Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	10D0902966	05/19/2021
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
D0000	A recertification survey conducted on 5/5/21 to 5/19/21. LEWIS GOTTLIEB SALTZMAN EDEP & BRODSKY MD LLP clinical laboratory was found not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on survey findings Immediate Jeopardy was identified and the laboratory was notified of the Immediate Jeopardy on 5/19/21 at 2:00 pm, the laboratory provided a cease testing letter for coagulation tests Prothrombin Time (PT) and the Activated Partial Thromboplastin Time (APTT) from 5/13/2021. The laboratory used expired controls level 1 and 2 for PT and APTT from 7/20/19 to 5/13/21. The laboratory failed to have documentation of the range values used for these controls from 6/1/19 to 5/13/21. The laboratory used controls out of range for the tests of reference based on review from 6 /1/19 to 4/30/21. The following conditions were cited: -D5400 Analytic Systems -D6000 Moderate Complexity Laboratory Director
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel form, personnel files and American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Chemistry and Hematology specialty for 2019 and 2020 for 1 of 2 testing personnel reviewed. Findings include: Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 04/20/2021 had 2 testing personnel listed (TP A, TP B). Personnel files review revealed that TP B started working on May 2019. Review of API PT records for 2019 and 2020, revealed that, there was no documentation of PT testing in 2019 and 2020 for the Chemistry and Hematology

	specialties for TP B. During an interview on 05/05/2021 at 3:00 pm, Testing personnel A confirmed that TP B failed to participate in PT during 2019 and 2020.
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 record review and staff interview, the laboratory failed to have a written policy on training and competency assessment, failed to have initial and 6 months competency evaluation for 1 out of 2 testing personnel (TP) from 2019 to 2021 and failed to have an approved designee to sign the competency for 2 out of 2 years reviewed. Findings include: -Review of the procedure manual signed by the laboratory director in December of 2019 revealed that there was no Personnel Policy to establish and define the competency evaluation for TP. -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 04 /20/2021 revealed that there were 2 TP (TP A and TP B). -Review of personnel records revealed that TP B started on 05/19, no initial and 6 months competency assessment documented for TP B. -Review of TP competency assessments for 2019 and 2020, revealed the laboratory failed to include the name of the test or task the TP performed and failed to have the signature of the laboratory director or an authorized designee. During an interview on 05/07/2021 at 3:30 pm, with office manager, she confirmed that the laboratory failed to have the policy for personnel, failed to have initial and 6 months competency for the TP B and failed to have the laboratory director sign the TP competency assessments for the period reviewed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings include: -The laboratory failed to label complete blood cell (CBC) controls for ABX Micros 60 analyzer with open and expiration dates. The laboratory stored brain natriurectic peptide controls above the required temperature. Refer to D 5415. -The laboratory used expired controls for coagulation tests and alphalyse reagent for CBC analyzer. Refer to D5417. -The laboratory failed to perform twice a year calibration for CBC analyzer. Refer to D5437. -The laboratory failed to run 3 control level for CBC analyzer. Refer to D5441. -The laboratory failed to run CBC controls before patients testing. Refer to D5447. -The laboratory failed to have controls in range before doing patient testing. Refer to D5481.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to label complete blood controls (CBC) currently in use with open and expiration dates. The laboratory stored the Quidel Traige BNP B-type controls for the brain natriuretic peptide (BNP) test above the required temperature. Findings include: -Review of the Horiba Medical Hematology Devices Minotrol 16 control product insert revealed that controls are stable for 16 days after opening if properly handled. Review of the Quidel Traige BNP Control Product Insert revealed that the control has to be stored at -20 degrees C or colder in a non defrosting freezer. -Procedure manual review signed by the laboratory director in December 2019, revealed that the laboratory will label controls and reagents with open and expiration dates. -During the laboratory tour on 5 /5/21 at 10:00 am, the surveyor observed that the CBC controls in use did not have the open and expiration dates. The surveyor found the BNP controls were stored in a freezer compartment at -17 degrees C. - Record review of freezer temperature logs from 6/19 to 4/21 revealed that the storage temperature was -17 degrees C. During an interview on 5/5/21 at 2:00 p.m., the TPA confirmed that CBC controls in use should be labeled with open and expiration dates and that the storage temperature for BNP was out of manufacturer's instruction range.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory had expired controls for coagulation tests Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) from 7/21/19 to 5/13/21. The laboratory used an expired reagent for complete blood cell analyzer ABX Micros 60 from 3/18/21 to 5/5 /21. Findings include: -During the laboratory tour on 5/5/21 at 10:00 am, the surveyor observed that the laboratory was using a coagulation level 1 control expired since 6/5 /20. The laboratory had in use ABX alphalyse for the Horiba Complete Blood Cell analyzer expired since 3/18/21. - Review of coagulation controls product insert revealed that the controls should not be used beyond the expiration date. Review of C1 and C2 control levels print outs revealed that the laboratory used expired controls from 7/21/2019 to 8/7/2019 (C2), from 11/17/2019 to 2/25/2020 (C1) and from 6/6 /2020 to 5/13/2021 (C1). -Observation of Control C1 bottle in use revealed that the laboratory was using lot number K151076 with expiration date 6/5/2020. Review of C1 control print out for 6/30/2020, revealed that the laboratory changed the expiration from 6/5/2020 to 12/30/2020. Review of C1 print out on 4/17/21, revealed that the

	laboratory changed the expiration date to 12/5/2021. - Review of controls print outs from 6/1/2019 to 4/30/2021, revealed that the laboratory changed the expiration dates to a new expiration date, for lot numbers expired, the laboratory failed to provide documentation to support the changes in expiration dates. During an interview on 05 /13/2021 at 10:30 am with testing personnel A, she confirmed the use of the expired controls and reagent.
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 staff interview, the laboratory failed to perform calibration of the ABX Micros 60 cell counter twice a year for 2019 and 2020. Findings include: -This is a repeated deficiency from the previous inspection, the Plan of Correction submitted by the laboratory on 6/13/2019 stated that the laboratory will perform twice a year calibration as recommended by analyzer manufacturer. -Review of ABX Micros 60 cell blood counter (CBC) records, revealed that from 2018 to 2021 the laboratory performed the following calibrations 12/18/18, 12/19/19, 11/16/20. During an interview on 5/5/2021 at 11:00 AM, the testing personnel A confirmed that the laboratory failed to calibrate the CBC analyzer twice a year.
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 record review and interview with testing personnel (TP), the laboratory failed to monitor quality control (QC) over time for shifts and trends for the period reviewed (6/19 to 4/21) for the hematology Analyzer ABX Micros 60, Chemistry Analyzers Integra 400 plus and TOSOH A1A 900 and Coagulation Analyzer Destiny

	Plus. The laboratory failed to run 3 controls levels for Hematology analyzer from 6/19 to 4/21. Findings include: 1-Review of QC records for Hematology Analyzer ABX Micros 60, Chemistry Analyzer Integra 400 and TOSOH A1A 900 , Coagulation Analyzer Destiny, revealed only daily QC. There was no documentation of monitoring the shift and trends of the QC over time for the instruments listed from 6 /19 to 4/21. 2-Review of procedure manual signed by the laboratory director in December 2019, revealed that the laboratory will perform, daily three controls levels for complete blood counting (CBC). -Review of daily CBC controls from 6/19 to 4 /21, revealed that the laboratory ran 2 control levels each testing day. During an interview on 05/5/2021 at 12:00 PM, TP A confirmed that there was no documentation of monitoring the shifts and trends of the QC over time and that the laboratory ran 2 control levels for CBC testing from 6/19 to 4/21.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform Hematology controls for 11 testing days out of 52 days reviewed from 6-7/20 to 3-4 /21 Findings include: Review of Hematology controls print outs revealed that the laboratory failed to have controls on the following days: 6/2/20, 6/3/20, 6/5/20, 6/8 /20, 6/12/20, 6/17/20, 6/24/20, 6/26/20, 7/1/20, 4/21/21, 3/24/21. During an interview on 05/07/21 at 2:30 PM, the testing personnel A stated that the laboratory did not have documentation of the controls on the days of reference and that she can not print records for the days of reference.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and testing personnel (TP) A interview, the laboratory failed to have 2 control levels within acceptable range for Coagulation tests Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT), for 11 months reviewed from 6/19 to 4/21. Review of Chemistry controls for 2 months (6/20 and 4 /21) revealed controls out of range for Creatinine, Cholesterol and Blood Urea Nitrogen (BUN). Findings include: -Review of procedure manual signed by the laboratory director on December 2019, revealed that the laboratory will run controls every testing day and controls must be within range before patient testing. -Review of PT and APTT control print outs for C1 and C2 level revealed: -a) There was no control log record of the lots used for controls. There was no record of expiration dates, calculation of ranges and lot changes. b) Records from 6/19 to 4/21 revealed

	that there were controls out of the range on the months 6/2019, 7/2019, 8/2019, 1 /2020, 2/2020, 3/2020, 6/2020, 10/2020, 11/2020, 12/2020, 4/2021 for C2 control. - From 6/1/19 to 5/13/21 the lab used the following lots for C1 and C2. C1 lot: - J312875 (expiration 11/16/19), in use from 6/1/19 to 2/25/20. One record of manual calculation for range evaluation found and one instrument print out with no date. Lot - K151076 (expiration 6/5/20), used from 2/26/20 to 5/13/21, no documentation of the manual calculation, no instrument prints out to support the range assigned. C2 lot: J19473 (expiration 7/20/19), used 6/1/19 to 8/8/19. No documentation of the range evaluation. Lot K131060 (expiration 5/17/20), used from 8/9/19 to 1/16/20, no documentation of manual calculation for the ranges assigned. Lot K130394 (expiration 5/17/21), used from 1/17/20 to 5/13/21. For this lot, the laboratory initially used a range of 77, 5 to 107, 5 seconds for APTT, the laboratory failed to have documentation of the manual calculation and instrument print out for the range values assigned from 1/17/20 to 12/10/20. From 12/11/20 a new range of 60 to 90 seconds for APTT for this lot assigned based on the manual calculation and instrument print out, found in the records (without a date). -Review of daily QC for Chemistry analyzer Integra 400 for 6/20 and 4/21 revealed that the laboratory failed to have 2 controls within range for: a) 4/21: no controls for days 5, 6 and 7 b) Creatinine on 6/ 20 days 9, 10, 11, 12 and 15. On 4/21 the days 1, 2, 8, 9, 12, 13, 14, 15, 16, 19, 20, 21, 23, 26, 27. c) Cholesterol on 6/20 days: 1, 2, 4, 4, 5, 8, 9, 15, 16, 17. On 4/21 day 9, 12, 13, 15, 19, 20. d) BUN on 6/20 days:18, 19, 22, 23, 24, 25, 26. No corrective actions for controls out of range. During an interview on 05/07/21 at 2:30 PM with TP A, she explained that for Coagulation controls range the laboratory performed manual calculations and explained that for the C2 lot in use K130394, she used first one range, later the supplier company told her to correct the range and she did it, she could not provide the dates for the changes, no documentation of the notifications for range change. For chemistry she confirmed that the days of reference the controls were out.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and testing personnel interview the laboratory Quality Assessment (QA) program failed to identify and correct the quality control problems associated with coagulation tests Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) tests. The QA failed to ensure the laboratory ran 3 control levels for complete blood cell count (CBC) daily and failed to ensure the laboratory performed twice a year calibration for the ABX complete blood analyzer (CBC) for 2 out of 2 years reviewed (2019 and 2020) Findings include: -Review of QA program indicated that the laboratory will monitor the performance using the quality assurance evaluation sheet (QAES). In the QAES the laboratory listed the topics to review which included instrument calibration (frequency for the ABX Micros 60 listed twice a year), Quality Control (QC) monthly and proficiency testing (PT). -Review of the monthly QAES from 5/19 to 4/21, revealed that: a) The laboratory failed to record calibration dates and failed to correct the deficiency of not performing the twice a year calibration for the CBC analyzer. Refer to D5437. b) The laboratory failed to make corrections to quality control problems found from 6/19 to 4

	/21. Refer to D5441, D5447 and D5481. -During an interview with office manager on 5/7/21 at 4:00 pm, the office manager confirmed that the laboratory QA failed to identify and correct the deficiencies listed above.
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 record review and staff interview, the laboratory director failed to effectively oversee the laboratory from 6/19 to 4/21. Findings include: -Failed to ensure the laboratory performed ABX Micros 60 complete blood counter calibrations every 6 months. Refer to D6013. -Failed to ensure the laboratory followed the quality control and quality assurance policy. Refer to D6022. -Failed to ensure the procedure manual had a policy for competency evaluation of testing personnel and failed to sign the competency assessment. Refer to D6030.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory performed calibration of the ABX Micros 60 hematology analyzer at least every 6 months for 2019 and 2020. Refer to D5437.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that the laboratory followed quality control (QC) and quality assurance (QA) policies. Refer to D5791, D5415, D5417, D5441, D5447, and D5481.

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 record review and staff interview the laboratory director failed to ensure the procedure manual had a policy for personnel competency assessment and failed to sign the competency assessment for testing personnel. Refer to 5209.