

Urgent Field Safety Notice

CC 15-23.A.OUS

August 2015

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® XPT

Confirmatory Results for ADVIA Centaur HBsAgII

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

Table 1. Affected Product(s)

Assay	Siemens Material Number (SMN)	Lot Number
HBsAgII	10492138	55825056, 56167056, 56244056

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified an error on the ADVIA Centaur Confirmatory Card that is included in ADVIA Centaur HBsAgII kit lots 55825056, 56167056 and 56244056. The error causes an interpretation of 'Invalid' and a flag of 'Conf N/A' when the HBsAgII Positive Control is tested with the HBsAgII Confirmatory (Conf) assay.

The issue is limited to ADVIA Centaur HBsAgII kit lots 55825056, 56167056 and 56244056.

These kits are not used on the ADVIA Centaur CP systems, therefore ADVIA Centaur CP systems are not affected.

Risk to Health

An "Invalid" result of the positive quality control material delays reporting of positive patient samples during confirmatory testing. The risk to health is negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT HBsAgII kit lots 55825056, 56167056 and 56244056 may be used to generate HBsAgII results, however, an alternate lot or alternate method must be used for reporting confirmed results, if confirmatory testing is required.
- Please review this letter with your Medical Director.

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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.

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the ADVIA Centaur XPT is not available in all countries.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Confirmatory Results for ADVIA Centaur HBsAgII

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 15-23.A.OUS, dated August 2015 regarding Confirmatory Results for ADVIA Centaur HBsAgII. Please read the question below and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.