SIEMENS

Urgent Field Safety Notice

10819175, Rev. A

August 2014

ADVIA Centaur®
ADVIA Centaur® XP

Incorrect Patient Demographic Information

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

Table 1. ADVIA Centaur Systems Affected Product

Production	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 has identified an issue with patient demographic information sent to the LIS from the ADVIA Centaur®/ADVIA Centaur® XP Immunoassay systems. Siemens has confirmed that under extremely rare circumstances patient demographic data from the previous order received from the LIS is merged with the next order.

This issue can occur when the LIS data buffer on the ADVIA Centaur system becomes full and a particular character is found in the last five locations in the LIS data buffer. In this case, the incorrect patient demographic information will be transmitted to the LIS and will be displayed on the ADVIA Centaur user interface and instrument generated printed reports.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

Risk to Health

Patient results are not impacted as the ADVIA Centaur/ADVIA Centaur XP Immunoassay systems use the Sample ID (SID) as the primary identifier for all results. There is no risk to health.

Actions to be Taken by the Customer

- If the instrument is interfaced to an LIS system that does not transmit patient demographics, no action is required.
- If the instrument is interfaced to an LIS system that transmits patient demographics with each order, perform the following:
    - Check the event log for the following message: “500 03 01 Unknown format message.” If the message is not present, no further action is required.
    - If the message is present, review patient demographic information for all work orders after the time of this event. If no orders have incorrect patient demographic information, no further action is required.
    - For any work orders that have incorrect patient demographic information, perform the following:
        - Identify if any specific ranges defined for age or sex apply to the order and ensure the necessary action is taken for this result.
        - Check for rejected results on the LIS. Some systems reject results sent with incorrect patient demographic information.
        - Check any result printouts from the instrument for the work order.
- **Complete and return the Field Correction Effectiveness Check attached to this letter within 14 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 Centre 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 Centre or your local Siemens technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Incorrect Patient Demographic Information

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819175, Rev. A dated August 2014 regarding Incorrect Patient Demographic Information. Please read the question and indicate the appropriate answer. Please return this form, completed, to the contact details shown below.

Ref: CI 14-07 [C/2837]

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐

Name of person completing questionnaire:	
Title:	Date:
Organisation:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Country:
Email:	Signed:

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

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