Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0902966	08/12/2025
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	An onsite recertification survey conducted on July 30. 2025 to August 12, 2025, found Premier Cardiology of Boca Raton laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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 observation, record review, and interview, the laboratory failed to document corrective actions for temperatures recorded that were out of the acceptable range of -20 degrees Celsius (C) or colder for Triage Brain Natriuretic Peptide {BNP} Controls stored in the laboratory freezer for 353 of 508 days from 08/01/2023 to 07/28 /2025. Findings: 1. During a tour of the laboratory on 07/30/2025 at 9:45 AM, the Quidel Triage BNP Controls were observed in the laboratory freezer. 2. Review of the Quidel Triage BNP Control Product Insert stated "Store froze at -20 degrees C or colder in a non-defrosting freezer." 3. Review of the Quality Assurance Daily Monitoring Sheet showed temperatures for the freezer were out of range on the following dates: 08/01/2023 recorded -18 degrees C 08/02/2023 recorded -18 degrees C 08/03/2023 recorded -18 degrees C 08/04/2023 recorded -18 degrees C 08/07/2023 recorded -18 degrees C 08/08/2023 recorded -18 degrees C 08/09/2023 recorded -18 degrees C 08/10/2023 recorded -18 degrees C 08/11/2023 recorded -18 degrees C 08 /14/2023 recorded -18 degrees C 08/15/2023 recorded -18 degrees C 08/16/2023 recorded -18 degrees C 08/17/2023 recorded -18 degrees C 08/18/2023 recorded -18 degrees C 08/21/2023 recorded -18 degrees C 08/22/2023 recorded -18 degrees C 08 /23/2023 recorded -18 degrees C 08/24/2023 recorded -18 degrees C 08/25/2023 recorded -18 degrees C 08/28/2023 recorded -18 degrees C 08/29/2023 recorded -18

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D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records, review of the procedure manual, and interview, the laboratory failed to run proficiency testing samples for hematology in the same manner as it runs patients for four of four (2024 1st, 2nd, 3rd, 2025 1st) events for hematology. Findings: 1. Review of the procedure manual titled proficiency testing noted, "Survey material will be analyzed exactly like a patient sample whenever possible." The procedure also noted, "Upon completion of analysis, the person performing the test will complete the information required on the evaluation form(s). These forms, along with a copy of all pertinent log sheets, QC, instrument tapes, etc will be reviewed by another person to verify all information including results, units of measurement, sample ID, and testing person ID has been recorded correctly." 2. Review of the API PT showed the laboratory was enrolled in Hematology for the following analytes: White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin, Hematocrit, Platelets, Mean Corpuscular Volume, Red Cell Distribution Width (RDW), Granulocytes, Monocytes and Lymphocytes. 3. Review of the PT results showed proficiency testing results for Hematology contained results from the first running of the samples and the second running of the sample for the following: a. 2024 1st event sample HEM-02 RBC results from the first run was 6.10 and second run was 6.15, the PT results submitted to API for the RBCs was from the first run and all the other results were reported from the second run. b. 2024 2nd event sample HEM-07 Granulocytes results from the first run was 33.3, and second run was 34.1. The PT results submitted to API for the Granulocytes was from the first run and all the rest of the results were report from the second run. c. 2025 1st event sample HEM-01 RBC results from the first run was 3.85 and second run was 3.51, the PT results submitted to API for the RBCs was from the first run and all the rest of the results except the WBCs were reports from the second run. d. 2025 1st event HEM-03 Granulocytes percentage results from the first run was 34.8 and second run was 33.9, Monocytes percentage results from the first run was 9.3, and second run was 7.4. The Lymphocytes percentage from the first run was 55.9 and second run was 58.7. The PT results submitted to API for the Granulocytes, Monocytes and Lymphocytes was from the first run and all the rest of the results were reports from the second run. 4. Review of the API Performance Evaluation showed the RBCs results were reported out to the second decimal point and the results for Hematocrit were reported out the first decimal point. 5. During an interview on 07/30 /2025 at 2:42 PM, Testing Personnel A stated they reported out the second run on patient samples if the results were flagged and re-run. 6. Review of the PT results showed proficiency testing for Hematology results submitted to API were not found in the results from the first or second running of the PT samples for the following: a. 2024 1st event sample HEM-03 for Platelets results from the first run was 94 and second run was 81. The results submitted to API was 92. b, 2024 1st event sample HEM-01 for RBC results from the first run was 4.09. The results submitted to API was 4.10. c. 2024 1st event sample HEM-03 for RBC results from the first run was 2.05, and second run was 2.03. The results submitted to API was 2.00. d. 2024 1st event sample HEM-04 for RBC results from the first run was 3.54, and second run was 3.53. The results submitted to API was 3.50. e. 2024 2nd event sample for HEM-06 RBC results from the first run was 5.12, and second run was 4.95. The results submitted to API was 5.10. f. 2024 2nd event sample HEM-07 for Hemoglobin results from the first run was 3.3, and second run was 5.3. The results submitted to API was 5.1: RDW results from the first and second runs was 16.6, and the results submitted to API was 16..1: Platelets results from the first run was 50, and second run was 84. The results submitted to API was 75. Monocyte Percentage results from the first run was 9.5, and second run was 7.0. The results submitted to API was 7.5. Lymphocyte Percentage results from the first run was 57.2, and second run was 58.9. The results

	submitted to API was 59.2. g. 2024 3rd event sample HEM-11 for Hematocrit results from the first run and second run were 25.3. The results submitted to API was 25.0. 2024 3rd event sample HEM-12 for Hematocrit from the first run was 42.1, and second run was 42.6. The results submitted to API was 42.0. h. 2024 3rd event sample HEM-13 for Hematocrit from the first run was 32.3 , and second run was 31.8. The results submitted to API was 32.0. i. 2024 3rd event sample HEM-14 for Hematocrit from the first run was 15.7, and second run was 15.8. The results submitted to API was 16.0. j. 2025 1st event sample HEM-01 for Hematocrit from the first run was 28.3, and second run was 25,6. The results submitted to API was 26.0. k. 2025 1st event sample HEM-02 for Hematocrit from the first run was 46.3, and second run was 45.5. The results submitted to API was 46.0. l. 2025 1st event sample HEM-03 for Hematocrit from the first run was 16.8, and second run was 15,2. The results submitted to API was 15.0. m. 2025 1st event sample HEM-04 for Hematocrit from the first run was 41.2, and second run was 26.2. The results submitted to API was 41.0. n. 2025 1st event sample HEM-05 for Hematocrit from the first run was 34.4. The results submitted to API was 34.0. 7. During an interview on 08/12/2025 at 3:15 PM, Testing Personnel A stated she did not know where the numbers that were not from the reports with the test results came from and that they may be a clerical error.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the correct specimen collection times for 3 out of 3 patients reviewed, (!, #2, #3). Findings Included: Review of CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) APPLICATION FOR CERTIFICATION read, Hours of laboratory testing are from 9AM to 6 PM Monday through Friday. Review of Culminative Reports stated the following: 1.Patient 1 was collected at 6/5/2025 at 12:00 AM and tested on 6/5/2025 at 2:57 PM for Complete Blood Count (CBC) testing. 2. Patient 2 was collected at 7/30/2025 at 12:00 AM and tested on 7/30/2025 at 4:02 PM for CBC. 3. Patient 3 was collected on 5/27/2025 at 12:00 AM and tested on 5/27/2025 at 2:18 PM for CBC. Review of patient requisitions revealed the following: 1. Patient 1 had a requisition for check in time for CBC collection on 6/5 /2025 at 8:34 AM. 2. Patient 2 had a requisition for check in time for CBC collection on 7/30/2025 at 12:47 PM. 3. Patient 3 had a requisition for check in time for CBC collection on 5/27/2025 at 8:11 AM. Review of the laboratory's Policy and Procedure revealed the lab had no policy for monitoring specimen collection times. On 7/30 /2025 at 4:08 PM, Testing personnel A stated patient report collection times did not match the requisition times and report could not be changed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)

	(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document verification of a new quality control lot acceptability for Complete Blood Count (CBC) testing from November 2023 to May 2025. Findings Included: Review of New Lot of Quality Control How to Verify Acceptability of an assayed control read, "1. One week before the current lot of control expires, run all levels of controls for 5 days using different staff if possible 2. out the files and compare results to package insert. 3. When all are within the range stated on the package insert, staple the printouts to the package insert, write "OK" on the front of the package insert with your initials and the date and file in the binder behind the "package inserts"Tab.4. Document acceptance by Laboratory Director or Technical Consultant." Review of CBC Quality Control Weekly Review Worksheet revealed the following: The following dates had new CBC quality control lots changed: 11/10/2023, 6/5/2024, 9/6/2024, 11/15/2024, 1/25/2025 and 5/8/2025. There was no documentation of package inserts and instrument runs for new CBC control lots and was not reviewed by the laboratory director or technical consultant. On 7/30/2025 at 4:52 PM, technologist A stated verification of the new lot acceptability for CBC testing from November 2023 to May 2025 was not done.