Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2076677	04/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cardiovascular Institute Of Central Florida	2105 Sw 20th Pl, Ocala, FL	

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
D0000	A recertification survey was performed on 4/3/23 at Cardiovascular Institute of Central Florida, a clinical laboratory located in Ocala, Florida. Cardiovascular Institute of Central Florida was found NOT in compliance with the 42 CFR Part 493, Requirements for Laboratories.
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 record review and staff interview, the laboratory did not have documentation of signed attestations for four of four testing events reviewed. The findings include: The laboratory was unable to provide documentation of American Proficiency Institute (API) attestations signed by the Laboratory Director or designee for the 1st, 2nd, and 3rd Hematology event in 2022 and the 1st Hematology testing event in 2023. The interview with the Office Manager on 4/3/23 at 11:00am confirmed the documentation was missing.
D2123	HEMATOLOGY CFR(s): 493.851(c)

	Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) and resulted in a score of zero (0)% for the 2nd testing event in 2022. Findings include: Review of the American Proficiency Institute (API) records for 2nd Hematology event in 2022 showed the laboratory received a score of 0% for the analyte ACT (Activated clotting time). Notes on the API "Failures Summary" sheet stated "Failure to Participate" for the "ACT (i-Stat)" and "ACT (Medtronic)". During an interview on 4/3/23 at 11:15am, the Office Manager stated that the laboratory had ceased testing using both the Medtronic and i-Stat instruments for ACT testing. He was unsure why API scored a 0% for both instruments.
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 employee competency records, and interview with the Office Manager, the Laboratory Director or Technical Consultant failed to document complete competency evaluations for two out of two Testing Personnel (#A and #B) who perform hematology testing on the i-Stat in 2022 and the Laboratory Director failed to perform competency evaluations for two out of two Technical Consultants (#C and #D) in 2022 or 2023. The findings included: Record review of the Form CMS 209 signed by the Laboratory Director on 3/31/2023 showed two Testing Personnel (#A and #B). Review of employee competency records showed Testing Person A and Testing Person B were assessed for competency on 12/1/2022. The two documents titled "Testing Personnel Competency Assessment" were not signed by a Technical Consultant or the Laboratory Director. Record review of the Form CMS 209 signed by the Laboratory Director on 3/31/2023 showed two Technical Consultants (#C and #D). The laboratory was unable to provide documentation of competency assessments for the two Technical Consultants. On 4/3/22 at 11:30 a.m., the Office Manager confirmed the documents for competency were not signed and the Technical Consultants did not provide the documentation of their assessment.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory failed to review proficiency test scores for 3 of 3 testing events in 2022. Findings include: Review of American Proficiency Institute (API) proficiency test records showed the Laboratory Director or designee failed to document review of the 1st, 2nd, and 3rd Hematology testing events in 2022. During interview on 4/3/23 at 11:15am, the Office Manager confirmed the laboratory did not document review of proficiency test scores for the events listed above. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform external quality control (QC) on the i-Stat for the analyte ACT each day of patient testing or establish an IQCP (Individualized Quality Control Plan) for 15 out of 15 months (January 2022 - March 2023) reviewed. Findings include: Review of QC records for the Abbott i-Stat system showed that external QC was not performed each day of patient testing in 2022 and 2023. During an interview on 4/3/23 at 11:20am, the Office Manager confirmed that external QC was not performed each day of patient testing and confirmed the laboratory had not developed an IQCP.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when QC was unacceptable on 2/23/2022 for ACT testing. Findings include: The review of the "i-Stat System Incoming Cartridge QC Log" showed on 2 /23/2022, the ACT Celite cartridge with lot number R22009 was received. Quality control levels one and two were performed. The documentation for Level 2 control

	(lot number 271137) showed a result of 320. The expected range for lot number 271137 was 371 - 689 seconds. There was no documentation showing corrective action for the out of range control. During the interview on 4/3/23 at 11:15am, the Office Manager confirmed the documented QC result was out of range.