SIEMENS Healthineers

Urgent Field Safety Notice

AIMC 23-03.A-1.OUS

January 2023

Atellica® Solution

Atellica IM Folate –Negative Bias when Customers use Whole Blood (FoI) Calibration for Serum Samples

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

Table 1. Atellica IM Affected Product(s)

Assay	Siemens Material Number (SMN)	Kit Lot #	Mfg. Date (YYYY-MM-DD)	Exp. Date (YYYY-MM-DD)	Unique Device Identification (UDI)
Atellica IM Folate 140 test kit	10995572	15308337	2022-06-20	2023-03-20	(01)00630414598963(10)15308337(17)20230320
		27949339	2022-08-29	2023-05-29	(01)00630414598963(10)27949339(17)20230529
		41143343	2022-09-30	2023-06-30	(01)00630414598963(10)41143343(17)20230630
		41144343	2022-09-30	2023-06-30	(01)00630414598963(10)41144343(17)20230630
		62969345 and higher	2022-10-26	2023-07-26	(01)00630414598963(10)62969345(17)20230726
Atellica IM Folate 700 test kit	10995573	15307337	2022-06-20	2023-03-20	(01)00630414598970(10)15307337(17)20230320
		27948339	2022-08-29	2023-05-29	(01)00630414598970(10)27948339(17)20230529
		41142343	2022-09-30	2023-06-30	(01)00630414598970(10)41142343(17)20230630
		62968345 and higher	2022-10-26	2023-07-26	(01)00630414598970(10)62968345(17)20230726

This issue affects all current and future lots of the Atellica IM Folate assay until the Instructions for Use are updated.

Reason for Correction

Siemens Healthcare Diagnostics Inc. received customer complaints regarding a negative bias with serum samples for the Atellica IM Folate assay. The Siemens investigation found the negative bias occurred when a whole blood calibration (FoI) was used to test serum samples with the lots listed in Table 1. The purpose of this communication is to provide information regarding this bias and instructions on actions your laboratory must take.

Siemens previously announced the availability of improvements to the Atellica IM Folate assay through the implementation of distinct calibrations for serum and whole blood samples. The improvements were communicated through Customer Bulletin 11641601 *(Atellica IM Folate Assay Improvement – Distinct Calibration of Serum and Whole Blood*,) available on Siemens Document Library in September 2022. The bulletin provided specific instructions which must be followed to implement the improvements for the appropriate sample type(s) used in your laboratory. Tables 2

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and 3 below summarize the Test Definition (TDef) and Master Curve (MC) and software requirements for each sample type. Upon receipt of kit lots ending in 337 and above, customers who utilized the FoI test for serum samples as described in the Instructions for Use rather than the above mentioned bulletin may have obtained erroneously low results. Quality Control (QC) results, especially QC samples at the higher end of the assay range, may be out of range. Refer to Figure 1 in Additional Information for expected differences in results if the whole blood calibration is used for serum samples.

Customers who followed the instructions for serum samples in Customer Bulletin 11641601 are not affected.

Whole blood samples are not impacted by this issue as the Atellica IM Folate (SMN 10995344) Instructions for Use provide information regarding the treatment of whole blood samples and utilization of predefined ratio tests to generate results.

Table 2. Software and Test Definition Requirements

Platform	SW version	Test Definition ID and Version	Test Definition Sample Type Update
Atellica IM	1.20 and above	FoI 1.4	Update specimen type to whole blood, remove serum
		FolSerum 1.0	Specimen type is serum

Table 3. MC Card and LIS Information

Sample Type	TDef Assay ID/LIS Code[1]	Name on MC
Whole Blood (RBC Hemolysate)	FoI	FoI
Serum	FolSerum	FolSR

[1]For the Atellica® IM Analyzer, the LIS Code field in the test definition is customer definable.

In order to implement the enhancement to the Atellica IM Folate assay and obtain correct results for serum samples, the appropriate TDef and Master Curve Card and Calibrator Value assignment and software must be used to calibrate the assay for the sample type used in your laboratory. The Atellica IM Folate Instructions for Use will be updated accordingly. This issue impacts the lots listed in Table 1 and higher. However, once you have completed these instructions for one lot, no additional changes are required for subsequent lots.

Risk to Health

If this issue occurs, there is a potential for QC failures or erroneous patient results. There is negligible risk to health as the folate biases observed near the deficient/indeterminate/normal cutoffs would not lead to a clinically significant difference in patient management. Folate test results would be correlated with patient's clinical history, signs and symptoms, as well as evaluation of Vitamin B12 and other hematologic and neurologic parameters. Siemens Healthineers is not recommending a review of previously generated results.

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Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Follow the instructions in this Urgent Field Safety Notice until the Atellica IM Folate Instructions for Use are updated.
    - Before updating to the new reagent lot, ensure you have processed all serum samples necessary for lot-to-lot comparisons using your existing inventory.
    - Once you have updated to the new reagent lot, you will not be able to process serum samples with the previous reagent lot.
    - If your laboratory runs both serum and whole blood sample types, then both assays must be calibrated with the new reagent lot.
    - If your laboratory runs one sample type, only calibrate the sample type you use.
- Update Steps
    - **New folate customers**: Please scan the Fol MC Card first and then FolSR MC Card; this must be completed regardless of the sample type you chose to run.
    - **Existing folate customers**: If the existing Folate lot is expired, scan the Fol MC Card first and then the FolSR MC Card. If the existing Folate lot is NOT expired, the scan order of the Fol and FolSR MC Cards is not important.

  1. Scan the Fol MC Card for lot ending in 337 or above.

  2. Remove the serum sample type from the Fol test definition by performing the following steps.

  Note: These steps will need to be performed one time and will not need to be completed for subsequent lots.

    a. Log in as “Lab Manager” or CSE.

    b. On the Command Bar, select Setup > Test Definition > IM Test Definition.

    c. Select Fol.

    d. Go to Specimen type field and uncheck Serum.

    e. Select Save.

- Once you have completed these instructions for one lot, no additional changes are required for subsequent lots.
- 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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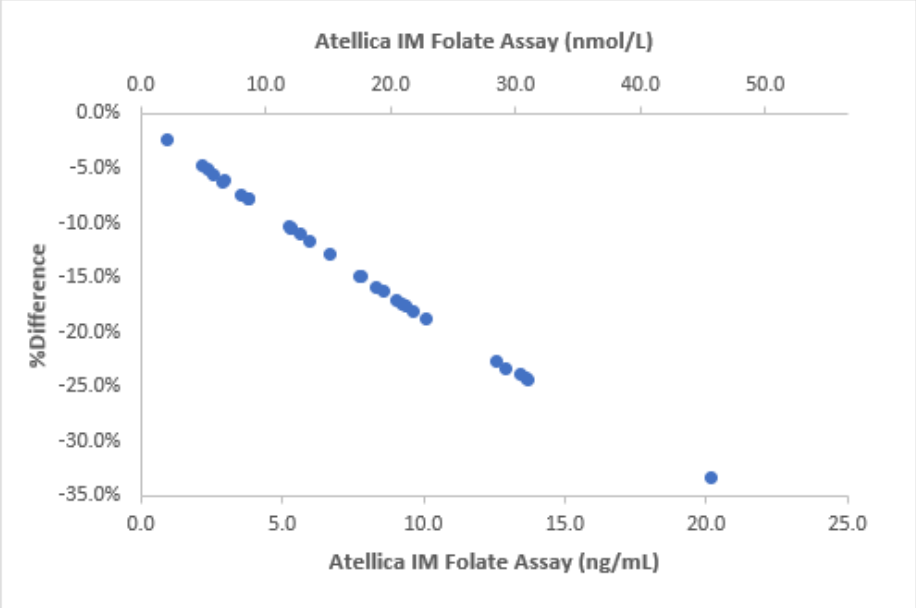
Additional Information

Figure 1 shows the percent difference observed when serum sample results are unintentionally generated using a whole blood calibration (Fol) compared to results generated using the appropriate Master Curve and Calibrator Assignments for serum samples. The graph below shows biases above 10% reside in the serum folate normal range.

Figure 1: Atellica IM Folate - Serum Samples



FIELD CORRECTION EFFECTIVENESS CHECK

Atellica IM Folate –Negative Bias when Customers use Whole Blood (Fol) Calibration for Serum Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) AIMC 23-03.A-1.OUS dated January 2023 regarding Atellica IM Folate –Negative Bias when Customers use Whole Blood (Fol) Calibration for Serum Samples Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN 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 send a scanned copy of the completed form via email to cruinnfsngroup@cruinn.ie.

Or to fax this completed form to the Customer Care Center at 01 6297400.

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

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