

## Urgent Field Safety Notice

10819217, Rev. A

June 2014

### ADVIA Centaur® CP

#### BNP Master Curve Card Error for Reagent Lot 038172

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

Table 1. ADVIA Centaur CP Affected Product(s)

| Assay | Catalog Number          | Siemens Material Number (SMN) | Kit Lots Ending in | Expiration Date |
|-------|-------------------------|-------------------------------|--------------------|-----------------|
| BNP   | 02816138<br>(100 tests) | 10309044<br>(100 tests)       | 172                | 17 April 2015   |
|       | 02816634<br>(500 tests) | 10309045<br>(500 tests)       |                    |                 |

#### Reason for Correction

Siemens Healthcare Diagnostics has received complaints of failed calibrations on the ADVIA Centaur® CP system when using BNP kit lots ending in 172. Siemens has confirmed that the failed calibration is due to an error on the ADVIA Centaur CP master curve card. The master curve card error results in a low calibration deviation outside the specified calibration evaluation range when using kit lots ending in 172 on the ADVIA Centaur CP. An invalid calibration status will prevent BNP results from being generated.

Please note, the master curve card contained in kit lots ending in 172 for the ADVIA Centaur and ADVIA Centaur XP platforms is **not** impacted and there is no calibration issue when using BNP kit lots ending in 172 on those systems.

#### Risk to Health

Failed calibration may delay the time to result for BNP. If the calibration is successful, the results will be valid. There is no risk to health.

#### Actions to be Taken by the Customer

- If a successful calibration is achieved with BNP kit lots ending in 172 and quality control results are in range, you can continue to report patient results.
- If you are unable to obtain a successful calibration on the ADVIA Centaur CP with BNP kit lots ending in 172, please switch to an alternate lot of BNP.
- Please review this letter with your Medical Director.

- 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 has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Siemens Healthcare Diagnostics  
511 Benedict Ave.  
Tarrytown, NY 10591  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

BNP Master Curve Card Error for Reagent Lot 038172

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics. Urgent Field Safety Notice 10819217, Rev. A dated June 2014 regarding BNP Master Curve Card Error for Reagent Lot 038172. 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<br>Product Catalog #/SMN #/Lot # | Quantity of Affected Product in<br>inventory that has been<br>discarded | Replacement Quantity<br>Required |
|--|---|----------------------------------|
| BNP 100 tests, 10309044, lot 172                     |   |                                  |
| BNP 500 tests, 10309045, lot 172                     |   |                                  |

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

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

Institution: \_\_\_\_\_

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.