

Atellica® IM

Atellica IM CKMB Calibrator Bias and Out of Range Results Using Master Curve Material (MCM)

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

Table 1. Atellica IM Affected Product(s)

Product	Catalog Number	Siemens Material Number (SMN)	Lot Number	Manufacturing Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Atellica IM CKMB Calibrator	10995532	10995532	57837A66 67443A66	2017-12-11	2018-12-11
Atellica IM CKMB MCM	10995534	10995534	11803	2016-08-10	2019-02-10

Reason for Recall

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions for your laboratory to take.

Siemens Healthcare Diagnostics has identified a bias with Atellica IM CKMB Calibrator kit lots ending in 66 (CK66) when compared to the internal standards and previously released Atellica IM CKMB Calibrator kit lots ending in 65 (CK65) on the Atellica IM system. The patient sample bias observed when comparing Atellica IM CKMB Calibrator kit lots ending in 66 to unaffected Atellica IM CKMB Calibrator kit lots ending in 65 is found in Table 2, Figure 1 and Figure 2.

Alignment to the internal standardization is restored with the release of Atellica IM CKMB Calibrator kit lots ending in 69 (CK69).

Customers may observe a shift in Quality Control (QC) material, Master Curve Material (MCM) and patient results when transitioning from Atellica IM CKMB Calibrator kit lots ending in 66. Refer to the *Additional Information* section for information related to patient sample bias and Bio-Rad controls.

Siemens has also identified the potential for out of range Atellica IM CKMB Master Curve Material results when using the Lot identified in Table 1 on the Atellica IM system.

The root cause is currently under investigation.

Table 2. CKMB Calibrator Lot-to-Lot Patient Sample Bias

Range of Patient Sample CKMB Values	Atellica IM
	CK66 vs. CK65
2.0 - 4.9 ng/mL (0.0250 - 0.0613 nmol/L) [Bias range]	0% [-3% to 4%]
5.0 - 25 ng/mL (0.0625 - 0.3125 nmol/L) [Bias range]	8% [5% to 10%]
26 - 50 ng/mL (0.3250 - 0.6250 nmol/L) [Bias range]	10% [10% to 11%]
51 - 150 ng/mL (0.6375 - 1.88 nmol/L) [Bias range]	12% [11% to 13%]
151 - 300 ng/mL (1.89 - 3.75 nmol/L) [Bias range]	14% [13% to 15%]

Figures 1 and 2 are bias plots created using the data from Table 2. Figure 1 includes the entire Analytical Measurement Range while Figure 2 focuses on the samples around the assay cutoff of 5 ng/mL (0.0625 nmol/L).

Figure 1. CKMB Calibrator Lot-to-Lot Bias on Atellica IM, 2.0 – 300 ng/mL (0.0250 – 3.75 nmol/L)

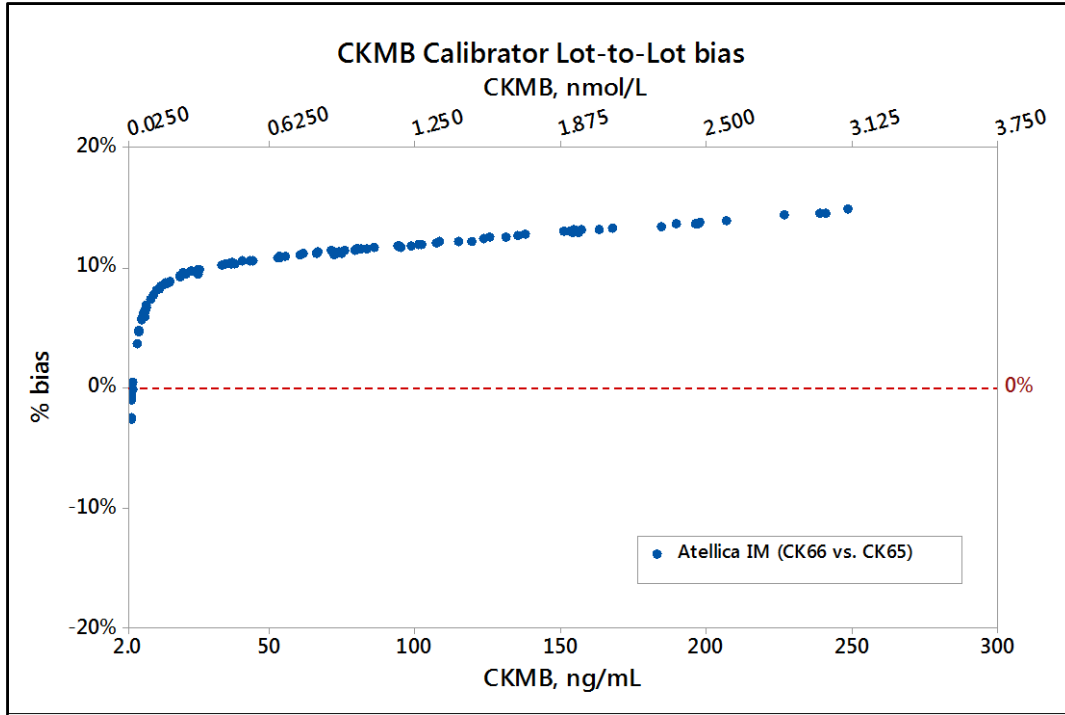
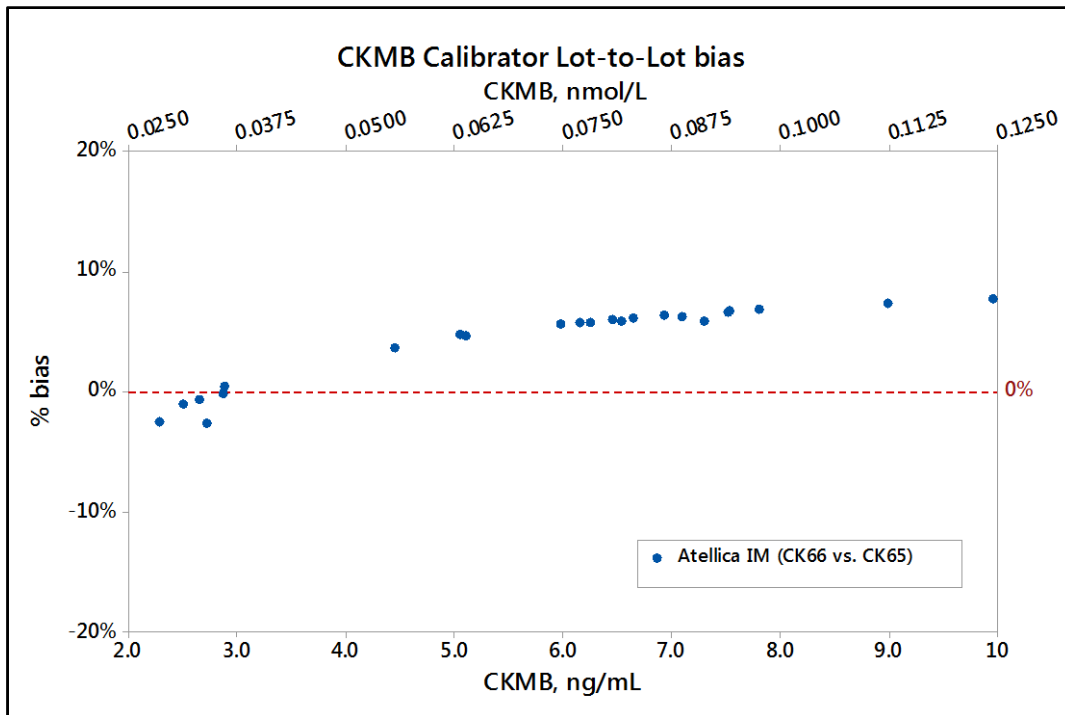


Figure 2. CKMB Calibrator Lot-to-Lot Bias on Atellica IM, 2.0 – 10 ng/mL (0.0250 – 0.1250 nmol/L)



Risk to Health

The differences in results across the assay range when using CK66 or when moving to CK69 (see *Additional Information*) would not be expected to cause a clinically significant difference in patient management during interpretation of serial CK-MB results and ECG assessment. There are minimal differences at the cutoff (**5 ng/mL or 0.0625 nmol/L**) for high suspicion of acute myocardial infarction. Failure of an MCM due to this issue is sporadic and would be apparent to the laboratory. The risk to health is negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Please review this letter with your Medical Director.

Atellica IM CKMB Calibrator kit lots ending in 66

- If you are currently using Atellica IM CKMB Calibrator kit lots in Table 1, review your inventory of these products and immediately order replacement Atellica IM CKMB Calibrator kit lots ending in 69 by completing the Field Correction Effectiveness Check Form attached to this letter.
- You may continue use of Atellica IM CKMB Calibrator kit lots in Table 1 until replacement product is received in your laboratory. Refer to Table 2, Figure 1 and Figure 2 for Atellica IM CKMB Calibrator lot bias information.
- Upon receipt of replacement product in your laboratory, discontinue use of and discard the Atellica IM CKMB Calibrator kit lots listed in Table 1.
- Atellica IM CKMB Calibrator kit lots ending in 65 may continue to be used until the assigned expiration date.

Refer to the *Additional Information* section for expected patient sample bias when transitioning to Atellica IM CKMB Calibrator kit lots ending in 69.

Atellica IM Master Curve Material

- Discontinue use of and discard the Atellica IM MCM lot in Table 1.
- Review your inventory of this product and order replacement Atellica IM CKMB Master Curve Material by completing the Field Correction Effectiveness Check Form attached to this letter.
- Utilize Atellica IM CKMB MCM Lot 39752 and future lots.

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 products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens 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 Customer Care Center or your local Siemens technical support representative.

Additional Information

When switching to Atellica IM CKMB Calibrator kit lots ending in 69, refer to the patient sample bias information in Table 3 and Figures 3 and 4. Table 3 data includes multiple calibrator lot and reagent lot combinations. Figures 3 and 4 represent a subset of the data in Table 3 and contain the bias observed between calibrator lots when using a constant reagent lot. Figure 3 includes the entire Analytical Measurement Range while Figure 4 focuses on the samples around the assay cutoff of 5 ng/mL (0.0625 nmol/L).

Table 3. CKMB Calibrator Lot-to-Lot Patient Sample Bias Across Various Reagent Lots

Range of Patient Sample CKMB Values	Atellica IM	
	CK69 vs CK65	CK69 vs CK66
2.0 - 4.9 ng/mL (0.0250 - 0.0613 nmol/L) [Bias range]	-2% [-21% to 6%]	-3% [-36% to 7%]
5.0 - 25 ng/mL (0.0625 - 0.3125 nmol/L) [Bias range]	-3% [-10% to 2%]	-7% [-14% to -4%]
26 - 50 ng/mL (0.3250 - 0.6250 nmol/L) [Bias range]	-3% [-8% to -2%]	-9% [-14% to -8%]
51 - 150 ng/mL (0.6375 - 1.88 nmol/L) [Bias range]	-4% [-10% to 2%]	-11% [-16% to -5%]
151 - 300 ng/mL (1.89 - 3.75 nmol/L) [Bias range]	-3% [-7% to -2%]	-11% [-15% to -10%]

Figure 3. CKMB Calibrator Lot-to-Lot Bias within Reagent Lots on Atellica IM, 2.0 – 300 ng/mL (0.0250 – 3.75 nmol/L)

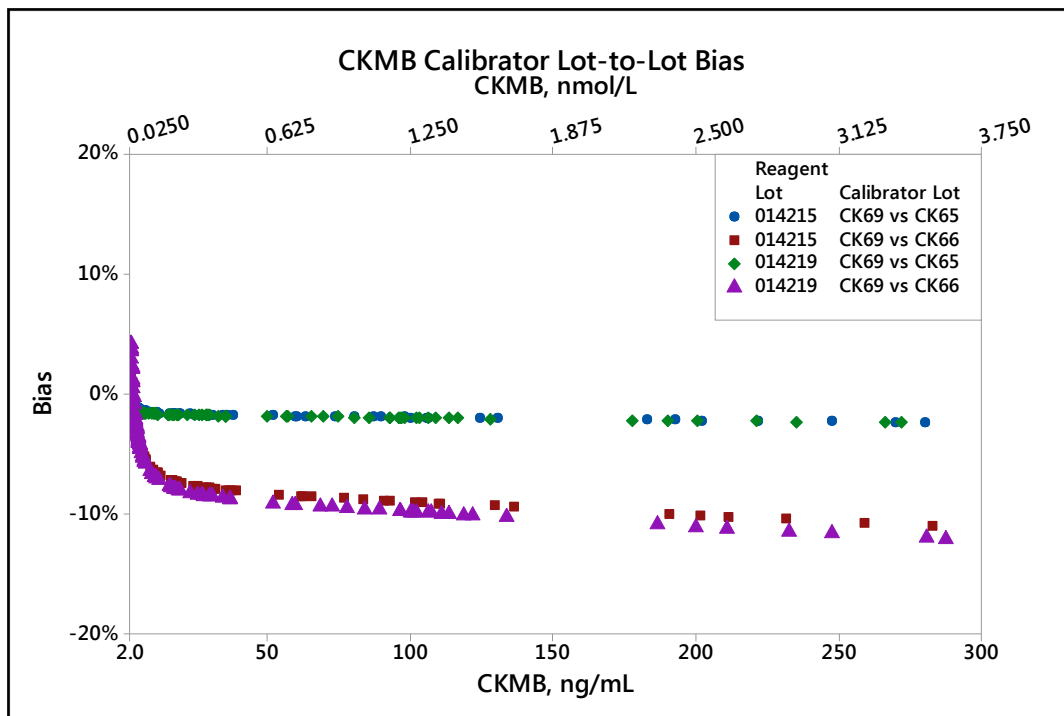
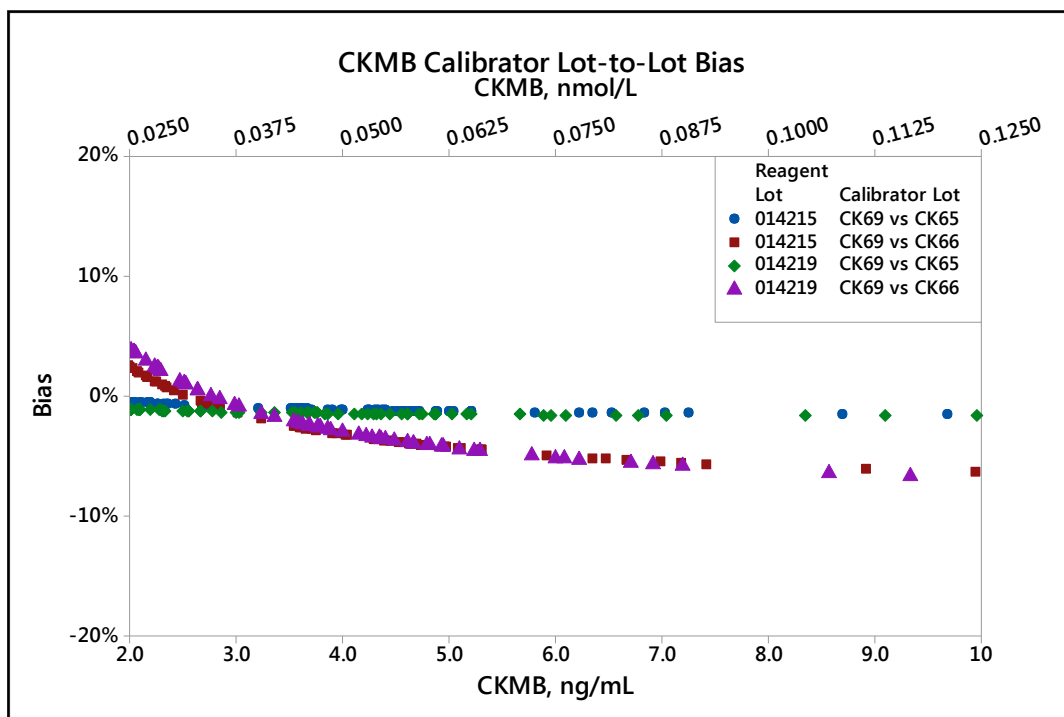


Figure 4. CKMB Calibrator Lot-to-Lot Bias Within Reagent Lots on Atellica IM, 2.0 – 10 ng/mL (0.0250 – 0.1250 nmol/L)



As stated in the Atellica IM CKMB assay Instructions for Use, each laboratory should select appropriate commercially available controls and evaluate control recovery based on their established internal laboratory quality control procedure. There are some changes to the Bio-Rad quality control material assignments resulting from this investigation. Please refer to the Bio-Rad website (www.qcnet.com) for new targets and ranges for Bio-Rad control products.

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the Atellica IM may not be available in all countries.

Atellica IM is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Atellica IM CKMB Calibrator Bias and Out of Range Results Using Master Curve Material (MCM)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated July 2018 regarding Atellica IM CKMB Calibrator Bias and Out of Range Results Using Master Curve Material (MCM). Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity Discarded/ Replacement Quantity Required
Atellica IM CKMB Calibrator/10995532 Lot 57837A66, 67443A66	
Atellica IM CKMB MCM/10995534 Lot 11803	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens technical support representative.