |
|---|---|---|
| ADVIA Centaur XP | 0.28 | 1.24 |
| ADVIA Centaur XPT | 0.28 | 1.24 |
| ADVIA Centaur CP | 0.37 | 1.09 |

**ADVIA® Centaur Systems Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Claims for Detection Capability**

Siemens Healthcare Diagnostics is currently investigating the root cause of the issue.

## Risk to Health

No risk to health is expected as a result of this issue. While the lowest measured value will be increased from the IFU, the revised interim lower limit of quantitation remains well below values observed in pregnant individuals.

## Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Create a linearity range utilizing the interim LOQ values provided in Table 2 with instructions available in the respective ADVIA Centaur Systems Operator's Guide and/or Online Help.
- All ADVIA Centaur XP, ADVIA Centaur XPT and ADVIA Centaur CP FBHCG assay kit lots can continue to be utilized with the interim LOQ until further notice. Results below the newly defined linearity range are flagged as 'Below Linearity' and may be reported as less than the interim LOQ.
- 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.

ADVIA Centaur® is a trademark of Siemens Healthcare Diagnostics Inc.

## ADVIA® Centaur Systems Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Claims for Detection Capability

### FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA® Centaur Systems Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Claims for Detection Capability

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice AIMC 23-08.A-2.OUS dated August 2023 regarding ADVIA® Centaur Systems Free Beta Human Chorionic Gonadotropin (FBHCG) Not Meeting Claims for Detection Capability. 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.

| | | |
|---|---|---|
| 1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. | Yes ☐ | No ☐ |
| 2. I have followed the instructions to create a linearity range utilizing the interim LOQ values provided in Table 2 and will report results below the linearity range as less than the interim LoQ per the Actions to be Taken by the Customer section of this communication. | 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 Healthineers technical support representative.