



Customer Notification

ACHC23-04.A.OUS

May 2023

Atellica® CH Analyzer

A-LYTE® Integrated Multisensor (IMT Na K Cl) Lot 120011 Chloride Calibration Slope Failures

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

Table 1. Atellica® CH Affected Product

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
A-LYTE® Integrated Multisensor (IMT Na K Cl)	11099315	00630414596518	120011	2023-10-24	2022-12-20

Reason for Customer Notification

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed through investigation of customer complaints that A-LYTE Integrated Multisensor (IMT Na K Cl) Lot 120011 may not routinely meet the Instructions For Use (IFU) Onboard Stability Claim of 14 days or 5000 samples.

Customers may observe Chloride calibration slopes outside of the acceptable range during the use life for some A-LYTE Integrated Multisensor cartridges from Lot 120011. After an IMT Multisensor cartridge fails to calibrate, Na, K, and Cl results from quality controls and patient samples cannot be generated. IMT Multisensor cartridge replacement is required to restore IMT processing.

Investigation has indicated that not all A-LYTE Integrated Multisensor cartridges for Lot 120011 are impacted.

Siemens is currently investigating the root cause of this issue.

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

A-LYTE® Integrated Multisensor (IMT Na K Cl) Lot 120011 Chloride Calibration Slope Failures

- If calibration is successful, no action is necessary and you may continue to use the A-LYTE Integrated Multisensor.
- If calibration is unsuccessful during the onboard stability period due to chloride slope failure, replace the A-LYTE Integrated Multisensor. If failures persist, you may request no-charge replacement with an alternate lot from your local Siemens Healthineers or distributor office. Please review your inventory of these product 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 this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

Atellica® CH is a trademark of Siemens Healthcare Diagnostics Inc.

A-LYTE® Integrated Multisensor (IMT Na K Cl) Lot 120011 Chloride Calibration Slope Failures

PRODUCT REPLACEMENT FORM

A-LYTE® Integrated Multisensor (IMT Na K Cl) Lot 120011 Chloride Calibration Slope Failures

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification ACHC23-04.A.OUS dated May 2023 regarding A-LYTE® Integrated Multisensor (IMT Na K Cl) Lot 120011 Chloride Calibration Slope Failures.

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

Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

Did the chloride calibration slope fail before the Instructions For Use (IFU) Onboard Stability Claim of 14 days or 5000 samples (whichever comes first)? Yes No

If the answer to both questions 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 Returned/ Replacement Quantity Required
A-LYTE® Integrated Multisensor/SMN 11099315/Lot 120011	

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 fscareportingunit.my@siemens-healthineers.com

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