SIEMENS Healthineers

Urgent Field Safety Notice

POC 23-009.A.OUS

March 2023

Atellica® DCA Analyzer

Labeling Error in Albumin:Creatinine Ratio (ACR) Assay Handling Instructions

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

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)
Atellica DCA Analyzer	11419264	00630414288574
	11419267	00630414288581
	11561560	00630414621678
	11561561	00630414621685
	11419268	00630414285375
Atellica DCA ACR Reagent Kit	10888779	00630414285702
	11537791 (Japan Only)	00630414295213

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the product documentation for products indicated in Table 1 and provide instructions and actions that your facility must take.

Siemens Healthcare Diagnostics has confirmed that errors exist in Atellica DCA Analyzer User Guide and Atellica DCA ACR Assay Instructions for Use (IFU). See details in Table 2.

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Table 2. List of Documents

Document	SMN	Affected Revision	Incorrect Instructions	Correct Instructions *(To be Available in the Next Document Revision)*
Atellica DCA ACR Assay IFU (*Language Group 1)*	10888782	B	Section: Prepare for the ACR Test -Storage and Stability After opening the foil pouch, the reagent cartridge must be used **within 1 hour.**	After opening the foil pouch, the reagent cartridge must be used **within 10 minutes.**
Atellica DCA ACR Assay IFU (*Language Group 2)*	10888783	A		
Atellica DCA ACR Assay IFU (*Language Group 3)*	11555865	A		
Atellica DCA Analyzer User Guide (*Binder – Language Group 1)*	11419352	E	Chapter 2: Testing Patient Samples- Preparing for an ACR Test Allow the reagent cartridge to warm up to room temperature for 15 minutes in an unopened foil pouch **or 5 minutes if you removed it from the foil pouch.**	Allow the reagent cartridge to warm up to room temperature for 15 minutes in an unopened foil pouch. After opening the foil pouch, the reagent cartridge must be used within 10 minutes.
Atellica DCA Analyzer User Guide (*Binder – Language Group 2)*	11419411	D		
Atellica DCA Analyzer User Guide (*Spare Binder – Language Group 1)*	11537707	A		
Atellica DCA Analyzer User Guide (*Spare Binder – Language Group 2)*	11556123	A		
Atellica DCA Analyzer User Guide (Language Specific)	Various Based Language	Various		

Siemens Healthcare Diagnostics has confirmed the following when the above incorrect instructions are followed:

- If the cartridge for the ACR assay is exposed to an extreme condition (30°C and 80-90% relative humidity) for up to one hour, the maximum bias observed for ACR is +11.6%.
- If the cartridge for ACR assay is exposed to a typical controlled lab environment for up to one hour, there is negligible performance impact.
- If the cartridge for ACR assay is warmed up to room temperature for 5 minutes after it is removed from the foil pouch, there is negligible performance impact.

This is a labeling issue and not a product performance issue. The analyzer and reagent cartridge perform as intended.

Risk to Health

The overall Risk to Health is negligible. In a worst-case scenario (improper exposure of cartridge for one hour to extreme conditions of temperature (30°C) and relative humidity (80% - 90%) followed by testing of a urine sample with only a trace amount of protein there could be a falsely

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elevated ACR that might lead to additional non-invasive testing. Urine samples with truly elevated levels of protein will still be correctly classified, and there will be no false negative results.

Siemens is not recommending a review of previously generated results because any positive result (either false positive or true positive) for proteinuria would normally be expected to lead to some type of non-invasive, follow-up testing to confirm the result.

Actions to be Taken by the Customer

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Follow the instructions in “Correct Instructions” column of Table 2 when preparing Atellica DCA ACR cartridge for testing.
- Keep this notification document with your User Guide/IFU for reference, as needed.
- Please review this letter with your Medical Director.

Please forward this letter to those who may have received the products listed in Table 1.

The labelling error will be corrected in the next revision of the documents. The revised user guide and the IFU will be available in Siemens Document Library once the new document revisions are released.

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.

Additional Information

Atellica® is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica DCA Analyzer Labeling Error in ACR Assay Handling Instructions

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 23-009.A.OUS dated March 2023 regarding Atellica DCA Analyzer Labeling Error in ACR Assay Handling Instructions. 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:

Please send a scanned copy of the completed form via email to XXXX@XXXX Or to fax this completed form to the Customer Care Center at XXXXXX

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

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