Urgent Field Safety Notice

PHC25-03.A.OUS

BCS XP System, CA-600 series, CS-2500 System, CS-5100 System, CN-3000 System, CN-6000 System

Title INNOVANCE VWF Ac – Elevated control and patient sample results

Date Issued June 2025

Products

Assay	Siemens Material Number / Unique Device Identification	Lot Number
INNOVANCE VWF Ac	10487040 / 00842768028014	All lots within shelf-life.
	10873906 / 00630414639468	

Issue Description

Siemens Healthineers has confirmed through the investigation of customer complaints that quality control and patient sample results for INNOVANCE VWF Ac might be falsely elevated, independent of the system and reagent lot used.

An increased number of complaints for the test INNOVANCE VWF Ac were received, where customers complained of quality control recovery issues for Control Plasma P (CPP). Results were found above the permitted range according to Table of Assigned Values.

There is a potential of elevated INNOVANCE VWF Ac patient results where quality control is within the permitted range.

New assigned values for INNOVANCE VWF Ac for Standard Human Plasma (SHP) lots within shelf-life are provided within the table below. For upcoming SHP lots starting with lot 563137, the updated value to be used will be provided within the Table of Analytical Values contained in the package of the corresponding SHP lot.

Impact to Results

Internal investigation confirmed falsely elevated quality control and patient VWF activity results may occur. In some cases when control results are within the permitted range, when INNOVANCE VWF Ac is used for a patient sample a falsely elevated value may occur. A bias of ≥+20 relative % above the true value was observed at the medical decision point of 50% of norm (range 23.1-30.9% relative, at true result of 40.6-53.8% of norm). Results of this assay should be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings such as activated partial thromboplastin time (APTT), platelet function analysis (PFA), VWF Ag, VWF Ac/Ag Ratio, Factor VIII:C and multimer analysis, as appropriate for a specific clinical situation.

Customer Actions

Please perform the instructions provided below:

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- 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.
- The table below provides new INNOVANCE VWF Ac target values for SHP lots within shelf-life. Moving forward, please use these when running the assay.

Standard Human Plasma new target values for INNOVANCE VWF Ac Table of Analytical Values

Standard Human Plasma Lot	New Target Value
563121	87%
563122	95%
563123	96%
563124	96%
563125	102%
563126	94%
563127	92%
563128	93%
563129	92%
563130	97%
563131	94%
563132	99%
563133	92%
563136	93%

Resolution

The above target values for Standard Human Plasma will ensure the comparison to WHO standard for control recovery and patient sample results. For upcoming SHP lots starting with lot 563137, the updated value to be used will be provided within the Table of Analytical Values contained in the package of the corresponding SHP lot.

Single Registration Number (SRN)

DE-MF-000005039

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,

This letter was created electronically and is valid without signature.

i.V. Nils Neumann
Director
Quality Systems & Compliance

i.V. Thomas Scholz
Marketing Manager
Global Marketing

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Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
D – 35041 Marburg, Germany

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice PHC25-03.A.OUS dated June 2025. 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** [for the OUS letter the information will be filled in by the region].

Or to fax this completed form to the Customer Care Center at **XXXXXX** [for the OUS letter the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending].

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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