

Urgent Field Safety Notice

HC25-01.A.OUS

ADVIA 120/2120/2120i Hematology Systems

Title	Potential Low Bias for Patient Platelet Values and High Control Values for Platelets
Date Issued	June-2025

Products	Calibrator / Control Products	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
	SETpoint Calibrator	10312285 / 00630414224343	SP251033	24-Feb-2025	23-Apr-2025
	SETpoint Calibrator	10312285 / 00630414224343	SP251043	24-Mar-2025	21-May-2025
	TESTpoint Control (ABN1)	10330063 / 00630414473406	TP251035	24-Feb-2025	22-Jun-2025
	TESTpoint Control (ABN1)	10330063 / 00630414473406	TP251045	24-Mar-2025	20-Jul-2025
	TESTpoint Control (Normal)	10316217 / 00630414473390	TP252035	24-Feb-2025	22-Jun-2025
	TESTpoint Control (Normal)	10316217 / 00630414473390	TP252045	24-Mar-2025	20-Jul-2025
	TESTpoint Control (ABN2)	10318905 / 00630414473413	TP253035	24-Feb-2025	22-Jun-2025
	TESTpoint Control (ABN2)	10318905 / 00630414473413	TP253045	24-Mar-2025	20-Jul-2025

Issue Description

Siemens Healthineers has confirmed through the investigation of customer complaints that the products listed in the above table have incorrect platelet (PLT) value assignments for the ADVIA 120/2120/2120i Hematology Systems.

Erroneously decreased patient platelet results may be reported if calibrator SETpoint lot SP251033 or SP251043 are used, and controls are recovering within the expected assigned value ranges. Siemens' investigation revealed a deviation of up to -18% in patient results across the assay range when these calibrators are used.

Since calibrators and controls may be used in any combination, the table below provides the possible scenarios and impact to PLT results.

Siemens has confirmed that the behavior is limited to PLT results generated with the indicated SETpoint and TESTpoint lots.

Calibration performed with Calibrator Lots:	TESTPoint Hematology Controls:	Impact to PLT Results:
lots prior to SP251033 / SP251043	TP251031 (expired), TP252031 (expired), TP253031 (expired), TP251025 (expired), TP252025 (expired), TP253025 (expired), TP251035, TP252035, TP253035, TP251045, TP252045, TP253045	Control PLT high bias. No impact on patient results.
lots prior to SP251033 / SP251043	TP251055, TP252055, TP253055	Controls within expected range. No impact on patient results.
lots SP251033 / SP251043	TP251031 (expired), TP252031 (expired), TP253031 (expired), TP251025 (expired), TP252025 (expired), TP253025 (expired), TP251035, TP252035, TP253035, TP251045, TP252045, TP253045	Controls within expected range. PLT patient values exhibiting a low bias up to -18%.
lots SP251033 / SP251043	TP251055, TP252055, TP253055	Controls may recover within expected range. PLT patient values exhibiting a low bias up to -18%.
lot SP251053	TP251031 (expired), TP252031 (expired), TP253031 (expired), TP251025 (expired), TP252025 (expired), TP253025 (expired), TP251035, TP252035, TP253035, TP251045, TP252045, TP253045	Control PLT high bias. No impact on patient results.
lot SP251053	TP251055, TP252055, TP253055	Controls within expected range. No impact on patient results.

Impact to Results

Erroneously decreased patient platelet results may be reported if calibrator SETpoint lot SP251033 or SP251043 are used, and controls are recovering within the expected assigned value ranges. Siemens' investigation revealed a deviation of up to -18% in patient results across the assay range when these calibrators are used. Results of this test should always be

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interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

Please perform the instructions provided below:

- Customers that have calibrated using SETPOINT lot SP251033 or SP251043 should perform a calibration using a subsequent lot. Customers that have not calibrated using SETPOINT lot SP251033 or SP251043 do not need to perform additional calibration.
- Discontinue use of and discard the calibrator SETPOINT lots SP251033 and SP251043.
- If you experience this issue, you may request credit for SETpoint products in Field Correction Effectiveness Check Form. Please review your inventory of these products and assess your laboratory's needs.
- Controls with PLT results that are within the expected assigned value ranges may continue to be used.
- Customers who observe PLT results that are consistently out of the expected assigned value ranges for the TESTpoint lots TP251035, TP252035, TP253035, TP251045, TP252045, TP253045 should discontinue use of and discard them and you may request credit for TESTpoint products in Field Correction Effectiveness Check Form.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Single Registration Number (SRN)

US-MF-000016560

Resolution

The issue is resolved beginning with Calibrator SETpoint lot SP251053 and TESTpoint Control lots TP251055, TP252055 and TP253055.

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 FORM

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice HC25-01.A.OUS dated June-2025 and request product credit. 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. Did you calibrate with SETpoint Lots SP251033 and/or SP251043?	Yes ☐	No ☐
3. Have you observed PLT results that are consistently out of the expected assigned value ranges for the TESTpoint lots TP251035, TP252035, TP253035, TP251045, TP252045, TP253045?	Yes ☐	No ☐
4. Were affected Site Personnel notified?	Yes ☐	No ☐
5. Was a copy of the letter retained and posted with the current product labeling?	Yes ☐	No ☐

If the answer to the question #2 and/or #3 above is yes, please indicate the quantity of affected product in your laboratory and product credit requested.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product Discarded/ Credit Quantity Required
SETpoint 2x6.1ml / SMN 10312285/ Lot SP251033	
SETpoint 2x6.1ml / SMN 10312285/ Lot SP251043	
TESTpoint Control (ABN1)/ SMN 10330063/ Lot TP251035	
TESTpoint Control (Normal)/ SMN 10316217/ Lot TP252035	
TESTpoint Control (ABN2)/ SMN 10318905/ Lot TP253035	
TESTpoint Control (ABN1)/ SMN 10330063/ Lot TP251045	
TESTpoint Control (Normal)/ SMN 10316217/ Lot TP252045	
TESTpoint Control (ABN2)/ SMN 10318905/ Lot TP253045	
Name of person completing questionnaire:	
Title:	
Institution:	
Street:	
City:	State: Zip Code:
Phone:	Country:

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Please send a scanned copy of the completed form via email to **XXXX@XXXX**.

Or 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.

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