

February 2016

IMPORTANT PRODUCT INFORMATION

Product Name	List #	Lot Numbers			
i-STAT [®] cTnI cartridge	06P23-25	L15230	P15285	P15292	P15296B
		L15230A	P15285A	P15293	P15300
		P15282D	P15287	P15294	P15301A
		P15283A	P15287A	P15294A	P15302
		P15284	P15288	P15295	P15302C

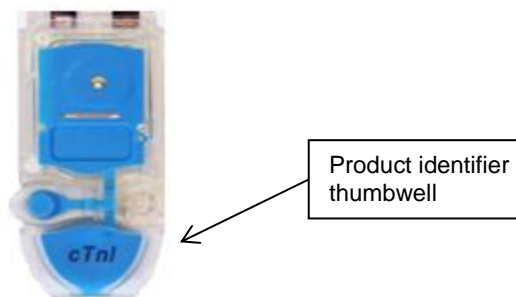
Dear Abbott Point of Care Customer,

This letter contains important information about the i-STAT[®] troponin I assay cartridge lot numbers that are listed above. If you have one or more of the affected lots at your facility, please review the information below.

BACKGROUND

The i-STAT cTnI test is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma samples. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Abbott Point of Care (APOC) has determined that there is a possibility that a very small percentage of i-STAT[®] cTnI cartridges distributed from the lot numbers above may have a product identifier other than cTnI embossed on the thumbwell of individual cartridges. The outside box and cartridge pouch were labeled correctly for these specified lots



The internal components, such as the reagent and analysis solution, are not impacted and the i-STAT System will appropriately recognize the cartridge as cTnI. Therefore the generated result is not impacted by this issue and will be within the expected performance of the troponin I assay.

APOC identified the cause, and appropriate steps have been taken via the APOC Corrective and Preventative Action system to address the issue and prevent recurrence.

APOC is communicating this information to ensure awareness for potentially affected customers. This communication is not being done to reduce risk to health.

REQUIRED ACTIONS

No action is required, as the cTnI cartridges from the lots listed above can continue to be used for patient testing. The cartridge will be recognized appropriately by the system and will generate results that are within the expected performance of the assay.

ADDITIONAL INFORMATION

If you have any questions regarding this information, please contact Abbott Point of Care Technical Support at 844-256-9531 or your Abbott Point of Care representative.

We appreciate your understanding in this matter, and thank you for your continued support of Abbott and Abbott products.

APOC2016-001

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.