

Follow-up Urgent Field Safety Notice

AIMC 24-04.B.OUS

Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System
ADVIA Centaur CP System

Title	Resolution: Atellica IM and ADVIA Centaur Erythropoietin (EPO) Negative Bias versus WHO Standardization
Date Issued	Oct-2024
Issue Description	<p>Siemens Healthineers is communicating the resolution to Urgent Field Safety Notice (UFSN) AIMC 24-04.A.OUS (Atellica IM and ADVIA Centaur Erythropoietin (EPO) Negative Bias versus WHO Standardization; released on Jan-2024) regarding the negative bias as compared to the 3rd World Health Organization (WHO) International Standard (NIBSC code: 11/170).</p> <p>Siemens Healthineers has restored alignment to the WHO Standard and verified the reference interval as claimed in the Instructions for Use (IFU) starting with the products listed in the table below.</p> <p>Customers using Atellica IM and ADVIA Centaur EPO WHO realigned assay must ensure use of WHO realigned Quality Control and Master Curve Material products as specified in the "Appendix" Table 1.</p> <p>See "Appendix" for Additional Data in Tables 2-5.</p>

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number
	Atellica IM Erythropoietin (EPO) Assay (100 Test)	EPO	10733006 / 00630414245775	Kit lot numbers ending in 046 and above
	ADVIA Centaur Erythropoietin (EPO) Assay (100 Test)	EPO	10995096 / 00630414010380	Kit lot numbers ending in 045 and above

Customer Actions	<ul style="list-style-type: none">• Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.• Perform the instructions provided below:<ul style="list-style-type: none">○ Users may evaluate and implement the restored Atellica IM and ADVIA Centaur EPO Assay kit lots.○ Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.○ Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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Resolution Atellica IM and ADVIA Centaur EPO kit lots listed in the table above incorporate the resolution to this issue.

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.

Appendix

Table 1. Atellica IM and ADVIA Centaur EPO (restored) Mandatory Lot Combinations

Component	Lot Combinations
Atellica IM EPO Assay 100 Test Kit (kit lots ending in)	046 and above
Atellica IM EPO Quality Control (QC) lots	0113451, 0113452, 0113453 and above
ADVIA Centaur EPO Assay 100 Test Kit (kit lots ending in)	045 and above
ADVIA Centaur EPO Quality Control (QC) lots	0113451, 0113452, 0113453 and above

Table 2. WHO International Standard (NIBSC code: 11/170) Recovery with ADVIA Centaur EPO kit lot ending in 045 (restored) on the ADVIA Centaur XP system*.

WHO Standard (11/170) Level	Recovery Target (mIU/mL)	Observed Concentration (mIU/mL)	% Recovery
01	0.00	0.00	N/A
02	5.26	5.26	100.0
03	10.52	10.73	102.0
04	105.23	108.28	102.9
05	210.46	221.69	105.3
06	315.69	326.20	103.3
07	420.92	427.27	101.5
08	526.14	536.04	101.9
09	631.37	639.06	101.2
10	736.60	733.18	99.5
11	800.00	841.83	105.2

N/A indicates the % recovery could not be calculated.

*These data are representative of Atellica IM, ADVIA Centaur XPT, and ADVIA Centaur CP performance.

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Siemens Healthcare Diagnostics Inc.
333 Coney Street
Walpole, Massachusetts 02032

Table 3. Sample Pool Results with Atellica IM EPO Kit Lots ending in 041 (affected) and 046 (restored) on the Atellica IM analyzer.

Sample Pools	EPO Kit Lots ending in 041 Concentration (mIU/mL)	EPO Kit Lots ending in 046 Concentration (mIU/mL)	% Bias
Sample Pool 1	<0.98	1.31	N/A
Sample Pool 2	7.96	10.2	28.1%
Sample Pool 3	25.0	29.6	18.4%
Sample Pool 4	390	477	22.3%
Average Bias			22.9%

N/A indicates the % bias could not be calculated.

Table 4. Sample Pool Results with ADVIA Centaur EPO Kit Lots ending in 042 (affected) and 045 (restored) on the ADVIA Centaur XP system*.

Sample Pools	EPO Kit Lots ending in 042 Concentration (mIU/mL)	EPO Kit Lots ending in 045 Concentration (mIU/mL)	% Bias
Sample Pool 1	<0.98	<0.98	N/A
Sample Pool 2	8.24	10.1	22.6%
Sample Pool 3	27.5	30.3	10.2%
Sample Pool 4	418	491	17.5%
Average Bias			16.7%

N/A indicates the % bias could not be calculated.

*These data are representative of ADVIA Centaur XPT performance.

Table 5. Sample Pool Results with ADVIA Centaur EPO Kit Lots ending in 042 (affected) and 045 (restored) on the ADVIA Centaur CP system.

Sample Pools	EPO Kit Lots ending in 042 Concentration (mIU/mL)	EPO Kit Lots ending in 045 Concentration (mIU/mL)	% Bias
Sample Pool 1	0.99	1.87	88.9%
Sample Pool 2	8.42	10.9	29.5%
Sample Pool 3	27.0	30.6	13.3%
Sample Pool 4	394	465	18.0%
Average Bias			37.4%

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice AIMC 24-04.B.OUS dated Oct-2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1.

Have you read and understood the instructions provided in this letter.

Yes ☐

No ☐
2.

Were affected Site Personnel notified.

Yes ☐

No ☐
3.

Was a copy of the letter retained and posted with the current product labeling.

Yes ☐

No ☐

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	Zip Code:
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**.

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.