

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D2040729	<b>(X3) Date Survey Completed</b>  11/17/2023
<b>Name of Provider or Supplier</b>  Palmetto Primary Physicians -	<b>Street Address, City, State</b>  2550 Elms Center Road, North Charleston, SC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated on 11/17/2023 and concluded on 11/17/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on document reviews and interviews, the laboratory failed to ensure proficiency testing (PT) was rotated among all testing personnel (TPs). Specifically, PT for 4 of 5 events reviewed were performed by 1 (TP #1) of 5 TPs employed by the laboratory. Findings included: Review of the "Laboratory Personnel Report," signed by the Laboratory Director and dated 11/16/2023, revealed five individuals held the position of TP, TPs #1, #2, #3, #4, and #5, and all were qualified to perform moderate complexity testing. Review of the "Attestation Statement" for the "2023 Chemistry Core 1st Event," revealed TP #1 signed the Attestation Statement on 01/14/2023, to indicate she completed PT of the samples. Review of the "Attestation Statement" for the "2023 Hematology / Coagulation 1st Event," revealed TP #1 signed the Attestation Statement on 03/09/2023, to indicate she completed PT of the samples. Review of the "Attestation Statement" for the "2023 Hematology / Coagulation 2nd Event," revealed TP #1 signed the Attestation Statement on 07/14/2023, to indicate she completed PT of the samples. Review of the "Attestation Statement" for the "2023 Chemistry Core 3rd Event," revealed TP #1 signed the Attestation Statement on 09/12/2023, to indicate she completed PT of the samples. During an interview on 11/17/2023 at 12:40 PM, TP #2, who also served as the laboratory supervisor, stated the laboratory allowed TP #1 to conduct the PT because she was there Monday through</p>

Friday. TP #2 stated the other TPs worked during the weekday; however, he just preferred TP #1 to conduct PT. During an interview on 11/17/2023 at 1:00 PM, the Technical Consultant acknowledged the laboratory failed to ensure all TPs conducted PT in 2023.

**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 observation, document review, and interview, the laboratory failed to ensure 1 (Sysmex XN-330) of 1 hematology instrument was approved by the Laboratory Director (LD) before testing began. Findings included: Review of the "Certificate of Reportable Range Verification" document with a certification date of 03/10/2020, revealed the laboratory certified and validated their new hematology instrument on 03/10/2020. The Certification of Reportable Range Verification revealed the LD did not sign the document to indicate the new hematology instrument. On 11/17/2023 at 10:00 AM, the surveyor observed the Sysmex XN-330 in the laboratory. During an interview on 11/17/2023 at 1:00 PM, the Technical Consultant acknowledged the laboratory failed to ensure the LD signed and approved the validation records and procedures for the newly installed hematology instrument, the Sysmex XN-330.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on document reviews and interviews, the Technical Consultant (TC) failed to ensure 5 (Testing Personnel [TP] #1, #2, #3, #4, and #5) of 5 TPs completed an annual competency assessment. Findings included: Review of the laboratory policy titled, "Employee Competency," dated May 2012, revealed, "It is the Director's responsibility to determine if and when an employee is competent to perform patient sample testing. Each employee shall have in his/her personnel file: \* Record of formal education \* Record of certification and/or license \* Record of continuing education \* Annual review of job performance by lab director or designee." Review of the "Laboratory Personnel Report," signed by the Laboratory Director and dated 11/16/2023, revealed five individuals held the position of TP, TPs #1, #2, #3, #4, and #5, and all were qualified to perform moderate complexity testing. A review of the personnel files for TPs #1, #2, #3, #4, and #5, revealed no evidence of a completed annual competency assessment. During an interview on 11/17/2023 at 12:40 PM, TP #2, who also served as the laboratory supervisor, stated he did realize TP needed an

annual competency assessment. During an interview on 11/17/2023 at 1:00 PM, the TC stated he assumed the position of TC in June 2023 and did not realize employee competencies were not being conducted. The TC stated it was his responsibility to ensure initial, six-month, and annual competency assessments were completed for all employees. The TC acknowledged the laboratory failed to ensure TP completed an annual competency assessment.