

## **Urgent Field Safety Notice**

078D0843-01 2009-08

## ADVIA Centaur<sup>®</sup> ADVIA Centaur XP

## ADVIA Centaur V 4.0 and ADVIA Centaur XP V 6.0 System Software Missing Range Flags and No Reflex Testing after Restoring Definition Files; and Reflex for HBsAg is not Updated

Our records indicate that you are an ADVIA Centaur<sup>®</sup> or ADVIA Centaur XP system customer who may be using software V.4.0 (with or without SP1/SP2) or V.6.0 on your system and may have customer-defined user ranges.

Internal testing conducted by Siemens Healthcare Diagnostics has confirmed that due to a modification of a Test Definition table in these software versions, back-ups, including reference ranges (with or without reflex testing defined), do not restore properly into the modified table. The outcome is missing range-related flags and reflex testing not performed.

In addition, when new Test Definitions are installed, Siemens-defined reflex for HBsAg is not updated correctly to the Confirmatory test.

Siemens recommends that on an ADVIA Centaur system with software version 4.0 (with or without SP1/SP2) or an ADVIA Centaur XP system with V.6.0, the following actions should immediately be taken:

For customer-defined user ranges, edit all reference ranges or reflex testing as follows:

1. From the **Setup** menu, select **Test Definition Summary**.

The Test – Summary window opens.

- 2. Select the appropriate assay from the list.
- 3. Select the Ranges button.

The Test – Ranges window opens.

- 4. Select Edit.
- 5. Edit any one field associated with the defined assay reference range.
- 6. Select Save.

**NOTE**: You only have to edit one field, such as retyping a range name. You do not need to edit the reflex definition. When you select to save the change, the table is updated properly for all items associated with the definition.

## Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue Tarrytown, NY 10591

www.siemens.com/diagnostics

Page 1 of 2

© 2009 Siemens Healthcare Diagnostics Inc. All rights reserved.

For the Siemens-defined HBsAg assay, if you want the HBsAg assay to confirm positive results, verify that the reflex test for HBsAg is enabled as follows:

- At the workspace, select Setup > Test Definition Summary. The Test – Summary window opens.
- 2. Verify that Conf is defined as the reflex test for HBsAg as follows:
  - a. Select HBsAg in the list.
  - b. Select the Ranges button.
    The Test Ranges window opens.
  - c. Select the **Reflex Tests** button.

The Test – Reflex Tests window opens.

- d. Verify that **Conf** is displayed in the "Schedule If > 0.99" field.
- 3. If the **Conf** is not displayed in the "Schedule If > 0.99" field, go to the Test Ranges window and do the following:
  - a. Select the Edit button.
  - b. Select the **Reflex Tests** button.

The Test – Reflex Tests window opens.

- c. Select **Conf** in each of the 3 drop down lists.
- d. Select the **Continue** button.
- e. In the Test Ranges window select **Save**.

Patient results are not affected; therefore, no retesting is required.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

Please forward this notification to whomever you may have distributed this product.

We apologize for the inconvenience that this situation may have caused.

Thank you for your continuing support of Siemens Healthcare Diagnostics products.