Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2207679	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Park Slope Cardiology Pc	370 9th Street - Unit 1b, Brooklyn, NY	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records as well as an interviews with the Testing Personnel (TP) and Laboratory Director (LD), the laboratory failed to enroll in an approved PT program. FINDINGS: 1. There was no documentation of enrollment or performance in an approved PT program for each of the testing specialties and subspecialties. 2. The LD and TP confirmed the findings on August 14, 2024, at 11:30 A.M.
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 standard operating procedures (SOPs), personnel training records,

	competency evaluation documentation, as well as interview with the LD, the LD failed to draft, approve training and competency evaluation policies as well as perform and document TP initial training, six-month, and annual competency evaluations. FINDINGS: 1. The LD failed to draft and approve a written training, competency evaluation policy comprising of the following guidelines: a. Direct observations of routine patient test performance, specimen preparation, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, PT results, and preventive maintenance records. d. Direct observations of instrument maintenance performance and function checks. e. Assessment of patient test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f. Assessment of problem-solving skills. 2. There was no documentation of TP initial training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the current, approved SOPs, i-Stat manufacturer's instructions, lack of temperature and humidity records, as well as interview with the TP, the laboratory failed to monitor and document, refrigerator, room temperature and humidity in the area where patient specimen testing and test kit storage occurred. FINDINGS: 1. There was no documentation of refrigerator, room temperature and humidity in the area where patient specimen testing and test kit storage occurred from 2022 through the date of survey. 2. The i-Stat manufacturer's instructions specified analyzer operating temperature range of 16-30C (61-86F). 3. There was no documentation of temperature monitoring for the refrigerator utilized for storage of i-Stat test cartridges. The i-Stat manufacturer's instructions specified test kit storage temperature between 2-8C (35-46F). 4. Approximately forty one patients were tested in 2022 and 2023. 5. The current, approved SOPs did not include instructions for monitoring and documenting refrigerator, room temperature and humidity in the area where patient specimen testing and test kit storage occurred. 6. The TP confirmed the findings on August 14, 2024, at 11:30 A.M.
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 review of Quality Control (QC) records, Individualized Quality Control Plan (IQCP), and interview with the TP, the laboratory failed to comply with established requirements for QC testing. FINDINGS: 1. The current, approved IQCP specified performance of external QC for new lot/shipment (two positive and one negative) and at least every thirty-one days. 2. In an interview with the TP, it was determined that one level of QC was performed on new lots. 3. Approximately forty one patients were tested in 2022 and 2023. 4. The TP confirmed the findings on August 14, 2024, at 11: 30 A.M.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of SOPs, personnel training records, competency evaluation documentation, lack of Quality Assurance (QA) policies, as well as interview with the LD, the LD failed to provide overall management for all phases of patient specimen testing. FINDINGS: The LD failed to: 1. Draft, approve QA policies for all phases of moderate complexity testing. Refer to D6021. 2. Perform and document TP training and competency evaluations. Refer to D6029. 3. Draft and approve policies for monitoring personnel who perform moderate complexity testing to assure training and competency. Refer to D6030. 4. Specify in writing, TP duties and responsibilities for all phases of laboratory testing. Refer to D6032. 5. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on lack of PT documentation as well as interviews with the TP and LD, the LD failed to enroll the laboratory in an HHS approved PT program. Refer to D2000.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of SOPs, lack of QA policies, and interview with the LD, the LD failed to draft, approve, and maintain QA policies for all phases of the general laboratory system. FINDINGS: 1. The current, approved SOPs did not include QA policies assuring quality of laboratory services provided. 2. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(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 review of personnel training records, competency evaluation documentation, as well as interview with the LD, the LD failed to ensure that training and competency evaluations were performed, documented for TP responsible for moderate complexity patient specimen testing. FINDINGS: 1. The current, approved SOPs did not include instructions for personnel training, competency evaluation. 2. There was no documentation of TP initial training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of personnel training and competency documentation, the LD failed to

	ensure compliance with policies and procedures for monitoring personnel who conduct specimen testing to assure training and competency. FINDINGS: 1. The current, approved SOPs did not include instructions for personnel training, competency evaluation. 2. There was no documentation of TP initial training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
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 lack of personnel training, competency evaluation records as well as interview with the LD, the LD failed to specify in writing, TP duties and responsibilities for all phases of laboratory testing. FINDINGS: 1. The current, approved SOPs did not include instructions for personnel training, competency evaluation. 2. There was no documentation of TP initial training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on August 14, 2024, at 11:30 A.M.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of QC records, IQCP, and interview with the TP, the LD failed to comply with current, approved requirements for QC testing. Refer to D5445.