Customer Notification

POC 26-007-A-OUS

DCA Vantage® DCA / Atellica® DCA

Title HbA1c Reagent Cartridge Bias Issue due to Delamination

Date Issued **July 2026**

Products

Product	Lot Number	Siemens Material Number	Unique Device Identification	Manufacturing Date	Expiration Date
DCA Vantage HbA1c (Japan)	0989115	10333427	00630414532813	November 2025	November 2027
Atellica DCA HbA1c Monitor Kit (Japan)	05310226	11419271	00630414298054	February 2026	February 2028
DCA Vantage HbA1c (DX Claim)	0916065	10698915	00630414592633	June 2025	June 2027

Issue Description

Siemens Healthineers has confirmed through customer complaint investigations and internal testing that delamination of the buffer pull-tab may occur in a small subset of cartridges. Delamination occurs when bonded material layers within the pull-tab separate, preventing full release of the buffer solution into the reaction chamber and reducing the reagent volume available for analysis.

When delamination occurs, it may result in falsely low (negatively biased) HbA1c results or instrument-generated error codes that prevent completion of the test. The issue observed in approximately 0.07–0.5% of cartridges in these lots. The majority of cartridges in these lots continue to perform as intended.

Customer Actions

- You may continue to use the cartridges or request replacements if you experience issues with these lots.
- If you choose to continue testing with these lots, repeat testing if an HbA1c result is inconsistent with the patient's clinical presentation, and follow standard troubleshooting procedures if an error code is displayed.
- If you prefer replacements, review your inventory of these products to determine your laboratory's replacement needs and complete the replacement form below.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution Only the lots listed in the table above are affected by this issue.

Single Registration Number (SRN) US-MF-000016560

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 POC 26-007-A-OUS dated July 2026. 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.	Do you have the affected product(s) on hand? Please check inventories before answering.	Yes ☐	No ☐
2.	Are you exorincign issue with this lot and therefore requesting replacements?	Yes ☐	No ☐
3.	Were affected Site Personnel notified?	Yes ☐	No ☐
4.	Was a copy of the letter 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 **Product Catalog #/SMN #/Lot #**	**Quantity of Affected Product in inventory** **Replacement Quantity Required**	
DCA Vantage HbA1c (Japan) – Lot# 0989115		
Atellica DCA HbA1c Monitor Kit (Japan) – Lot# 05310226		
DCA Vantage HbA1c (DX Claim) – Lot # 0916065		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	**State:**	**Zip Code:**
Phone:	**Country:**	
Customer Sold To #	**Customer Ship To #**	

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com.

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