

## Urgent Field Safety Notice

CC 17-12.A.OUS

March, 2017

ADVIA Centaur®  
ADVIA Centaur® XP  
ADVIA Centaur® XPT  
ADVIA Centaur® CP

### ADVIA Centaur BR (CA 27.29) Assay Exclusion from Use with Multi-Diluent 1 Kit Lots Ending in 2577 and All Future Lots

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

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

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
ADVIA Centaur BR assay (50 tests)	BR	02419937 (116734)	10333349	All lots
ADVIA Centaur BR assay (250 tests)	BR	03896216 (116735)	10334837	All lots

### Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed that the ADVIA Centaur BR (CA 27.29) assay does not dilute linearly when used with Multi-Diluent 1 kit lots ending in 2577 and all future lots until further notice. When diluted, some samples over-recover the expected neat value by greater than 120%. The root cause of this issue is currently under investigation.

### Risk to Health

Dilution of samples with results greater than the analytical measuring range for the ADVIA Centaur BR (CA 27.29) assay may be important for serial measurements during treatment. Elevated results that are above the expected range will alert the physician to the need for follow up and continued serial monitoring. Results may be used as an adjunctive assessment but not in isolation to make decisions regarding therapy. Therefore, a look back of previous results is not recommended.

### Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue dilution of samples using the ADVIA Centaur systems BR (CA 27.29) with Multi-Diluent 1 kit lots ending in 2577 and future lots of Multi-Diluent 1 until further notice.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

***ADVIA Centaur BR (CA 27.29) Assay Exclusion from Use with Multi-Diluent 1 Kit Lots Ending in 2577 and All Future Lots***

---

- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

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.

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the ADVIA Centaur XPT is not available in all countries.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.