

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.

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.