Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0863855	07/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Cardiology Oncology Associates	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) 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) for the 2nd and 3rd events of 2025. The findings include: 1. The Laboratory Director and TP failed to sign the attestation statements for the 2nd and 3rd events of 2025 3. TP #1 as listed on the CMS 209 form confirmed on 7/7/26 at 11: 35 am, the laboratory failed to maintain signed attestation statements for the above mentioned PT events.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(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 Medonic M series analyzer from 3/5/24 to 7/7/26. The findings include: 1. The Boule QC MPI stated the stability of QC material changes once opened. The opened vial stability of QC material is 14 days. 2. The laboratory failed to write open and expiration dates on QC material in use to reflect the open vial stability date. 3. The TP #1 confirmed on 7/7/26 at 11:45 am, the laboratory failed to write open and expiration dates on opened QC material. Note: This was previously cited 3/12/24.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 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 have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing hematology patient specimens in a manner that ensures accurate and reliable patient test results and reports from July 2024 to 7/7/26. The finding includes: 1. There were no CA procedures for Failed Quality Control (QC) results. 2. The TP#1 listed on CMS form 209 confirmed on 7/7/26 at 12:00 pm that the laboratory failed to have available CA procedures.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Testing Personnel (TP), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 3/13/24 to 7/7/24. The finding includes: 1. The laboratory failed to have a procedure to monitor and assess Quality Control (QC) shifts and trends for Hematology testing. 2. The laboratory did not have a policy with criteria on when to repeat a patient test. 3. The TP#1 listed on CMS form 209 confirmed on 7/7/26 at 10:40 am that the laboratory failed have an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system as mentioned above.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 documentation on 7/7/26. The findings include: 1. There were no education records for two out of five TP listed on the CMS 209 form. 2. TP #1 as listed on the CMS 209 form confirmed on 7/7/26 at 11:40 am, the LD failed to ensure all TP had the appropriate education records.