

Customer Notification

ACHC26-01.A.OUS

Atellica CI Analyzer

Title	Atellica CH Gentamicin (Gent) Not Meeting Pack Calibration Interval on the Atellica CI Analyzer										
Date Issued	Nov-2025										
Products	<table border="1"><thead><tr><th>Assay</th><th>Test Code</th><th>Siemens Material Number/Unique Device Identification</th><th>Lot Number</th></tr></thead><tbody><tr><td>Atellica CH Gentamicin (Gent)</td><td>Gent</td><td>11097516/00630414595979</td><td>All lots</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Atellica CH Gentamicin (Gent)	Gent	11097516/00630414595979	All lots		
Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number								
Atellica CH Gentamicin (Gent)	Gent	11097516/00630414595979	All lots								
Issue Description	<p>Siemens Healthineers has confirmed the potential for a negative drift in quality control (QC) results when using the Atellica CH Gentamicin (Gent) assay on the Atellica CI analyzer. The negative drift in QC may require calibration of the assay prior to the 30-day interval indicated in the Instructions for Use (IFU). A maximum bias of -29% was observed at day 30 of the pack calibration. The investigation determined that calibrating more frequently at a 14-day pack calibration restores assay performance.</p> <p>QC failures will alert the operator to the issue before patient results are reported.</p> <p>This issue applies to all in-date and future Atellica CH Gent lots for use on the Atellica CI analyzer until further notice. Siemens Healthineers is actively investigating the root cause. The performance of the Atellica CH Gent reagent on the Atellica CH analyzer is not affected.</p>										
Customer Actions	<ul style="list-style-type: none">As a temporary mitigation, perform the instructions provided below to edit the pack calibration interval to 14 days on the Atellica CI analyzer:<ol style="list-style-type: none">Invalidate all valid pack calibrations for Gent. Refer to Online Help section: <i>About Calibration Results > About Invalidating a Calibration in Calibration Results.</i>Navigate to the Gent CH Test Definition and change the pack calibration interval from 30 days to 14 days and save. Refer to Online Help section: <i>Calibration in CH Test Definition > Modifying the Calibration Interval for CH Reagent Packs</i> for assistance.When valid calibration is achieved and QC meets defined ranges, patient samples may be processed.Please retain this letter with your laboratory records and forward this letter to those who may have received this product.										
Resolution	A follow-up communication will be provided when "Customer Actions" are no longer required.										
Single Registration Number (SRN)	US-MF-000016560										
	<p>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.</p>										

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