

Urgent Field Safety Notice

HC25-01.A.OUS

ADVIA 120/2120/2120i Hematology Systems

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

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|---|---|
| Customer Actions | <p>Please perform the instructions provided below:</p> <ul style="list-style-type: none">• 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 10 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 <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Did you calibrate with SETpoint Lots SP251033 and/or SP251043? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 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 <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. Were affected Site Personnel notified? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. Was a copy of the letter retained and posted with the current product labeling? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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: |

Please send a scanned copy of the completed form via email to fscreportingunit.my@siemens-healthineers.com.

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