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Urgent Field Safety Notice:

Atellica CH Analyzer
Atellica CI Analyzer

Atellica CH β2-Microglobulin (B2M) Auto-dilution Discrepant Results

To whom it may concern,

Siemens Healthineers has confirmed the potential for falsely depressed auto-diluted results for samples above the measuring interval of 18.00 mg/L, up to 30.00 mg/L, when using the Atellica CH β2-Microglobulin (B2M) reagent. Results within the measuring interval (0.25-18.00 mg/L) are not impacted.

This issue applies to all in-date and future Atellica CH B2M reagent lots for use on Atellica® CH and Atellica® CI Analyzers. The Instructions for Use (IFU) will be updated to support manual 1:2 dilution only with saline for samples > 18.00 mg/L.

Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
Atellica CH β2-Microglobulin (B2M)	B2M	11097635/00630414595566	All lots

Impact to Results

The impact is limited to β2-Microglobulin results above the measuring interval of 18.00 mg/L, up to 30.00 mg/L. In this range, results will recover falsely depressed upon auto-dilution. The issue may be apparent due to a “conc error” flag or the discordance between an undiluted result above the measuring interval that recovers erroneously within the measuring interval after dilution. Internal testing has demonstrated the observed auto-dilution recovery may be as low as 71% at a true concentration of 18.01 mg/L. See the Appendix, Table 1, for observed results. Results of this assay should always be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Manually dilute patient samples that are > 18.00 mg/L:
  1. Navigate to the CH Test Definition screen.
  2. Under Measuring Interval, uncheck "Repeat when Outside Measuring Interval."
  3. For samples that generate test results > 18.00 mg/L, prepare a **1:2** manual dilution with saline solution (0.9% unbuffered Isotonic saline).
  4. From the Create Patient Order screen, order the sample and enter "**2**" in the manual dilution field on the left of the screen.

     Note: The system will apply the 1:2 dilution factor and calculate the final result.
  5. Process the manually diluted sample.
  6. Report results greater than 36.00 mg/L as "**>36.00 mg/L**."
- 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.

Resolution

The Atellica CH B2M assay IFU will be updated with the above steps to support manual 1:2 dilution only with saline for samples > 18.00 mg/L. Please see Appendix, Table 2, for data using these revised instructions.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
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Product Manager CEE

Appendix I: Additional Data Describing the Product Issue

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Table 1. Representative Atellica CH B2M Auto-diluted Samples

Expected Result mg/L	Auto-diluted Result mg/L	% Recovery
18.01	12.81	71
25.00	19.18	77
27.00	21.04	78

Table 2. Representative Samples Manually Diluted with 0.9% Unbuffered Isotonic Saline

Sample	Dilution Factor (DF)	B2M Mean Results mg/L			% Recovery
		Expected	Test	Test x DF	
1	2	27.00	13.25	26.50	98
2	2	19.50	8.64	17.28	89
3	2	32.00	14.13	28.26	88