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Urgent Field Safety Notice:

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

Biotin Interference in the Cyclosporine, DHEA-SO4, Folate and HBc IgM Assays

Dear Sirs,

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

Table 1. ADVIA Centaur Systems Affected Product(s) – All Lots

Assay	Assay Code	Catalog Number	Siemens Material Number (SMN)
Cyclosporine (50 test kit)	CSA	04564446	10335448
DHEA-SO_4 (50 test kit)	DHEAS	06489701	10282227
Folate (100 test kit)	FOL	06367974	10310308
Folate (500 test kit)	FOL	06891541	10325366
HBc IgM (100 test kit)	aHBcM	00504619	10308978

Reason for Correction

Siemens Healthcare Diagnostics has confirmed through internal investigation that the assays listed in Table 1 are susceptible to biotin interference. This occurs when biotin present in patient samples interferes with the biotin-streptavidin assay architecture on the ADVIA Centaur platforms.

- The concentrations of Biotin listed in the ***Interferences*** section of the current Instructions for Use (IFUs) for ADVIA Centaur systems Cyclosporine (CSA) and DHEA-SO_4 (DHEAS) do not correctly reflect the level at which biotin causes a ≤10% bias.

- The Instructions for Use (IFU) for ADVIA Centaur systems Folate (FOL) and HBc IgM (aHBcM) currently do not list biotin in the ***Interferences*** section.

Tables 2 through 4 contain the biotin concentrations that result in a less than or equal to 10% bias, or cause no change in clinical interpretation. Concentrations of biotin greater than those listed in Table 2 through Table 4 can potentially result in interference greater than 10% (CSA, DHEAS, FOL) or cause a change in qualitative interpretation (aHBcM); leading to either falsely elevated or falsely depressed results.

CSA, DHEAS and FOL exhibited falsely elevated results with biotin concentrations above those listed in Table 2 and Table 3.

aHBcM exhibited falsely depressed results with biotin concentrations above that listed in Table 4.

Table 2. Biotin Interference for CSA and DHEAS

Assay	Biotin Concentration stated in IFU that causes ≤ 10% bias	Revised Biotin Concentration that causes ≤ 10% bias*
CSA	100 ng/mL	50 ng/mL
DHEAS	100 ng/mL	12.5 ng/mL

Table 3. Biotin Interference for FOL

Assay	Biotin concentration that causes ≤ 10% bias*
FOL	50 ng/mL

Table 4. Biotin Interference for aHBcM

Assay	Biotin concentration that causes no change in qualitative interpretation*
aHBcM	150 ng/mL

*Concentrations of biotin greater than those listed in the tables above can potentially result in interference >10% or a change in qualitative interpretation.

Risk to Health

The probability of misinterpretation of results for the above assays due to this issue is remote. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing and/or serial testing, depending on the analyte.

Siemens is not recommending a lookback as a result of this issue.

Actions to be Taken by the Customer

- Please refer to the information provided in Tables 2 through 4 until the appropriate IFU updates regarding biotin interference are completed.
- 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 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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