**Atellica IM Analyzer**

**ADVIA Centaur XP System**

**ADVIA Centaur XPT System**

siemens-healthineers.tld/keyword

**Customer Notification**

**AIMC 24-12.A.OUS**



|  |  |  |
| --- | --- | --- |
| **Title**  |  | Atellica IM and ADVIA Centaur Folate (Fol) Invalid Calibration for Whole Blood Sample Types |
| **Date Issued** |  | June 2024 |
| **Issue Description** |  | Siemens Healthineers has investigated customer complaints and confirmed the potential for intermittent invalid red blood cell (RBC) Folate calibrations with the Atellica® IM and ADVIA Centaur® Folate (Fol) assay when using whole blood samples due to calibrator deviation outside of the defined specification range. * The serum Folate calibration is not affected.
* If a valid RBC Folate calibration is achieved for the whole blood sample type and quality controls (QC) meet defined ranges, then patient results are considered accurate and acceptable for reporting. No further action is needed.
* If you are unable to obtain a valid RBC Folate calibration, you may attempt multiple re-calibrations.
* Per the Instructions for Use (IFU), if an invalid calibration is obtained, QC and patient sample testing cannot be performed. Further action is defined below in the “Actions to be Taken” section.

Siemens is currently investigating the root cause of the RBC Folate calibrator deviation failures. The following Folate kit lots listed in the table below are susceptible to an invalid RBC Folate calibration. |
|  |  |  |  |  |  |  |  |
| **Products** |  | **Assay** | **Test Code** | **Siemens Material Number/Unique Device Identification** | **Kit Lot Number** |
|  |  | Atellica IM Folate(140 Test) | Fol | 10995572 / 630414598963 | Kit lot numbers ending in 359 and above |
|  |  | Atellica IM Folate(700 Test) | Fol | 10995573 / 630414598970 |
|  |  | ADVIA Centaur Folate (100 Test) | FOL | 10310308 / 630414204192 | Kit lot numbers ending in 358 and above |
|  |  | ADVIA Centaur Folate (500 Test) | FOL | 10325366 / 630414450940 |
|  |  |  |  |  |  |
| **Customer Actions** |  | * For the product(s) listed in the table above , please perform the following steps for addressing a potential invalid RBC Folate calibration:
* Patient results may continue to be reported when a valid calibration and in range quality control results are obtained.
* When a valid calibration cannot be obtained after multiple attempts, you may request no-charge replacement product from your local Siemens Healthineers or distributor office.
* Please review your inventory of these products and assess your laboratory’s replacement needs.
* Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).
* Please retain this letter with your laboratory records and forward this letter to those who may have received the product.
 |
| **Resolution** |  | A follow up communication will be provided when “Customer Actions” are no longer required. |

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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**PRODUCT REPLACEMENT FORM**

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification **AIMC 24-12.A.OUS** dated June 2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

|  |  |  |
| --- | --- | --- |
| 1. Have you been unable to obtain a valid RBC Folate calibration of the Atellica IM and ADVIA Centaur Fol assay due to calibrator deviation?
 | Yes [ ]  | No [ ]  |
| 1. All affected Site Personnel have been notified.
 | Yes [ ]  | No [ ]  |
| 1. A copy of the letter has been retained and posted with the current product labeling.
 | Yes [ ]  | No [ ]  |

If the answer to the question #1 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

|  |  |
| --- | --- |
| **Product Description****SMN #/Kit Lot #** | **Quantity of Affected Product in inventory / Replacement Quantity Required** |
| *Atellica IM Folate (140 Test)**SMN: 10995572 Kit Lot Numbers ending in 359 and above* |  |
| *Atellica IM Folate (700 Test)**SMN: 10995573 Kit Lot Numbers ending in 359 and above* |  |
| *ADVIA Centaur Folate (100 Test)SMN: 10310308 Kit Lot Numbers ending in 358 and above* |  |
| *ADVIA Centaur Folate (500 Test)SMN: 10325366 Kit Lot Numbers ending in 358 and above* |  |
| **Name of person completing questionnaire:** |  |
| **Title:** |  |
| **Institution:** |  |
| **Street:** |
| **City:** |  | **State:** | **Zip Code:** |
| **Phone:** |  | **Country:** |  |

Please send a scanned copy of the completed form via email to **XXXX@XXXX**.

Or fax this completed form to the Customer Care Center at **XXXXXX**.

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.