Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0213986	07/19/2019
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to successfully participate in the American Proficiency Institute (API) PT program for white cell count differential (D2122); and the laboratory failed to investigate the three of four failures in hematology and implement a plan of correction to prevent additional failures (D2103).
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid

	approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on record review on 06/21/19 at the laboratory, review of OSCAR federal 153 and 155 reports and interview with the technical consultant, the laboratory failed to successfully participate in the American Proficiency Institute (API) proficiency testing (PT) program for hematology testing in which the laboratory is certified under CLIA (Refer to D2016). Findings: 1. The laboratory failed to successfully participate in the API PT program for three of four testing events. 2. The OSCAR reports showed that the laboratory received a score of 27% for WBC diff during the 1st event in 2018; a score of 73% during the 2nd event of 2018; and a score of 60% for the 1st event of 2019. The laboratory failed to attain an overall score of 80% for three of four failures for WBC diff . 3. During the survey on 06/21/19 at 2:00 PM the technical consultant confirmed that the laboratory had not completed the investigation into the failures and was in the process of performing off-cycle PT.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of Certification and Survey Provider Enhanced Reporting (CASPER) system Individual Laboratory Profile, review of proficiency testing (PT) documentation and interview with the technical consultant, the laboratory failed to attain an overall score of at least 80% for three of four failures in hematology events. Findings: 1. The CASPER Report showed that the laboratory received a score of 27% for WBC diff during the 1st event in 2018; a score of 73% during the 2nd event of 2018; and a score of 60% for the 1st event of 2019. 2. During the survey on 06/21/19 at 2:00 PM the technical consultant confirmed that the laboratory failed to attain an overall score of 80% for three of four failures for WBC diff .
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on review of Certification and Survey Provider Enhanced Reporting (CASPER) system Individual Laboratory Profile, review of the American Proficiency Institute (API) proficiency testing (PT) documentation and interview with the technical consultant, the laboratory failed to investigate the three of four failures in hematology and implement a plan of correction to prevent additional failures. Findings: 1. The CASPER Report showed that the laboratory received a score of 27% for WBC diff during the 1st event in 2018; a score of 73% during the 2nd event of 2018; and a score of 60% for the 1st event of 2019. 2. During the survey on 06/21/19 at 2:00 PM the technical consultant confirmed that an investigation had not been conducted for the three of four failures for WBC diff to prevent future failures and ensure the accuracy of patient test during that time period.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) records, the operator's manual and interview with the technical consultant (TC) on 07/19/19, the laboratory failed to follow the manufacturer's instructions when switching to a new lot number of QC materials. Findings: 1. According to the operator's manual for the Cell-Dyn 1700 (hematology analyzer) the user is required to follow the six steps listed under the "Assay Verification" procedure. The laboratory is required to test the new QC materials alongside of the old QC materials, "Run the new controls twice a day for five days to establish a mean", and calculate the new mean and standard deviation (SD). 2. The hematology QC records for 2018 and 2019 showed that the laboratory started using the QC materials once the old QC materials expired. 3. During the exit survey on 07/19/19 at 1:00 pm the TC confirmed that the laboratory records did not show that the laboratory followed the six steps listed under the "Assay Verification" procedure as required.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of the procedure manual and interview with the technical consultant, the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the survey on 06/21/19 at 2:00 pm the technical consultant confirmed that the laboratory's procedure manual did not specify in writing the duties and responsibilities of the laboratory testing personnel.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the testing personnel, the technical consultant failed to ensure that remedial actions were taken and documented when quality control results were not within acceptable limits (D6043); failed to ensure that all testing personnel received an annual competency review for 2017.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: I. Based on review of the Levey-Jennings (L-J) Report, Action Logs, the documented review performed by the technical consultant (TC) and interview with the TC and chemistry testing personnel, the TC failed to ensure that remedial actions were taken and documented when quality control (QC) results were not within acceptable limits. Findings: 1. The laboratory batches the chemistry specimens and performs the testing once a week. There are usually 3 to 4 chemistry QC tested each month. 2. Review of the L-J Report for August and November 2018 showed that both levels of QC materials were only tested once for Carbon Dioxide (CO2) for each month. 3. Review of the Action Logs did not show that there were problems with the CO2 for the months of August and November in 2018 and that the QC had been tested or retested for CO2 failures. 4. The review performed by the TC did not include an investigation into the reason why the QC materials were only tested once in the months of August and November 2018 for CO2 and the rest of the analytes had been tested 3 times. 5. The chemistry testing person stated that when the when the calibration fails the analyzer will not report patient results for the analyte that failed. The testing person stated that the doctor is notified of the failure so he can let them know if the analyte(s) are needed. If the doctor decides that the analyte(s) are not need then testing continues and only the analytes that passed calibration are reported. 6. During the survey on 06 /21/19 at 2:30 pm the TC confirmed that the laboratory records did not include documented remedial actions by the chemistry testing person and the TC who reviewed the records. II. Based on review of the L-J Report, Action Logs, the

	documented review performed by the TC and interview with the TC, the TC failed to ensure that remedial actions were taken and documented when endocrinology quality control (QC) results were not within acceptable limits. Findings: 1. The laboratory batches the endocrinology specimens and performs the testing once a week. There are usually 3 to 4 endocrinology QC tested each month. 2. The laboratories policy is to repeat any QC result that are greater than 2 SD. 3. Review of the L-J Report for December 2018 showed that one of three levels of QC materials for estradiol was greater than 3SD and no remedial actions were documented. 4. Review of the L-J Report for December 2018 showed that one of three levels of QC materials for insulin was greater than 3SD and one of three levels of QC was greater than 2SD and no remedial actions were documented. 5. Review of the Action Logs did not show that there were problems with the estradiol and insulin for the month of December in 2018 and that the QC had been tested or retested for the failures. 6. The review performed by the TC did not include an investigation into the reason why the QC materials were not repeated when the results were greater than 2SD. 7. During the survey on 06/21/19 at 2:30 pm the TC confirmed that the laboratory records did not include documented remedial actions by the endocrinology testing person and the TC who reviewed the records. III. Based on review of the L-J Report, Action Logs, the documented review performed by the TC and interview with the TC, the TC failed to ensure that remedial actions were taken and documented when creatine kinase (CK) QC results were not within acceptable limits and the L-J report listed two different means for the same lot number. Findings: 1. The November 2018 L-J reports for CK were reviewed. 2. For level 2 the expected mean was 316.0 and 2SD was equal to 63.0 for 11/07/18, 11/14 /18 and 11/29/18. 3. For level 3 the expected mean was 532.5 and 2SD was equal to 106.5 for 11/07/18, 11/14/18 and 11/29/18. 4. On 11/29/18 the result for level 2 was 241 and level 3 was 0.0 according to the L-J report both levels were which was greater than 2SD. 5. Review of the Action Logs showed that on 11/28/19 patient CK results were not reported but there was no documentation explaining why. 6. The December 2018 L-J reports for CK were reviewed. 7. For level 1 the expected mean was 97.5 and 2SD was equal to 19.5 for 12/05/18 and 12/12/18. For 12/19/18 and 12 /28/19 the expected mean was 77.5 and 2SD was equal to 15.5. 8. For level 2 the expected mean was 422.5 and 2SD was equal to 84.5 for 12/05/18. For 12/12/18, 12 /19/18 and 12/28/19 the expected mean was 316.0 and 2SD was equal to 63.0. 9. Review of the Action Logs did not show that there were problems with the CK for the month of December in 2018. 10. The TC signed off as having reviewed the QC results but failed to investigate the incorrect date for patient CK results not being reported in November 2018 and the change in the mean and SD without a change in lot number and expiration date for November 2018. 11. During the survey on 06/21/19 at 2:30 pm the TC confirmed that the laboratory records did not include a documented investigation explaining why CK patient results were not reported on 11/29/18 and why there were changes in the mean and SD of the CK QC for the month of December 2018.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by:

	Based on review of the annual evaluations and interview with the technical consultant, the technical consultant failed to ensure that all testing personnel received an annual competency review for 2017. Findings: 1. The laboratory currently has three testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." 2. The testing personnel evaluation records for 2017 and 2018 were reviewed. Two of the three testing persons did not have documentation showing that their annual reviews had been performed in 2017. 3. During the survey on 10/12/2018 at 2:00 PM the testing personnel confirmed that the annual evaluations for 2017 and 2018 were not performed by the qualified technical consultant and some of the training was not available