

Urgent Field Safety Notice

11219615, Rev. A

January 2015

ADVIA Centaur[®]
ADVIA Centaur[®] XP
ADVIA Centaur[®] CP
ADVIA Centaur[®] XPT

ADVIA Centaur Systems Progesterone Kit Lots Ending in 268

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lot Number	Expiration Date
ADVIA Centaur Progesterone	PRGE	02382928 (1-pack)	10310305	42564268 42621268 43834268	May 22, 2015
		01586287 (5-pack)	10315522	42565268 42624268 43538268	May 22, 2015
		02177364 (5-pack Ref)	10333111	42590268 43742268 44847268	May 22, 2015

Reason for Correction

Siemens Healthcare Diagnostics has confirmed a high bias on results greater than 30 ng/mL (95.4 nmol/L) when compared to the master curve when using the ADVIA Centaur[®] Progesterone kit lots listed in Table 1. The high bias may cause neat serum samples with results greater than 60 ng/mL (190.8 nmol/L) to recover within the assay range upon dilution (dilution factor applied). On the ADVIA Centaur Systems, for samples greater than 30 ng/mL (95.4 nmol/L), customers may observe an average dilution recovery between 48.3% and 105.0%.

Samples (both neat and diluted) with values below 30 ng/mL (95.4 nmol/L) do not demonstrate this bias.

This issue is specific to ADVIA Centaur Systems Progesterone kit lots ending in 268.

Risk to Health

There is no risk to health associated with positive bias of samples greater than 30 ng/mL (95.4 nmol/L). Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Customers may continue using ADVIA Centaur Systems Progesterone, kit lots ending in 268.
- To mitigate the patient bias observed with ADVIA Centaur Systems Progesterone kit lots ending in 268, samples greater than 30 ng/mL (95.4 nmol/L) must be diluted. No special action is required for samples with values below 30 ng/mL (95.4 nmol/L) or other kit lots. Refer to the ADVIA Centaur Operator's Guide for instructions to set the linearity check point of the assay to indicate that the sample should be diluted.
- Please continue to follow Urgent Field Safety Notice 10819674, Rev. A (*Information Regarding the ADVIA Centaur Systems Calibrator E*), dated September 2014.
- 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 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.

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur Systems Progesterone Kit Lots Ending in 268

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11219615, Rev. A dated January 2015 regarding ADVIA Centaur Systems Progesterone Kit Lots Ending in 268. Please read the 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.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

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.