Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0902966	05/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Premier Cardiology Of Boca Raton, Llp	1000 Nw 9th Ct Ste 201, Boca Raton, FL	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not have documentation of signed attestations for the past two years. Findings include: Review of all proficiency records for the past two years on 05/29/2019 revealed that there were no signed attetations. During an interview with testing person A, she said that she didn't know she had to keep the attestations.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory

	received an unsatisfactory score for one analyte in the third testing event in routine chemistry. Findings include: Review of proficiency testing records on 05/29/2019 revealed that the laboratory received an unsatisfactory score of 20% in low density lipoprotein (LDL) cholerol in the third testing event of 2018.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory received a 0% for complete blood counts for the first testing event of 2019. Findings include: Review of proficiency testing records on 05/29/2019 revealed that the laboratory received a 0% for nonparticipation in the first testing event of 2019. During an interview with testing person A at 12:00 p.m. on 05/29/2019, she said that she might have sent them in late. After further investigation, she discovered that she had sent them in on time but had not submitted them.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not document all of the manufacturer defined maintenance on the Tosoh chemistry analyzer. Findings include: Review of maintenance records for the Tosoh chemistry analyzer for the past two years at 11:30 a.m. on 05/29/2019 revealed that no monthly maintenance was documented for 8/2017, 10/2017, 1/2017, 4/2018, 6/2018, or 8/2018. The trimonthly maintenance had been documented on 7/2017 and 10/2018. During an interview with testing person A at 12:00 p.m. on 05/29/2019 she confirmed that there was no documentation for that maintenance.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not follow the criteria for calibration frequency for the cell counter that was specified in their procedure manual. Findings include: Review of hematology records on 05/29 /2019 revealed that over the past two years, the cell counter had been calibrated once a year. The hematology procedure manual specified that calibrations should be performed quarterly, when a new control lot is put to use, after a major maintenance procedure, when control is outside of 2 standard deviations (SD) twice and procedures to correct it did not resolve the problem. During an interview with testing person A at 12:00 p.m. on 05/29/2019, she confirmed that the calibrations had been done yearly.
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 record review and interrview with laboratory personnel, the laboratory director did not ensure that corrective action was taken when the laboratory received unacceptable or unsatisfactory scores. Findings include: Review of proficiency testing records on 05/29/2019 revealed that the laboratory received the following unsatisfactory scores: 1. The laboratory received 0% for nonparticipation for complete blood counts for the first testing event of 2019. 2. The laboratory receibed 20% for lo density lipoprotein (LDL) cholesterol for the third testing event of 2018. There was no documentation to indicate that any corrective action had been taken.During an interview with testing person A at 12:00 p.m on 05/29/2019, she confirmed that she had not documented any corrective action or explanation for the unsatisfactory proficiency testing scores.