

Urgent Field Safety Notice

10819177, Rev. A

August 2014

ADVIA Centaur®
ADVIA Centaur® XP

Improper Manual Loading of Sample Racks

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

Table 1. ADVIA Centaur Systems Affected Products

Product	Siemens Material Number (SMN)
ADVIA Centaur Immunoassay System	10284980, 10286140, 10309524, 10309525, 10310210, 10313282, 10314322, 10316248, 10316372, 10316968, 10317060, 10317403, 10319111, 10319433, 10320929, 10321568, 10322149, 10322731, 10323204, 10325015, 10326217, 10327008, 10327379, 10328250, 10328647, 10329364, 10330873, 10331013, 10332617, 10334139, 10334759, 10337512, 10337526, 10339677, 10340551, 10340737, 10341051, 10341110, 10361010, 10361011, 10361012
ADVIA Centaur XP Immunoassay System	10285219, 10316507, 10317207, 10317284, 10319668, 10320757, 10323213, 10324519, 10327135, 10327836, 10328940, 10329339, 10336292, 10338631, 10364455, 10388696, 10471899

Reason for Correction

Siemens Healthcare Diagnostics is conducting a field correction for the ADVIA Centaur® and ADVIA Centaur® XP Immunoassay systems, regarding manually loaded sample racks that are improperly loaded or pushed too far on the sample entry queue during normal operation of the ADVIA Centaur and ADVIA Centaur XP Immunoassay systems.

Pushing the sample racks may cause misreads of Sample IDs (SID) if the sample rack loading instructions are not followed exactly as described in the ADVIA Centaur or ADVIA Centaur XP Operator's Guide. Refer to Figure 1 in the Actions to be Taken by the Customer section.

Risk to Health

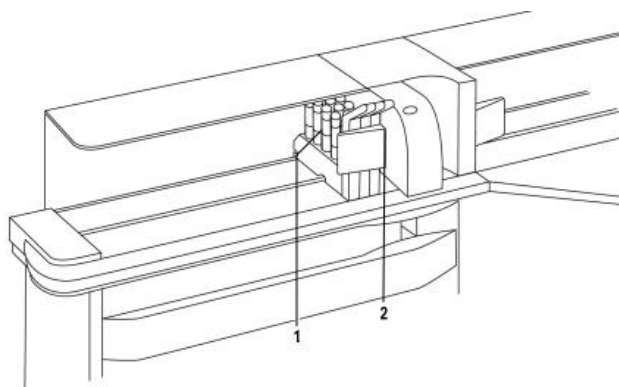
If a sample rack is manually pushed with a slight forward nudge to the entry position without placing it on the rack positioning guide, the barcoded tube SID can be assigned to different positions in the rack. This may lead to misreported results.

A review of previously reported results is not warranted due to the extremely low occurrence rate and the limited benefit in retesting original samples.

Siemens recommends discussing the content of this letter with your laboratory director.

Actions to be Taken by the Customer

Figure 1. Sample Entry and Inprocess Queues



When loading a sample rack, ensure the sample rack notch rests on the raised area of the sample entry queue (1) and the system automatically moves the rack to the loading position. This raised guide ensures the sample rack is positioned correctly and will accurately scan each barcode as it enters the inprocess queue (2). **Do not** push the sample racks into the system.

During the next service visit, service engineers will affix the following label onto the system to reinforce the proper loading technique of the sample rack:

Figure 2. Sample Rack Loading Label



In addition, please perform the following:

- Please review this letter with your Medical Director.

Improper Manual Loading of Sample Racks

- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens 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 Customer Care Center or your local Siemens technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Improper Manual Loading of Sample Racks

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819177, Rev. A dated August 2014 regarding Improper Manual Loading of Sample Racks. Please read the question and indicate the appropriate answer. Fax or email this completed form to Siemens Healthcare Diagnostics.

Ref: CI 14-06 [C/2826]

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Country:
Email:	Date:

It is important that your organisation takes the actions detailed in the FSN and reply immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the UFSN. Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the UFSN and the MHRA may need to issue a Medical Device Alert.

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