Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0213986	10/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Heart Center, The	7610 Carroll Avenue Suite 300, Takoma Park, MD	

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
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 review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure PT records included the statements signed by the testing person (TP) and laboratory director (LD) or designee attesting to the routine integration of the PT samples into the patient workload using the laboratory's routine methods. Findings: 1. Records for six PT events were reviewed. 2. All six events were missing attestation statements that were signed by the TP and LD or designee. 3. During the survey on 10/02/2023 at 3:30 PM, the TC confirmed that the statements attesting to the routine integration of PT samples into the patient workload were not signed by the TP and LD or designee.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to test endocrinology PT samples the same number of times it routinely tested patient samples. Findings: 1. Records for six PT events were reviewed and showed that the PT samples tested on the Tosoh analyzer for

	thyroid-stimulating hormone, free triiodothyronine, and free thyroxine were run in duplicate. 2. During the survey on 10/02/2023 at 2:58 PM, the TP confirmed that PT samples were run in duplicate when patient samples were run a single time.
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 (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the review of the PT results evaluation was documented. Findings: 1. Records for six PT events, three in 2022 and three in 2023, and two 2022 off-cycle PT events were reviewed. 2. Evaluations from all five PT events from 2022 (three regular and two off-cycle events) did not have a signature and date from the laboratory director or designee indicating that the PT results were reviewed. 3. During the survey on 10/02/2023 at 3:30 PM, the TC confirmed that the five PT events from 2022 were not signed as reviewed by the laboratory director or designee.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director failed to ensure that unacceptable PT results had documentation of an investigation into the root cause of the failures and the corrective actions taken to ensure accuracy of test results. Findings: 1. Records for five 2022 PT events were reviewed (three regular and two off-cycle events). 2. The 2022 1st Chemistry-Core PT event was not submitted to the PT provider prior to the cutoff date and the laboratory received 0% for all analytes. A self-evaluation performed in the beginning of February 2022 gave results of 20% for low-density lipoprotein, 80% for lactate dehydrogenase (LD), 20% for creatinine, and 80% for albumin. 3. For the 2022 2nd Chemistry-Core PT event, the laboratory received 40% for bilirubin and reported a test problem with cholesterol, carbon dioxide, creatinine, potassium, and sodium. 4. The laboratory received 20% for bilirubin in an off-cycle PT performed in 08/2022. 5. For the 2022 3rd Chemistry-Core PT event, the laboratory received a 60% for free triiodothyronine, 60% for free thyroxine, and 20% for creatinine and reported AST, bilirubin, carbon dioxide, and LD as suspended. 6. For all 2022 PT results listed above, there was no documentation that the results evaluations were reviewed (cross-refer to tag D5211 for details) and no documentation of an investigation into the root cause of the PT failures, whether patient specimens may have been affected, or what corrective actions were

	implemented to ensure accuracy of test results. 7. During the survey on 10/02/2023 at 3:30 PM, the TC confirmed that there was no documentation of the investigations into 2022 failed PT results and what corrective actions were taken.