SIEMENS Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

CC 19-07.A.OUS

July, 2019

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® XPT

Homocysteine Assay May Cause Elevated Results in the Folate Assay

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)	Lot Number
Folate (100 Test Kit)	FOL	06367974	10310308	All lots
Folate (500 Test Kit)	FOL	06891541	10325366	All lots

Reason for Correction

Siemens Healthcare Diagnostics has confirmed the potential for the ADVIA Centaur Homocysteine assay (100 Test Kit SMN 10310374; 500 Test Kit SMN 10310375) to intermittently interfere with the Folate assay when testing is performed on the ADVIA Centaur, ADVIA Centaur XP or ADVIA Centaur XPT systems. The interference is observed intermittently with only the first replicate of Folate when the assay is tested immediately following Homocysteine assay testing.

This issue may cause

- serum samples to be elevated and serum controls to recover high out of range for the ADVIA Centaur Folate assay.
- folate-deficient samples may result in the indeterminate range and
- folate indeterminate samples may result in the normal range.

The above is described in Table 2.

Table 2 shows the range of sample results in each category tested before and immediately after Homocysteine as well as the median and range of absolute biases of the folate results if tested immediately after Homocysteine.

Whole blood samples do not experience the same effect.

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Table 2. Effect of Homocysteine interference on the first replicate of Folate serum samples when tested immediately after the Homocysteine assay

Category of Expected Values from Instructions for Use	Range of Serum Folate Results tested before Homocysteine	Range of Serum Folate Results tested after Homocysteine	Median Bias of Serum Folate Results Observed after Homocysteine	Range of Bias of Serum Folate Results Observed after Homocysteine
Deficient <3.38 ng/mL (<7.64 nmol/L)	0.91 - 2.99 (2.06 - 6.77)	1.81 - 3.97 (4.10 - 8.99)	0.88 (1.99)	-0.02 - 1.51 (-0.04 - 3.42)
Indeterminate 3.38 - 5.38 ng/mL (7.64 to 12.19 nmol/L)	3.47 - 4.60 (7.86 - 10.4)	4.47-5.99 (10.1 - 13.6)	1.04 (2.36)	0.59 - 1.61 (1.34 - 3.65)
Normal >5.38 ng/mL (>12.19 nmol/L)	5.76 - 18.9 (13.0 - 42.8)	6.48-20.2 (15.5 - 45.8)	0.8 (1.81)	0.28 - 2.09 (0.63 - 4.73)

Results for nmol/L provided in parenthesis

The ADVIA Centaur CP system is not affected.

The root cause of the issue is currently under investigation and Siemens is actively working to identify a solution to the interference. This issue affects all current and future lots of ADVIA Centaur Systems Folate assay until a solution is implemented.

Risk to Health

While considered remote, when this issue occurs the potential exists for misinterpretation of serum folate levels which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical symptomology and additional laboratory diagnostic testing such as vitamin B12, homocysteine, methylmalonic acid (MMA) and/or complete blood count and blood smear. The overall risk to health is negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have multiple ADVIA Centaur, ADVIA Centaur XP or ADVIA Centaur XPT systems in your laboratory, Siemens recommends testing the ADVIA Centaur Folate and ADVIA Centaur Homocysteine assays on separate systems to avoid potential interference.
- If you do not have multiple ADVIA Centaur systems in your laboratory but you do have access to another Siemens solution such as an Atellica® IM Analyzer, ADVIA Centaur CP System, IMMULITE® 2000/IMMULITE 2000 XPi System or Dimension Vista® System, Siemens recommends testing Homocysteine on an alternate system to avoid potential interference.
- If you are testing the ADVIA Centaur Folate and ADVIA Centaur Homocysteine assays on the same ADVIA Centaur, ADVIA Centaur XP, or ADVIA Centaur XPT system, test all

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Homocysteine samples together followed by the Daily Cleaning Procedure (DCP) prior to testing the Folate assay to mitigate the interference. Perform Folate serum Quality Control testing prior to Folate patient sample testing.

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.

ADVIA Centaur, Atellica, Dimension Vista and IMMULITE are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Homocysteine Assay May Cause Elevated Results in the Folate Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 19-07.A.OUS dated July, 2019 regarding Homocysteine Assay May Cause Elevated Results in the Folate Assay. Please read each question and indicate the appropriate answer.

Return this completed form to Cruinn Diagnostics as per the instructions 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 ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to cruinnfsngroup@cruinn.ie.

Or to fax this completed form to the Cruinn Customer Care Center at 01-6297401.

If you have any questions, contact your local Siemens technical support representative.

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