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Urgent Field Safety Notice (HSW 21-01):

ADVIA® 2120 Hematology Systems
ADVIA® 2120i Hematology Systems

Potential Sample Identification (SID) Mismatch with14-Character Barcodes

Dear Sirs,

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

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Management: Joachim Bogner, Stefan Scheidler,
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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 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:

  o 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

  o 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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Letter of March 19, 2021
to

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

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

i.A. DI Gottfried Prechtl
Product Manager Austria & SEE