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Date January 09, 2024

Document Ref# ACHC24-01.A.OUS

Urgent Field Safety Notice:

Atellica® CH Analyzer
Atellica® CI Analyzer

Potential for Negative Bias with Atellica CH Immunoglobulin M_2 (IgM_2) Reagent

To whom it may concern,

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

Table 1. Atellica CH and Atellica CI Affected Product

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Immunoglobulin M_2	IgM_2	11097620	00630414595627	221764 and above

Reason for Correction

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 Healthineers has confirmed the potential for a negative bias with quality control (QC) and patient sample results when using the Atellica CH Immunoglobulin M_2 (IgM_2) reagent. The negative bias was observed after the IgM_2 reagent was stored onboard the analyzer regardless of whether the reagent wells were punctured or unpunctured. Unopened reagents stored refrigerated at 2 - 8 °C are unaffected. See Tables 2 and 3 in the Additional Information section for observed results.

This correction is applicable to all future lots until further notice. Siemens Healthineers is currently investigating the root cause of this issue.

Risk to Health

When this issue occurs, there is a potential for erroneously depressed IgM patient results. This is not expected to lead to a significant effect on assessment of IgM results in the context of the assay intended use.

Actions to be Taken by the Customer

Siemens Healthineers recommends batch testing samples for Atellica CH IgM_2 as follows:

1. Remove and discard any Atellica CH IgM_2 reagent packs onboard the analyzer.
2. Load a **single** fresh Atellica CH IgM_2 reagent pack onto the analyzer.
3. Perform a **Lot calibration** and process Quality Control (QC).
4. Immediately process a batch of patient samples and conclude with a repeat run of QC.

   Patient results should not be reported until the QC performed at the end of the batch run has been assessed.

   - If the QC results are within the established range, patient results can be reported.
   - If the QC results are not within the established range, do not report patient results and repeat steps 1 – 4 above.
5. Remove and discard the Atellica CH IgM_2 reagent pack at the end of the batch run.

- Siemens Healthineers does not recommend using the ADVIA IgM_2 reagent on the Atellica CH or Atellica CI Analyzers.
- 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 within 30 days.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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 or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
Date: Jan 8, 2024 10:37 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
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Signature: *Electronically signed by: Carina Marie Viehboeck*
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i.A. DI[in] Carina Viehböck
Product Manager CEECA

Annex I: Additional Information

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Table 2. Atellica CH IgM_2 Quality Control Results Across Four Hours*

Time (hour)	QC Level 1		QC Level 2		QC Level 3	
	mg/dL (g/L)		mg/dL (g/L)		mg/dL (g/L)	
	Rep 1	Rep 2	Rep 1	Rep 2	Rep 1	Rep 2
0 (after calibration)	47.0 (0.47)	45.5 (0.46)	76.3 (0.76)	72.2 (0.72)	90.4 (0.90)	88.9 (0.89)
1	41.6 (0.42)	38.9 (0.39)	72.2 (0.72)	70.1 (0.70)	79.8 (0.80)	84.7 (0.85)
2	38.4 (0.38)	37.1 (0.37)	65.4 (0.65)	64.7 (0.65)	77.5 (0.78)	78.5 (0.79)
3	34.5 (0.35)	33.9 (0.34)	63.3 (0.63)	64.7 (0.65)	75.5 (0.76)	75.4 (0.75)
4	32.2 (0.32)	33.5 (0.34)	63.1 (0.63)	63.1 (0.63)	73.2 (0.73)	75.9 (0.76)

*Quality Control (QC) materials are representative of patient samples. Bio-Rad Multiqual Assayed Control Lot 45960 was used for testing.

Table 3. Atellica CH IgM_2 Patient %Bias Results at 24 Hours**

Range of Patient Serum Sample IgM_2 Values	%Bias Range	Average %Bias
23 – 50 mg/dL (0.23 - 0.50 g/L)	[-14.9 to -26.5%]	-20.7%
51 – 100 mg/dL (0.51 - 1.00 g/L)	[-6.7 to -15.4%]	-11.0%
101 – 200 mg/dL (1.01 - 2.00 g/L)	[-4.1% to -6.3%]	-5.2%
201 – 330 mg/dL (2.01 - 3.30 g/L)	[-2.9% to -4.7%]	-3.8%

**Initial result was obtained immediately after calibration of a freshly loaded reagent pack. A repeat result was obtained 24 hours after calibration from the same reagent well.