

Abbott i-STAT Troponin Assay Point of Care, Emergency Centers

Laboratory Bulletin

Corewell Health was notified by the Abbott Point of Care division that the FDA issued a warning letter on November 8, 2022, indicating that the current version of the i-STAT cTnI (point of care troponin assay) is not FDA cleared due to changes made to the product since 2003.

Abbott Point of Care has performed testing that confirmed that the product continues to meet the vendor established performance specifications. Abbott has issued a statement indicating that they have determined that there are no indications of adverse testing performance using the i-STAT cTnI cartridge for patients.

The i-STAT troponin cartridges have been retired at Corewell Heath East. However, these cartridges had been used at the Canton and Dearborn campuses during the dates listed below:

Canton: 10/14/2002 to 9/6/2022
Dearborn: 1/26/2001 to 5/3/2022

The Abbott Point of Care division continues to investigate this issue. Please contact the Corewell Health Point of Care laboratories listed below for assistance.

Canton Point of Care: 734-671-3441
Dearborn Point of Care: 313-436-2367 or 313-593-7970

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