Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2166119	09/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Heart Center Cardiology Pc, The	121 N 20th Street Ste 20b, Opelika, AL	

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 a review of the API (American Proficiency Institute) proficiency testing (PT) records, a review of the personnel files, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. One of three testing personnel (TP) listed on the Form CMS-209 (Laboratory Personnel Report) performed all or a portion of the testing on six out of seven PT surveys in 2020 - 2022. The finding include: 1. A review of the 2020 - 2022 API PT records revealed Testing Personnel #1 had signed all attestation statements as the testing personnel on 2020 Event #1 (D-Dimer testing), and had signed as performing all the testing on 2020 Event #2 and #3, 2021 Event #1 and #2, and 2022 Event #2. Testing Personnel #2 had not performed a PT survey since January 2020. 2. A review of the personnel files revealed Testing Personnel #3 was a full time employee and had been trained to perform moderate complexity patient testing since the previous CLIA survey on 10/30 /2019. However, the laboratory had failed to include TP #1 in the rotation schedule to perform PT in 2021 and in 2022. Testing Personnel #2 was trained to perform moderate complexity patient testing in March 2021, however she had only performed one PT survey, 2021 Event #3. 3. In an interview on 9/6/2022 at 12:50 PM the surveyor reviewed the requirement for rotation of proficiency testing with Testing Personnel #1, who confirmed the above findings. .
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records, a review of the policy and procedure manual, and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statement for one of eight 2020-2022 PT surveys. The findings include: 1. A review of the API 2022 Event #1 Chemistry survey records revealed the Laboratory Director and the Testing Personnel failed to sign the attestation statement. 2. During an interview on 9/6/2022, at 12:55 PM, surveyor reviewed the instructions on the attestation statement requiring the Laboratory Director (or designee) and testing personnel to sign the document; Testing Personnel #1 confirmed the Laboratory Director and Testing Personnel had failed to sign the attestation for the above survey. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement Quality Assurance (QA) reviews to ensure completeness of documentation and ensure PT performance was rotated between all testing personnel and instruments on which patient testing was performed. This was noted in PT surveys from 2020 through 2022. The findings include: 1. A review of QA records revealed the laboratory failed to implement PT reviews and procedures to ensure: A) Proficiency testing was rotated between all personnel who performed patient testing. (Refer to D2007.) B) Attestation statements were signed by the Laboratory Director and Testing Personnel. (Refer to D2009.) C) Proficiency testing for D-Dimer and Cardiac Profiles was performed on both Alere Triage Meters (alternate PT surveys). The surveyor noted no PT was performed using Triage Meter #1 (Serial #83099) since 2/1/2021 (API 2021 Event #1), and the laboratory had not implemented any other mechanism to compare results between the two instruments. (Refer to D5775.) During an interview on 9/6/2022 at 12:50 PM, Testing Personnel #1 stated the Triage Meters (#1 and #2) were both used equally for patient testing. 2. During the exit summation on 9/6/2022 at 4:30 PM, the above findings were reviewed and confirmed with Testing Personnel #1. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must

	have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a lack of comparison data for D-dimer and Cardiac Profile (Troponin T and CK-MB [Creatine Kinase-MB]) on Alere Triage Meter #1 (Serial #83099) and #2 (Serial #82979), and interviews with Testing Personnel #1, the laboratory failed to implement comparison activities twice a year to evaluate and compare test results between the two instruments in 2020-2022. The findings include: 1. A review of Alere Triage Meter records revealed the laboratory failed to implement a mechanism to compare D-dimer and Cardiac Profile results between Meter #1 and #2. 2. During an interview on 9/6/2022 at 12:50 PM, Testing Personnel #1 stated the Triage Meters (#1 and #2) were both used equally for patient testing. 3. During an interview on 9/6/2022 at 4:25 PM, Testing Personnel #1 confirmed the laboratory had not performed and documented any comparisons between the two Triage Meters. SURVEYOR ID #32558 Licensure and Certification Surveyor