SIEMENS

Urgent Field Safety Notice

10814117

August 2013

ADVIA® 2120/2120i, ADVIA® Autoslide

Erroneous Slide and Sample Identification Matching

Our records indicate that you have an ADVIA® 2120/2120i Hematology system (SMN 10361162 or SMN 10361798).

Reason for Correction

Siemens Healthcare Diagnostics is conducting a field corrective action for ADVIA 2120/2120i Hematology systems that may be connected to ADVIA® Autoslide systems (SMN 10286141 or SMN 10286142). Siemens has determined that if an autosampler rack jam error occurs during operation of an ADVIA 2120/2120i connected to an ADVIA Autoslide, it is possible that the next slide processed by the Autoslide could be labeled with the wrong sample identification information.

Risk to Health

The overall risk of patient impact is low. The mismatching of the compared results from the Autoslide and the ADVIA 2120/2120i are obvious to the operator and would lead to further investigation. A review of previously reported results is not warranted.

The contents of this bulletin should be discussed with the Laboratory Director.

Action to be Taken by Customers

NOTE: If you do not have an ADVIA Autoslide connected to your system, no action is required.

To avoid the possibility of mislabeling a slide when an ADVIA 2120/2120i Rack Jammed error occurs:

- Eject the sample rack.
- Troubleshoot and correct the reason for the Rack Jammed error.
- Rerun the sample rack.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

Please forward this notification to whomever you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support. Siemens is committed to providing continued solutions and communication to improve the user experience with our products.

Trademark Information

ADVIA is a trademark of Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Erroneous Slide and Sample Identification Matching

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated August 2013 regarding Erroneous Slide and Sample Identification Matching.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. Did you read and understand this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####.

