



July 2025

IMPORTANT PRODUCT INFORMATION

Product Name	List Number	Lot Number
i-STAT TriControls Calibration Verification Set	05P70-01	24057
		24124
		24212
		24306
		25091

Dear Valued Abbott Customer,

This letter contains important information regarding the *i-STAT* TriControls Calibration Verification Set lots 24057, 24124, 24212, 24306 and 25091.

BACKGROUND

When testing with *i-STAT* blood gas and chemistry cartridges, a five-level set of *i-STAT* TriControls Calibration Verification fluids may be used to confirm the calibration of the test system throughout the reportable range for each test.

Abbott Point of Care (APOC) has identified that when testing with vials from the *i-STAT* TriControls Calibration Verification Set lots listed above, low ionized calcium results outside of the value assignment sheet (VAS) ranges may be observed for some vials of Calibration Verification Level 5 lot from the sets. All other *i-STAT* TriControls Calibration Verification and Control fluid levels and lots perform as expected.

Abbott has made the decision to communicate this information to potentially affected customers. This action is not being conducted to reduce risk to health.

RECOMMENDED ACTIONS

Our records show that your facility has received fluids from *i-STAT* TriControls Calibration Verification Set lots 24057, 24124, 24212, 24306 and 25091. Please note, while we are working to address this issue, running of additional vials of Calibration Verification Level 5 may be required to achieve results within the value assignment sheet ranges for ionized calcium.

Alternatively, *i-STAT* Calibration Verification Set (list number 06F15-01) lots not impacted by this issue are available to support ionized calcium. Please note the equivalent high calcium level is Calibration Verification Level 1 in the *i-STAT* Calibration Verification Set. Additionally, a whole blood sample collected with lithium heparin and spiked with ionized calcium could also be used to evaluate the calibration verification.

If you have provided any of the *i-STAT* TriControls Calibration Verification Set lots 24057, 24124, 24212, 24306 and 25091 to another facility, please provide a copy of this letter to them.

ADDITIONAL INFORMATION

If you have any questions regarding this information, please contact Abbott Point of Care Technical Support at 1-844-256-9531 or via email at apoc_productinformation@abbott.com.

Abbott sincerely apologizes for any inconvenience this may create for your facility. We appreciate your understanding in this matter and thank you for your continued support of Abbott and Abbott products.

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i-STAT is a registered trademark of Abbott