

## Urgent Field Safety Notice

10819793, Rev. A

October 2014

ADVIA Centaur®  
 ADVIA Centaur® XP  
 ADVIA Centaur® CP

### BNP ReadyPack Lot 038174 Labeling Error

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

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

Assay	Catalog Number	Siemens Material Number (SMN)	Kit Lots	Expiration Date
BNP	02816138 (100 tests)	10309044 (100 tests)	43305174 43278174	July 11, 2015
	02816634 (500 tests)	10309045 (500 tests)	43306174 43279174	

### Reason for Recall

Siemens Healthcare Diagnostics has confirmed that there may be an incorrect side label on a small percentage of the ADVIA Centaur® Systems BNP ReadyPacks from reagent lot 038174. Incorrectly labeled ReadyPacks are included within kit lots 43305174, 43278174, 43306174 and 43279174. The human-readable side label may incorrectly identify the ReadyPack as ADVIA Centaur Systems FT4 ReadyPack. The ReadyPack end label and the barcode end label correctly identify the ReadyPack as the ADVIA Centaur Systems BNP ReadyPack and the ReadyPack will scan correctly as BNP when loaded onto the ADVIA Centaur Systems. The kit boxes are correctly labeled as BNP. Other ADVIA Centaur BNP kit lots ending in 174 are not impacted.

The reagent in the ReadyPack has been verified as BNP reagent and will generate valid results when calibrating and running quality control or patient samples using the ADVIA Centaur Systems BNP ReadyPack kit lots listed in Table 1.

### Risk to Health

The ADVIA Centaur Systems will correctly identify the ReadyPack as BNP and appropriately generate BNP results. There is no risk to health.

### **Actions to be Taken by the Customer**

- Customers should examine their inventory of the kit lots listed in Table 1. Any ReadyPacks identified with the human-readable FT4 side labels should be discarded. Please contact your Siemens Customer Care Center or your local Siemens technical support representative for information on product replacement.
- Customers may continue to report patient results with correctly labeled ReadyPacks from the ADVIA Centaur BNP ReadyPack kit lots listed in Table 1.
- Please review this letter with your Medical Director.

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.