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Urgent Field Safety Notice:

ADVIA® 2120/2120i Hematology System with ADVIA Autoslide Slide Maker Stainer
Incorrect Stain Solution in ADVIA Autoslide Giemsa Stain Lot L61225

To whom it may concern,

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

Table 1. ADVIA 2120/2120i Hematology System with ADVIA Autoslide Slide Maker Stainer Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
ADVIA Autoslide Giemsa Stain	10718483	00630414594965L6122520231217	L61225	2023-12-17	2022-06-17

Reason for Correction

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

Siemens Healthcare Diagnostics Inc. has confirmed through investigation that the ADVIA Autoslide Giemsa Stain Lot L61225 was incorrectly filled with another stain solution. This results in pale staining of hematological slides.

Siemens Healthcare Diagnostics is currently investigating the root cause of this issue.

Risk to Health

Worst case, this issue may lead to an apparent delay in patient sample testing and reporting for various blood cells while the QC failure is investigated. The apparent delay would be mitigated by standard laboratory policies and procedures for back-up testing to enable uninterrupted generation of results to help guide patient care, as required by the clinical setting.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Discontinue use of and discard the kit lot listed in Table 1.
- Review your inventory of this product to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
Date: Feb 24, 2023 10:40 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
Quality Management CEECA

Signature: *Electronically signed by: Gottfried Prechtl*
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