SIEMENS Healthineers

Resolution
Urgent Field Safety Notice

AIMC 23-07.B.OUS

February 2024

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

Atellica IM and ADVIA Centaur Systems Urine Cortisol Negative Bias

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

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

Product	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot #	Expiration Date (YYYY-MM-DD)	Date of Manufacture (YYYY-MM-DD)
Atellica IM Cortisol 50T	10995538	(01)00630414602950(10)42320361(17)20250410	42320361 and higher	2025-04-10	2024-01-10
Atellica IM Cortisol 250T	10995537	(01)00630414602950(10)42319361(17)20250410	42319361 and higher	2025-04-10	2024-01-10
ADVIA Centaur Cortisol 50T	10994924	(01)00630414602950(10)38133361(17)20250410 (01)00630414602950(10)38134361(17)20250410	38133361, 38134361 and higher	2025-04-10	2024-01-10
ADVIA Centaur Cortisol 250T	10994926	(01)00630414602950(10)38135361(17)20250410	38135361 and higher	2025-04-10	2024-01-10

Reason for Correction

Siemens Healthcare Diagnostics Inc. is communicating the resolution to Urgent Field Safety Notice AIMC 23-07.A.OUS regarding the negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.

Siemens has implemented an improvement to a raw material specification that restores assay performance with urine samples. Customers can begin to use urine patient samples and urine cortisol QC with the Atellica IM and ADVIA Centaur Systems Cortisol assay with kit lot numbers listed in Table 1.

Serum and plasma samples *remain unaffected*, and customers can continue to use the Cortisol assay with these sample types.

333 Coney Street
East Walpole, Massachusetts 02032

Risk to Health

Worst case, there is a potential for erroneously depressed urine Cortisol patient results, which may lead to a delayed differential diagnosis of hypercortisolism, such as Cushing Syndrome. Mitigations include correlation of results to patient's clinical signs and symptoms, additional laboratory and repeat testing findings.

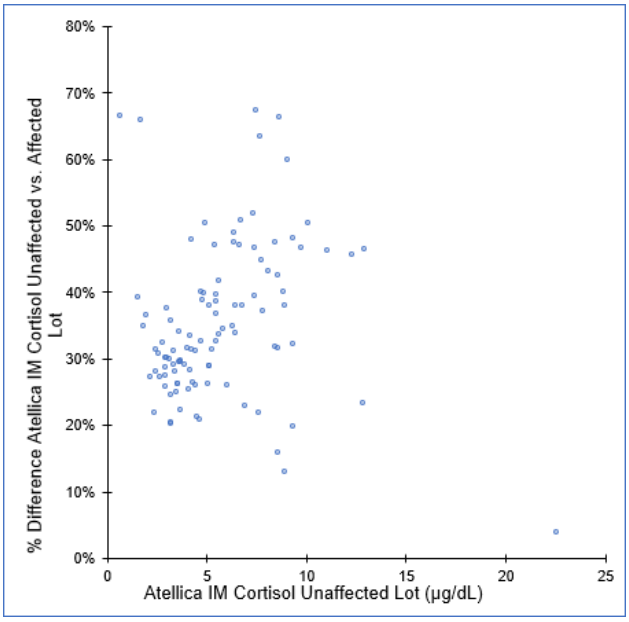
Actions to be Taken by the Customer

- Follow the instructions for urine patient samples and urine cortisol QC as stated above.
- If using product(s) listed in original Field Action AIMC 23-07.A.OUS (kit lots ending in 360 and below), continue following the guidance stated in that Field Action letter.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Additional Information

One-hundred-three (103) urine patient samples spanning the Assay Measuring Range were evaluated on both an unaffected reagent lot and an affected reagent lot. Figure 1 shows the "fixed" observed % differences (bias). This data is representative of all in-date Atellica IM lots from kit lots ending in '361' and higher.

Figure 1: Atellica IM Cortisol Unaffected versus Affected Lot % Difference Plot



New Bio-Rad QC material targets and ranges for use with Atellica IM and ADVIA Centaur Systems Cortisol kit lots ending in '361' and above will be added to the Bio-Rad website (http://myeinserts.qcnet.com/) when available.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

333 Coney Street
East Walpole, Massachusetts 02032

FIELD CORRECTION EFFECTIVENESS CHECK

Resolution: Atellica IM and ADVIA Centaur Systems Urine Cortisol Negative Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) AIMC 23-07.B.OUS dated February 2024 regarding Resolution: Atellica IM and ADVIA Centaur Systems Urine Cortisol Negative Bias. Please read the 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 UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

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 016297401.

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

333 Coney Street
East Walpole, Massachusetts 02032