

Atellica® CH 930 Analyzer

β2-Microglobulin (B2M) Reagent Lot 211446 Bias with Quality Control and Patient Sample Results

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

Table 1. Atellica CH Affected Product

Assay	Test Code	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
β2-Microglobulin	B2M	11097635	211446	2022-06-01	2021-04-12

Reason for Correction

The purpose of this communication is to inform you of a bias with Quality Control (QC) and patient sample results when using the Atellica CH β2-Microglobulin (B2M) lot 211446 listed in Table 1.

Siemens Healthcare Diagnostics, Inc. has confirmed that the Atellica CH B2M lot 211446 exhibits a positive bias on patient samples of up to +20.9% at a B2M concentration of approximately 1.5 mg/L and a negative bias on patient samples of up to -10.5% at a B2M concentration of approximately 15 mg/L when compared to lot 201319. Siemens' investigation showed a similar bias when using Bio-Rad® Liquichek™ Immunology Controls. Refer to Figures 1, 2 and Table 3 in the Additional Information section for details.

This bias is specific to Atellica CH B2M lot 211446. Alternate lots of this product are available that are not impacted.

Siemens Healthcare Diagnostics is currently investigating the root cause of this issue.

Risk to Health

There is negligible risk to health for the described issue as the B2M biases observed would not lead to a clinically significant difference in patient management. Siemens is not recommending a review of previously generated results.

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Actions to be Taken by the Customer

- Discontinue use of and discard the kit lot listed in Table 1.
- Review your inventory of this product to determine your laboratory’s replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- Please review this letter with your Medical Director.
- 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.

Additional Information

Figure 1. Atellica CH B2M Lot 201319 (Reference Lot) vs 211446 (Impacted Lot) Method Comparison

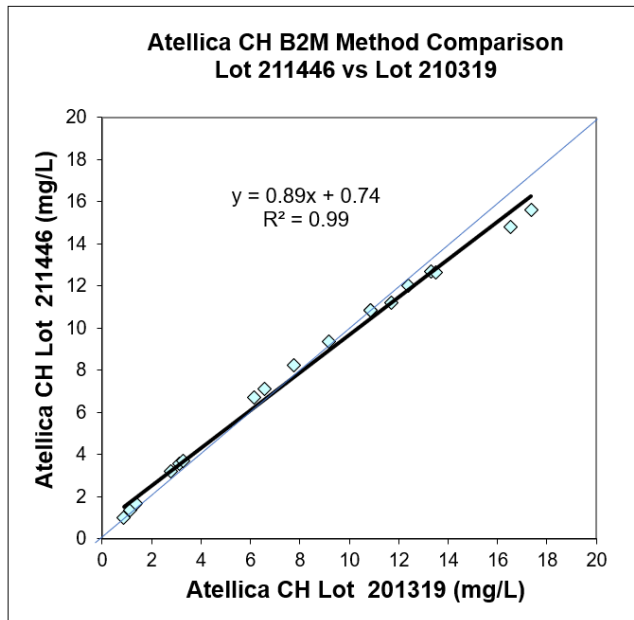


Figure 2. Atellica CH B2M Lot 201319 (Reference Lot) vs 211446 (Impacted Lot) Bias Plot

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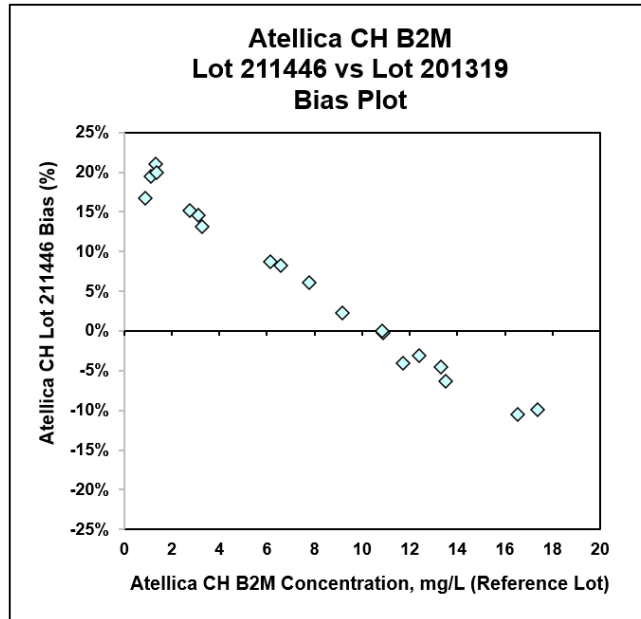


Table 3. Representative Bio-Rad® Liquichek™ Immunology Control Data Atellica CH B2M Lot 201319 (Reference Lot) vs 211446 (Impacted Lot)

QC Lot	Peer Mean (mg/L)	Peer SD (mg/L)	3SD Peer Range (mg/L)	Atellica CH Lot 201319 Mean (mg/L)	Atellica CH Lot 211446 Mean (mg/L)
Level 1 68951	0.78	0.089	0.51 – 1.05	0.74	0.88
Level 2 68952	1.70	0.173	1.18 – 2.22	1.58	1.84
Level 3 68943	3.01	0.193	2.43 – 3.59	2.81	3.26

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