

## Urgent Field Safety Notice

10819676, Rev. A

September 2014

ADVIA Centaur®  
 ADVIA Centaur® XP  
 ADVIA Centaur® CP

### HBc Total Assay Lot 100064 Imprecision and Positive Bias

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

**Table 1. ADVIA Centaur Affected Product(s)**

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lot Number	Expiration Date
HBc Total	HBcT	07566733	10309508	36217064 36281064 36449064 37406064 38177064	February 10, 2015

### Reason for Recall

Siemens Healthcare Diagnostics has confirmed increased assay imprecision and a positive bias (increase in index values) in the low end of the assay with the ADVIA Centaur® Systems HBc Total (HBcT), kit lots listed in Table 1. The increased imprecision and positive bias is observed with patient samples and negative controls and can result in an increase in false reactive results.

Preliminary internal investigations indicate a raw material used in the manufacture of lot 100064 is contributing to the imprecision. At this time, no other reagent lots are impacted. Siemens continues to investigate the cause of the imprecision and the increase in index values.

Siemens recommends transitioning to the ADVIA Centaur Systems HBcT assay, reagent lots 100066 or above.

### Risk to Health

The increase in the number of false reactive results may cause additional testing but should not result in the reporting of an increased number of false positive results to physicians. The Instructions For Use (IFU) recommends that clinical interpretation be made in conjunction with other HBV serological markers.

### Actions to be Taken by the Customer

- Discontinue use of and discard the kit lots listed in Table 1.

- Please review this letter with your Medical Director.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens.
- Complete and return the Field Correction Effectiveness Check 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.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

HBc Total Assay Lot 100064 Imprecision and Positive Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819676, Rev. A dated September 2014 regarding HBc Total Assay Lot 100064 Imprecision and Positive Bias. Please read each question 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
  
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
07566733 / 10309508 / 100064		

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Phone: \_\_\_\_\_ Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_ Customer Ship To #: \_\_\_\_\_

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