SIEMENS

Urgent Field Safety Notice

10815761 Rev. B

September 2013

ADVIA Centaur
ADVIA Centaur XP
ADVIA Centaur CP

HIV Ag/Ab Combo (CHIV) Assay Analytical Sensitivity

Our records indicate that you have or may have received the following product:

Table 1. Affected Material

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number (Expiration Date)
CHIV	06520528	10283020	15145033 (2013-11-08) 15227033 (2013-11-08) 15646033 (2013-11-08) 15811033 (2013-11-08) 16187033 (2013-11-08) 17066034 (2013-12-14) 17132034 (2013-12-14) 17381034 (2013-12-14) 17823034 (2013-12-14) 18442036 (2014-01-20) 18757036 (2014-01-20) 19288036 (2014-01-20) 19692036 (2014-01-20) 20235036 (2014-01-20) 22282037 (2014-03-01) 22294037 (2014-03-01) 22413037 (2014-03-01) 23300038 (2014-04-12) 23301038 (2014-04-12) 23482038 (2014-04-12) 24391039 (2014-05-18) 24396039 (2014-05-18) 24838039 (2014-05-18) 25244039 (2014-05-18)

Through post-market surveillance activities, Siemens has determined that not all distributed lots would meet the performance criteria as currently described in the Instructions for Use (IFU) with respect to analytical sensitivity (i.e. 1.15 IU/mL). We are, therefore, updating our labeling to better reflect the observed and potential range of assay performance with respect to this parameter (i.e. < 2.0 IU/mL).

Instructions for Use (IFU) for ADVIA Centaur®/ADVIA Centaur XP (Rev. G, 2013-02) and ADVIA Centaur CP (Rev. E, 2013-02) currently provide the following information regarding Analytical Sensitivity:

ADVIA Centaur/ADVIA Centaur XP

Analytical Sensitivity

To examine the analytical sensitivity of the ADVIA Centaur CHIV assay, the HIV-1 p24 Antigen, 1st International Reference Reagent, NIBSC code 90/636, was used to prepare a dilution series that was assayed using one lot of reagents. Linear regression was used to determine the concentration of the International Reference Reagent that corresponds to the ADVIA Centaur CHIV cutoff value (Index value = 1.00). The HIV-1 p24 antigen, 1st International Reference Reagent concentration at the assay cutoff is 1.15 IU/mL.

ADVIA Centaur CP

Analytical Sensitivity

To examine the analytical sensitivity of the ADVIA Centaur CHIV assay, the HIV-1 p24 Antigen, 1st International Reference Reagent, NIBSC code 90/636, was used to prepare a dilution series that was assayed using one lot of reagents. Linear regression was used to determine the concentration of the International Reference Reagent that corresponds to the ADVIA Centaur CHIV cutoff value (Index value = 1.00). The HIV-1 p24 antigen, 1st International Reference Reagent concentration at the assay cutoff is 0.96 IU/mL.

To better describe the analytical sensitivity performance of the assay, Siemens Healthcare Diagnostics is revising the Analytical Sensitivity statement in both IFUs to the following:

Analytical Sensitivity

The ADVIA Centaur CHIV Assay has an analytical sensitivity of ≤ 2.0 IU/mL. To examine the analytical sensitivity of the ADVIA Centaur CHIV assay, the HIV-1 p24**.** Antigen, 1st International Reference Reagent, NIBSC code 90/636, was used to prepare a dilution series that was assayed using one lot of reagents. Linear regression was used to determine the concentration of the International Reference Reagent that corresponds to the ADVIA Centaur CHIV cutoff value (Index value = 1.00). In this study the HIV-1 p24 Antigen, 1st International Reference Reagent concentration at the assay cutoff is 1.15 IU/mL.

Risk to Health

There is no health risk associated with this change as the ADVIA Centaur systems CHIV methods meet the IVDD Common Technical Requirement of ≤ 2.0 IU/mL for analytical sensitivity and the clinical utility of the method remains intact; no adverse clinical impact is expected. There is no need to review previously reported CHIV results.

Actions to be Taken by the Customer

- Until the IFU revisions are available, keep this letter with your laboratory records.
- Please forward this notification to anyone to whom you may have distributed these products.
- Please complete and return the attached Field Correction Effectiveness Check.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur, ADVIA Centaur XP, and ADVIA Centaur CP HIV Ag/Ab Combo (CHIV) Assay Analytical Sensitivity

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated September 2013 regarding ADVIA Centaur, ADVIA Centaur XP, and ADVIA Centaur CP HIV Ag/Ab Combo (CHIV) Assay Analytical Sensitivity (10815761 Rev. B). Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in the September 2013 letter. Yes ☐ No ☐
2. Did we effectively communicate all necessary information? Yes ☐ No ☐

Name of person completing questionnaire:

Title: Account Number:

Institution: Instrument Serial Number:

Street:

City: State:

Phone:

Customer Sold To #: Customer Ship To #:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####