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Urgent Field Safety Notice:

**Atellica CH Analyzer
Atellica CI Analyzer
Resolution of the Potential for Negative Bias with Atellica CH Immunoglobulin M₂ (IgM₂) Reagent**

To whom it may concern,

In December 2023, Siemens Healthineers issued Urgent Field Safety Notice ACHC24-01.A.OUS communicating the potential for a negative bias with quality control (QC) and patient sample results when using the Atellica CH Immunoglobulin M₂ (IgM₂) reagent. Customers were instructed to batch test Atellica CH IgM₂ samples. Siemens is pleased to inform you that the root cause for the reagent instability has been identified and the manufacturing control system has been updated to ensure that there is no impact to future lots. The issue has been resolved, and beginning with lot 242315, batch testing of Atellica CH IgM₂ samples will no longer be required. Refer to the Customer Actions section below.

Products


Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
Immunoglobulin M ₂	IgM ₂	11097620/00630414595627	242315 and above

Customer Action

- Please review this letter with your Medical Director.
- If your laboratory is using a lot prior to lot 242315, you must continue to follow instructions in ACHC24-01.A.OUS.
- If your laboratory has lot 242315 or above, stop following the instructions in ACHC24-01.A.OUS.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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 have caused. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.
Sincerely yours,

Siemens Healthcare Diagnostics GmbH



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