Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2180164	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Primary Care Physicians -	7611 St Andrews Road, Irmo, SC	

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 was initiated on 02/15/2024 and concluded on 02/15/2024. The laboratory was found not to be in compliance with the laboratory requirements of 42 CFR Part 493. Standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy, proficiency testing (PT) rcords (2022, 2023), and confirmed in staff interview, the laboratory failed to ensure the labobatory director (or designee) and testing personnel signed the attestation documentation for eight of nine in 2022 and two of nine in 2023. Findings included: 1. The laboratory's Proficiency testing policy stated, "Upon completion, the proficiency testing attestation is signed by the testing personnel and the Laboratory Director or designee." 2. Review of PT records from 2022 and 2023 revealed the following events that were not signed by the laboratory director or testing personnel: a. Chemistry Core 2022, 1st Event b. Hematoloy/Coagulation 2022, 1st Event c. Immunology/Immunohematology 2022, 1st Event d. Miscellaneous Chemistry 2022, 1st Event e. Chemistry Core 2022, 2nd Event f. Hematology/Coagulation 2022, 2nd Event g. Chemistry Core 2022, 3rd Event h. Immunology/Immunohematology 2022, 3rd Event i. Miscellaneous Chemistry 2023, 1st Event j. Immunology/Immunohematology 2023, 3rd Event 3. In an interview on 02/15/2024 at 11:00AM in the laboratory office, the Technical Consultant (TC) acknowledged the laboratory's failure to follow its own Proficiency Testing policy.
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 a review of laboratory policy, laboratory freezer temperature logs (07/01 /2022 through 12/31/2022) and confirmed by staff interview, the laboratory failed to ensure the freezer temperature was within the acceptable range for 4 of 180 days. Findings included: 1. Review of the laboratory's enviromental monitoring policy revealed an acceptable freezer temperature range of -30-0 Celsius (C). 2. Review of the laboratory's freezer temperature logs from 07/01/2022 through 12/31/2022 revealed the following temperatures that were not within the acceptable range of -30 to 0 Celsius (C). a. Date: 07/12/2022 Temperature: -31 C Outside acceptable limits = 1 degree b. Date = 12/06/2022 Temperature = -31 C Outside acceptablle limits = 1 degree c. Date: 12/11/2022 Temperature: -31 C Outside acceptable limits = 1 degree d. Date: 12/20/2022 Temperature: -31 C Outside acceptable limits = 1 degree 3. In an interview on 02/15/2024 at 11:00AM in the laboratory office, the TC acknowledged the laboratory's failure to monitor the freezer temperature according to its own Environmental Monitoring policy.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory' s verification study data for the Ortho Clinical Diagnostics Vitros 5600 analyzer, and staff interview, the laboratory failed to perform complete verification studies for the 11/2021 installation of the Vitros 5600. Findings included: 1. Review of the laboratory's verification records from the 11/2021 installation of the Ortho Clinical Diagnostics Vitros 5600 revealed the studies failed to include: a. Accuracy b. Precision c. Reference interval (Normal Range) Studies. d. Analytic Measurement Range (AMR) 2. Further review of the laboratory's verification records revealed no evidence that raw data was statistically assessed for accuracy, precisioin, reference intervals, or AMR. 3. In an interview on 02/15/2024 at 11:30 am in the laboratory, the TC stated the Vitros 5600 had been relocated in November 2021 and confirmed that verification studies were not performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient records, and confirmed in staff interview, the laboratory failed to follow their own procedure for a biannual review of patient records for two of two years (2022 and 2023). Findings included: 1. A review of an undated facility policy titled "A Statement of Quality Assurance and Control" revealed, "4. Biannually, the laboratory will review 20 patient charts and review for specimen accuracy, identification, tests ordered, specimen type, appropriate handling and storage, and tests results." 2. A review of patient records for 2022 and 2023 revealed no evidence of a biannual chart review. 3. During an interview on 02/15 /2024 at 1:40 PM, the Technical Consultant confirmed the laboratory failed to perform biannual patient chart reviews as specified in the laboratory policy.