

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

Atellica IM and ADVIA Centaur Erythropoietin (EPO) Negative Bias versus WHO Standardization

Reason for Correction

Dear Valued Customer, this communication is to inform you of an issue with the product indicated in Table 1 below and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has confirmed an average negative bias of -35% compared to the 3rd World Health Organization (WHO) International Standard (NIBSC code: 11/170) that is proportional across the assay measuring interval. The reference interval as claimed in the Instructions for Use (IFU) is not achieved with lots listed in Table 1.

There are no unaffected, in date, EPO reagent lots available. Siemens Healthineers is working to restore the Atellica IM and ADVIA Centaur EPO assay as quickly as possible.

Table 1. Atellica IM and ADVIA Centaur Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Atellica IM Erythropoietin (EPO) Assay (100 Test)	10733006	(01)00630414245775(11)20230209(10)53982039(17)20240205	53982039	2023-02-09	2024-02-05
		(01)00630414245775(11)20230831(10)55439041(17)20240820	55439041	2023-08-31	2024-08-20
ADVIA Centaur Erythropoietin (EPO) Assay (100 Test)	10995096	(01)00630414010380(11)20230208(10)53984040(17)20240205	53984040	2023-02-08	2024-02-05
		(01)00630414010380(11)20230831(10)55443042(17)20240820	55443042	2023-08-31	2024-08-20

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Risk to Health

There is a potential for erroneously depressed EPO patient results. This may affect interpretation of EPO results used to aid in the diagnosis of anemias and polycythemias. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

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.
- Discontinue use of and discard the kit lots listed in Table 1.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- For continued EPO patient testing in your laboratory during this time, please contact your Siemens representative to discuss alternative Siemens Healthineers solutions.
- 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.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) AIMC 24-04.A.OUS dated January 2024 regarding Atellica IM and ADVIA Centaur Erythropoietin (EPO) Negative Bias versus WHO Standardization. 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 UFSN instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory.

Product Description, SMN and Kit Lot	Quantity of Affected Product in inventory Discarded
Atellica IM EPO Assay (100 Test) SMN: 10733006 Kit Lot 53982039	
Atellica IM EPO Assay (100 Test) SMN: 10733006 Kit Lot 55439041	
ADVIA Centaur EPO Assay (100 Test) SMN: 10995096 Kit Lot 53984040	
ADVIA Centaur EPO Assay (100 Test) SMN: 10995096 Kit Lot 55443042	

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 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.