# Urgent Field Safety Notice

**HSW21-01.A.OUS**

**March 2021**

**ADVIA® 2120 Hematology Systems**
**ADVIA® 2120i Hematology Systems**

## Potential Sample Identification (SID) Mismatch with14-Character Barcodes

Our records indicate that your facility may have received the following product:

**Table 1. ADVIA 2120/2120i Hematology Systems Affected Product(s)**

| Systems | Siemens Material Number (SMN) |
|---|---|
| ADVIA 2120 with Single Aspirate Autosampler | 10316162 |
| ADVIA 2120 with Dual Aspirate Autosampler | 10313419 |
| ADVIA 2120 REFURB SAA AUTOSAMPLER | 10374453 |
| ADVIA 2120 REFURB DAA AUTOSAMPLER | 10374454 |
| ADVIA 2120i with Single Aspirate Autosampler | 10488923 |
| ADVIA 2120i with Dual Aspirate Autosampler | 10285573 |
| ADVIA 2120i Refurb Single Aspirate | 11314044 |
| ADVIA 2120i Refurb Dual Aspirate | 11314045 |
| ADVIA 2120i (RoHS) with Dual Aspirate Autosampler | 11219529 |
| ADVIA 2120i (RoHS) with Single Aspirate Autosampler | 11219530 |

## Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has investigated a complaint and confirmed a potential that the ADVIA 2120/2120i Hematology System Software Versions 6.10 and 6.11 may misread patient sample 14-character Sample Identification (SID) barcodes which contain a non-alphanumeric




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character. This correction only applies to ADVIA 2120/2120i Hematology Systems running Software Version 6.10 or 6.11 and customers that have disabled the Barcode Encode Selectivity feature.

The issue only occurs if all the following conditions are met:

- Software Version 6.10/6.11 Software is installed with the new feature Barcode Encode Selectivity
- Barcode Encoded Selectivity is disabled
- The barcode must be equal to 14 characters (When the barcode is ≤ 13 characters the issue will not happen)
- The barcode includes a single non-alphanumeric character
- The barcode is read by the Autosampler barcode reader (Barcode reading by the manual barcode reader is not impacted)

This may cause a workorder mismatch or an SID that is not located. Due to the complexity of the scenario described above, a patient SID mismatch is remote but possible.

Siemens Healthcare Diagnostics is determining a permanent solution for this issue which will be communicated in a future update.

## Risk to Health

Worst case the potential exists, though remote, for misidentification of a patient sample due to this issue. This only would occur if the misread SID matches another valid, active SID and the ordered analytes are shared. Siemens is not recommending a laboratory look back of previously generated results due to the remote possibility of this event occurring and leading to a clinically significant difference in patient management.

## Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If you are using 14-character Sample Identification (SID) barcodes:
    - Ensure that the Barcode Encoding Selectivity feature is enabled.
        - Open the Sample Identification screen to determine if the checkbox to turn the Barcode Encoded Selectivity is on
    - If Barcode Encoding Selectivity is disabled, please perform the following steps to enable Barcode Encoding Selectivity:
        - Open the Sample Identification screen
        - Select the checkbox to turn the Barcode Encoded Selectivity on
- Whether or not you have the Barcode Encode Selectivity feature disabled, please complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.





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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.

## Additional Information

ADVIA is a trademark of Siemens Healthcare Diagnostics Inc.





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## FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA® 2120/2120i Hematology Systems – Potential Sample Identification (SID) Mismatch with14-Character Barcodes

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice HSW21-01 dated March 2021 regarding ADVIA® 2120/2120i Hematology Systems – Potential Sample Identification (SID) Mismatch with14-Character Barcodes. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

| | | | |
|---|---|---|---|
| 1. | I have read and understood the Urgent Field Safety Notice instructions provided in this letter. | Yes ☐ | No ☐ |
| 2. | Prior to receiving this letter, my laboratory had Software Version 6.10 or 6.11 and had the Barcode Encoded Selectivity feature disabled. | Yes ☐ | No ☐ |

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to cruinnfsngroup@cruinn.ie

Or to fax this completed form to the Customer Care Center at +353 1 629-7401

If you have any questions, contact your local Siemens Healthineers technical support representative.





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