

Customer Notification

AIMC24-10.A.OUS

Atellica IM Analyzer

Title Atellica IM Interleukin-6 (IL6) Pack Calibration Instability

Date Issued Sep-2024

Issue Description Siemens Healthineers has confirmed, through the investigation of customer complaints, the Atellica® IM Interleukin-6 (IL6) assay is showing a negative drift in quality control (QC) and patient results.

An internal investigation confirmed that, when using the Atellica IM IL6 assay, the pack calibration claim of 14 days per the Instructions for Use may not be met. The lot calibration interval and the reagent onboard stability of 42 days are not impacted.

This issue is applicable to all in-date and future Atellica IM IL6 lots until further notice. Siemens Healthineers is currently investigating the root cause of this issue.

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
	Atellica IM Interleukin-6	IL6	10733011 / 00630414245829	All in-date and future lots

Impact to Results A negative drift may impact both QC and patient results. A gradual change in results over time will be noticed by an apparent QC failure, which may delay patient result reporting.

Table 1 of the Appendix provides representative data of the drift that may be observed.

- Customer Actions**
- As a temporary mitigation for the products listed in the table above, perform the actions provided below to edit the pack calibration interval from 14 days to 3 days:
 1. Unload and discard any open IL6 reagent packs onboard the analyzer.
 2. Navigate to the IL6 Test Definition and change the pack calibration interval from 14 days to 3 days and save. Refer to the Atellica Solution Operator's Guide, Viewing IM Test Definition Settings section (11069101 Rev. 11, page 731-744), for assistance.
 3. Load a fresh IL6 reagent pack onto the analyzer.
 4. Recalibrate and ensure QC is in range.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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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.

**Single
Registration
Number (SRN)** US-MF-000016560

Appendix Table 1. Atellica IM IL6 Reagent Drift for QC and Patient Results

Day	Results in pg/mL							
	Control 1	Control 2	Control 3	Patient Pool 1	Patient Pool 2	Patient Pool 3	Patient Pool 4	Patient Pool 5
0	6.9	209.5	845.3	9.2	29.8	194.2	901.0	4090.5
7	4.3	140.3	606.7	5.8	19.6	131.3	650.6	3121.1
14	2.7	109.4	461.7	3.7	14.6	103.0	514.5	2518.6

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