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Urgent Field Safety Notice:

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

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

To whom it may concern,

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

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
Date: Jan 29, 2024 16:48 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
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Signature: *Electronically signed by: Carina Marie Viehboeck*
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Date: Jan 29, 2024 16:51 GMT+1

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