Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0914292	(X3) Date Survey Completed 03/13/2023
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and interview with the Technical Consultant (TC)#2, the laboratory failed to test 6 of 6 API PT Hematology/Coagulation samples with the laboratory's regular patient workload by personnel who routinely performed the testing in the laboratory in 2021 and 2022. Findings include: 1. On the day of survey 03/13/2023 at 09:15 am., review of the attestation statements revealed, that 3 of 3 API PT samples in 2021 and 3 of 3 API PT samples in 2022 were tested only by Testing Personnel #1. Testing Personnel# 2, # 3, #4 and #5 who routinely performed patient testing in 2021 and 2022 did not take part in the PT testing. 2. The TC confirmed the finding above on 03 /13/2023 around 09:30 am.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with Technical Consultant #2 (TC), the laboratory failed to establish a procedure to assess the

	competency of 1 of 2 Technical consultants for their supervisory responsibilities in 2021 and 2022. Findings include: 1. On the day of survey, 03/13/2023 at 09:20 am, TC #2 could not provide a procedure for the competency assessment for 1 of 2 TC (CMS 209 personnel # 3) for their supervisory responsibilities in 2021 and 2022. 2. No documentation was provided that competency assessments were performed for 1 of 2 TC (TC#2) for their supervisory responsibilities from 01/12/2021 to 03/13/2023 3. TC #2 confirmed the findings above on 03/13/2023 around 09:30 am.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on the review of test requisitions and interview with the Technical Consultant (TC), the laboratory failed to include the sex of the patient for Activated clotting time (ACT) examinations from 01/12/2021 to 03/13/2023. Findings Included: 1. On the day of survey 03/13/2023 at 09:20 am, a review of the patient test requisition revealed that the test requisition did not include the sex of the patient for ACT examinations from 01/12/2021 to 03/13/2023. 2. TC#2 confirmed the above finding on 03/13/2023 at 09:30 am.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of patient test reports and interview with Technical Consultant (TC), the laboratory failed to include the laboratory's address on patient test reports for Activated clotting time (ACT) examinations from 01/12/2021 to 03/13/2023. Finding Include: 1. On the day of survey, 03/13/2023 at 09:20 a.m., review of ACT

	test reports revealed, the final test reports did not include the laboratory's address from 01/12/2021 to the day of survey. 2. The TC confirmed the finding above on 03/13 /2023 around 09:30 am.