Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2102021	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Premier Cardiology Consultants Pllc	2001 Marcus Avenue, Suite E247-E249, Lake Success, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's package inserts for Abbott i-STAT Chem 8+ cartridge and interview with the practice manager, the laboratory failed to follow the manufacturer's requirements for performing external controls with each new kit for above test. FINDINGS: 1. The surveyor reviewed the manufacturer's package insert and the quality control (QC) requirements for the Abbott i-STAT Chem 8+ cartridge at survey. 2. The practice manager confirmed on November 20, 2019 at approximately 11:00 AM, that the laboratory failed to follow the manufacturer's requirements for external QC which requires that external QC to be tested with each new shipment of cartridge, each new lot of cartridge and monthly. The external QC was not performed from September 2018 through the survey date. 3. Approximately 200 patients' samples tested for Chem 8 from September 2018 through the survey date. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
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 surveyor review of records and confirmed in an interview with the practice manager at the time of this survey, the laboratory failed to establish and follow a written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor review of Quality Control (QC) records and confirmed in an interview with the practice manager at the time of the survey, the laboratory failed to follow the laboratory's established QC procedure for testing ACT using Hemochron Signature Elite device. Findings: 1. On November 20, 2019 at approximately 11:00 AM the practice manager confirmed surveyor's findings that the laboratory failed to perform Liquid Quality Control (LQC) as required by the manufacturer of the Hemochron Signature Elite device from March 26, 2019 through the survey date. 2. Approximately 80 patients were tested for ACT during the above time frames. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
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 surveyor findings and interview with the practice manager, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on September 4, 2018; 2. Maintained the laboratory's QC program for coagulation, refer to D6020; and, 3. Established and maintained a QA

	program for all phases of laboratory testing, refer to D6021. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor review of quality control (QC) records and confirmed in an interview at the time of this survey with the practice manager, the laboratory director failed to ensure that the QC program for coagulation testing was maintained to assure quality of laboratory services. Refer to: D1001, D5441 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
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 lack of quality assessment (QA) policy and confirmed in an interview with the practice manager at the time of the survey, the laboratory director failed to ensure that the laboratory established and maintained a QA program as part of the laboratory's overall quality systems program. Refer to D5291 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 4, 2018.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a surveyor's review of the personnel records and confirmed in an interview with the practice manager, the laboratory director failed to ensure that one of five

	testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma prior to performing patient testing. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a surveyor's review of personnel records and confirmed in an interview with the practice manager at the time of the survey, the laboratory director failed to ensure that the one of five testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.