SIEMENS

Urgent Field Safety Notice

10815970, Rev. A

July 2013

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® CP

Information Regarding the ADVIA Centaur Folate Assay

Our records indicate that you may have received the ADVIA Centaur Folate reagent kit lots listed below.

Table 1. ADVIA Centaur Folate ReadyPack® Lot 071218 Kit Lots

Description	REF Number	Kit Lot Number	Expiration Date
ADVIA Centaur Folate (100 tests)	SMN 10310308	22288218	17Feb2014
		22296218	
		22907218	
ADVIA Centaur Folate (500 tests)	SMN 10325366	22289218	
		22297218	
		22535218	
ADVIA Centaur Folate (500 tests)	SMN 10331250	22298218	
ADVIA Centaur Folate (2500 tests)	SMN 10340209	22299218	

Reason for the Correction

Siemens Healthcare Diagnostics is conducting a field corrective action of the ADVIA Centaur® Folate reagent lot number 071218 and kit lots listed in Table 1.

Siemens has confirmed that a portion of Folate ReadyPacks® in kit lots ending in 218 are exhibiting calibration failures and/or significant negative shifts in quality control (QC) and patient results.

If the calibration and QC on a ReadyPack are valid, results generated with this ReadyPack are not affected. However, due to the sporadic nature of the issue, successful calibration and QC on one ReadyPack may not reflect acceptable performance of other ReadyPacks in the lot. This issue is limited to the kits listed in Table 1.

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Risk to Health

Serum and erythrocyte Folate is used to detect potential deficiencies which can affect one-carbon transfer reactions. Deficiencies can potentially lead to increased Homocysteine accumulation and potentially anemia. Folate insufficiency is rare due to supplementation of flour and cereals. The negative bias could potentially lead to additional vitamin supplementation or dietary modification.

If a ReadyPack is impacted by this issue, all results from that pack are expected to be similarly negatively biased. The medical director should determine if repeat testing of patient samples that demonstrated results below the reference interval is appropriate. Retesting is not required for patient values that fall within or above the reference range.

Actions to be Taken by the Customer

- If you have an alternate lot of ADVIA Centaur Folate or an alternate method available in your laboratory, transition all folate testing to the alternate lot of ADVIA Centaur Folate method or alternate method.
- If you only have lots of ADVIA Centaur Folate **ending in 218** available, take the following actions to ensure acceptable performance:
  - If your laboratory establishes its own control ranges for folate then run multi-level controls at the start of each pack, ensuring at least one control is targeted >6 ng/mL (13.59 nmol/L). If the controls are within your established ranges, the pack may be used to generate patient results. If not, discard the pack.
  - If your laboratory uses control ranges provided by a QC vendor, then you must calibrate and run multi-level controls on each pack prior to use, ensuring at least one control is targeted >6 ng/mL (13.59 nmol/L).
  - Refer to the operator's guide or online help for instructions on ordering QC by ReadyPack ID number.
  - Any ReadyPacks with invalid calibration or a failing QC at any level must not be used to report patient results and should be discarded.
- After you receive a kit lot not ending in 218, immediately transition to the new lot.
- Please forward this notification to whomever you may have distributed this product.
- If you have any questions or need additional information, please contact your local Technical Support Provider or Distributor

We apologize for the inconvenience this situation has caused.