

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0914292	(X3) Date Survey Completed 01/12/2021
Name of Provider or Supplier Cardiology Associates Of Altoona Llp	Street Address, City, State 1321 11th Avenue, Altoona, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with Testing Person (TP) # 1 and (TP) # 2, the laboratory failed to perform external liquid quality controls (QC) of different concentration, each day of patient testing for Activated Clotting Time (ACT) test analyzed on the i-STAT analyzer in 2020. Findings include: 1. On the day of survey, 01/12/2021, review of ACT quality control records revealed that the laboratory performed external quality control for the i-STAT analyzer, on new shipments, new lot numbers and every month. 2. From 01-01-2020 through the date of survey laboratory performed the ACT test on 135 patient specimens. 4. TP # 1 and # 2 confirmed the findings above on 01/12/2021 around 13:30 pm.</p>