Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0863855	(X3) Date Survey Completed 03/12/2024
Name of Provider or Supplier Cardiology Oncology Associates	**Street Address, City, State** 400 Franklin Turnpike, Mahwah, NJ	

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 surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Testing Personnel (TP) and the Laboratory Director (LD), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology testing participated in all PT events from the American Proficiency Institute (API) in the calendar year of 2023. The findings include: 1. There were no signed attestation statements by TP that performed all PT events in 2023 2. During the interview with TP#1 and the LD, it was revealed that TP #1 performed all PT events in 2023. 3. TP#1 as listed on the CMS-209 form and the LD confirmed on 3/12/24 at 11:45 am that the laboratory failed to rotate all TP to participate in all Hematology PT events in 2023.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain all work records and signed attestation records for Hematology tests from American Proficiency Institute Associates (API) in the calendar years 2022 and 2023. The findings include: 1. The laboratory failed to maintain a copy of the work records for the 2nd PT event in 2022 and the 3rd PT event in 2023. 2. The Laboratory Director and TP failed to sign the attestation statements for all PT events performed in 2022 and 2023. 3. TP #1 as listed on the CMS 209 form confirmed on 3/12/24 at 1:35 pm, the laboratory failed to maintain a copy of all work records and have signed attestation statements for the above mentioned PT events.
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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow its policies and procedures for assessing the competency of TP in calendar years 2022 and 2023. The findings include: 1. The laboratory CA policy stated "Annual competency evaluations shall be completed and filed for all employees." 2. There was no documented evidence CA was performed on Four out of Four TP listed on the CMS 209 form in calendar years 2022 and 2023. 3. TP #1 as listed on the CMS-209 form confirmed on 3 /12/24 at 1:45 pm, the laboratory failed to follow its policies and procedures for assessing the competency of TP in 2022 and 2023.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have all applicable procedures for Hematology Tests on the date of survey. The findings include: 1. The "Panic Reports" procedure failed to include panic or alert values. 2. The laboratory failed to include Reference Intervals (RI) and source for the RI in the PM. 3. The laboratory failed to include the established Reportable Range for test results for the test system in the PM. 4. TP #1 as listed on the CMS-209 form confirmed on 3/12/24 at 12:00 pm that the PM failed to have all applicable procedures for Hematology tests. B) Based on surveyor review of the Procedure Manual (PM), the Manufacturers Package Insert (MPI) for the Coulter 4C-ES controls, and interview with the Testing Personnel (TP), the laboratory failed to have an accurate Quality Control (QC) procedure for Hematology Tests performed on the Beckman Coulter AcT diff 2 on the date of survey. The findings include: 1. The procedure "Material used for test control" states " Each controls are good for 3 months and doesn't matter how many times are run but they only can be take out of the refrigerator once a day." 2. The MPI states the 4C-ES controls have an open vial stability for a maximum of 20 times within 35 days. 3. TP #1 as listed on the CMS-209 form confirmed on 3/12/24 at 12:05 pm that the PM failed to have an accurate procedure for QC performed on the Beckman Coulter AcT diff 2.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material, review of the Manufacturers Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to write expiration dates on QC material used to perform Hematology tests on the Beckman Coulter AcT Diff 2 analyzer from 3/5/24 to 3/12 /24. The findings include: 1. The Coulter 4C-ES MPI stated the stability of QC material changes once opened. The opened vial stability of QC material is 20 times used within 35 days. 2. The laboratory failed to write expiration dates on QC material in use to reflect the open vial stability date. 3. The TP #1 confirmed on 3/12/24 at 1:45 pm, the laboratory failed to write expiration dates on opened QC material.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to follow the "Frequency of Calibration" procedure for Hematology tests performed on the Beckman Coulter AcT Diff 2 analyzer. The findings include: 1. The PM states "Calibration will also be performed on a weekly basis in addition to reagent lot changes." 2. During the interview with TP #1 as listed on the CMS 209 form, it was revealed that calibration verification was only performed every 6 months and not performed after reagent lot changes. 3. TP #1 as listed on the CMS 209 form confirmed on 3/12/24 at 1:00 pm, the laboratory failed to follow the "Frequency of Calibration" procedure.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) 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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), reagent inventory logs and interview with the Testing Personnel (TP), the laboratory failed to follow the "Reagent Validation" procedure for Hematology tests performed on the Beckman Coulter Act diff II analyzer on the date of survey. The findings include: 1. The PM states " To assure the new reagent is performing properly, please run controls. If the controls are within range and they do not show a shift, you are free to use the reagent. If not, you must try a different kit and or lot." "Please fill out the reagent inventory log and attach the Quality Control (QC) results." 2. There was no documented evidence the above procedure was followed and performed after a change of reagents was introduced. 3. TP #1 as listed on the CMS-209 form confirmed on 3/12/24 at 12:10 pm, the laboratory failed to follow the "Reagent Validation" procedure.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology QC used on the Beckman Coulter AcT Diff 2 analyzer from 1/2/24 to the 3/12/24. The findings include: 1. There was no documented evidence that QC material was verified for the following Lot numbers: a) 06900 L expiration date of 4/8/24 b) 07900 N expiration date of 4/8/24 c) 08900 H expiration date of 4/8/24 d) 068600 L expiration date of 1/15/24 e) 078600 N expiration date of 1/15/24 f) 088600 H expiration date of 1/15/24 2. TP #1 as listed on the CMS 209 form confirmed on 3/12/24 at 11:20 am that all assayed QC material was not verified before putting in use.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the lack of Performance Specification (PS) records and interview with Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter AcT Diff 2 analyzer were adequate from 6/20/19 to 3/12/24. The finding includes: 1. There was no documented evidence Precision, Accuracy, Reportable Ranges and other pertinent performance characteristics were verified before the use of patient testing for the Beckman Coulter AcT Diff 2 analyzer . 2. TP #1 confirmed on 3/12/24 at 1:20 pm, the LD failed to ensure the PS were adequate before put into use before patient testing.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Assessment (QA) plan, the Procedure Manual (PM), and interview with Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the QA program was maintained to assure the quality of laboratory services provided in calendar years 2022 and 2023. The findings include: 1. The laboratory failed to follow the Comprehensive Remedial Action (CRA) procedure as stated in the QA plan. 2. There were no CRA logs observed for calendar year 2023. 3. There were no Quality Assessment Reviews as stated in the QA plan performed in calendar years 2022 and 2023. 4. TP #1 as listed on the CMS 209 form confirmed on 3/12/24 at 1:30 pm that the LD failed to ensure the QA program was maintained.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Testing Personnel (TP) files and interview with TP, the Laboratory Director (LD) failed to ensure that all TP who performed Hematology testing had appropriate education and training documentation on the date of survey. The findings include: 1. There were no education records for Three out of Four TP listed on the CMS 209 form. 2. There were no training records for using the Beckman Coulter Act Diff II analyzer for Three out of Four TP listed on the CMS 209 form. 3. TP #1 as listed on the CMS 209 form confirmed on 3/12/24 at 1:40 pm, the LD failed to ensure all TP had the appropriate education and training records.