

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2180164	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier Palmetto Primary Care Physicians -	Street Address, City, State 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	An onsite announced recertification survey was conducted at Palmetto Primary Care Physicians on March 10, 2026. The facility was found to be out of compliance with the Medicare Conditions of Coverage at 42 CFR Part 493, CLIA Requirements for Laboratories. Standard level deficiencies were identified during the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interviews, the laboratory failed to provide competency assessments for the technical consultant(s) (TC). The laboratory specified at least one technical consultant as required for moderately complex testing for the 2 out of 2 years reviewed (2024, 2025). Findings included: 1. A review of the CMS 209 Laboratory Personnel Report reveals 1 TC and 2 testing personnel (TP). 2. A review of "CLIA Delegation of Responsibilities" document reveals laboratory manager, technical consultant, delegated TP1 duties as a TC. 3. A review of competency records reveals a lack of documentation for TC(s) competencies for specified TC noted on CMS 209 and delegated TC noted on delegation letter. 4. In an interview on March 10, 2026, at 2:30 pm in the conference room with TC, TP1 and TP2, the above findings were confirmed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and staff interview, the laboratory failed to investigate and or evaluate the results obtained on proficiency testing (PT) performed as specified in subpart H for 2 out of 2 years reviewed (2024, 2025). Findings included: 1. A review of proficiency testing records reveals the following results for Specialty/ subspecialty hematology: a. 2024 Hematology/Coagulation-2nd Event the laboratory received an unsatisfactory score of 50% for Sedimentation Rate (iSED) b. 2024 Hematology/coagulation-3rd Event the laboratory received an unsatisfactory score of 50% for Nitrite (Urinalysis) 2. A review of Proficiency Testing policy and procedure reveals a procedure step "all proficiency testing corrective action required for failures will be reviewed and signed by Laboratory Manager within one (1) week of completed corrective action(s)." 3. A review of PT records reveals a lack of documentation of evaluation and/or assessment of unacceptable PT score by TC and Laboratory Director (LD). 4. In an interview on March 10, 2026, at 2:30 pm in the conference room with TC, TP1 and TP2, the above findings were confirmed.

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 record review, lack of documentation, and staff interview, the laboratory failed to establish and/or follow 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 for 2 out of 2 years reviewed (2024, 2025). Findings included: 1. A review of quality assurance records including environmental logs, critical value logs, proficiency testing documentation, and quality control records reveals the laboratory lacks documentation of assessment with acceptable metrics and established written policies to prevent recurrence of problems. 2. A review of quality control records for 2025 serum mono test reveals a problem with the quality control materials. The laboratory lacks documentation that the problem identified was assessed and/or communicated to other staff for what was implemented to establish and prevent recurrence. 3. In an interview on March 10, 2026, at 2:30 pm in the conference room with TC, TP1 and TP2, the above findings were confirmed.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 record review, lack of documentation, and staff interview, the laboratory failed to provide documentation of reportable range for specialty and subspecialty for the analyte glucose for 2 out of 2 years reviewed (2024, 2025). Findings included: 1. Review of "Cola Critical" log reveal specialty and subspecialty analytes reported as follows: a. January 14, 2026 @3:44 pm analyte/test glucose reported as 23 mg/dl. 2. Review of Ortho Clinical Diagnostics analytical measurement range study-Glucose reveals a lack of documentation to report glucose in the reportable range of 20 to 625 mg/dl. 3. In an interview on March 10, 2026, at 2:30 pm in the conference room with TC, TP1 and TP2, the above findings were confirmed.

D6005

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and staff interview, the laboratory director failed to provide documentation of onsite visits at least once every 6 months, with at least 4 months between with a minimum of two on-site visits per year for 2 out of 2 years reviewed (2024, 2025). Findings included: 1. A review of records (quality control logs, environmental logs, and Cola critical log) reveals delegated TC reviewed and signed logs. 2. Records review reveals a lack of documentation of laboratory director visits at least once every 6 months. 3. In an interview on March 10, 2026, at 2:30 pm in the conference room with TC, TP1 and TP2, the above findings were confirmed.