

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1023061	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Palmetto Pediatrics	Street Address, City, State 23 Main Street Suite 301, Hilton Head Island, 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 CLIA recertification survey was conducted on February 26, 2025, at the clinical laboratory of Palmetto Pediatrics of the Lowcountry - Hilton Head Island by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirement for Laboratories. The following is a list of deficiencies cited during the February 26, 2025 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 records reviewed, lack of documentation, and staff interview, the laboratory failed to ensure documentation of testing personnel (TP) competency prior to performing patient testing for 11 out of 11 TP for two out of two years reviewed (2023 and 2024). Findings included: 1. Review of the laboratory policy and procedure manual reveals the laboratory's procedure for employee competency evaluation which states "Employees will be evaluated for proficiency in the following areas six months after hire date and then annually". 2. The policy titled "Employee Competency Evaluation" failed to include an initial proficiency evaluation. 3. Surveyor requested and the laboratory failed to provide initial, 6-months, and annual competency evaluations for 11 out of 11 TP. 4. In an interview with the office manager (OM) on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p>

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of laboratory records, personnel files, and staff interview, the laboratory director (LD) failed to ensure the documentation of initial competency for 11 out of 11 TP for two out of 2 years reviewed (2023, 2024) Findings included: 1. Review of the laboratory policy and procedure manual reveals the laboratory's procedure for employee competency evaluation which states "Employees will be evaluated for proficiency in the following areas six months after hire date and then annually". 2. The employee competency procedure lacks a requirement for an initial proficiency evaluation. 3 Review of laboratory manual reveals the laboratory failed to provide a written procedure to evaluate initial and 6-month competency as required for moderate complexity laboratory. 4. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(i)

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on records review, lack of documentation, and staff interview, the Technical Consultant(TC) failed to evaluate employee competency for all 6 components of competency assessment, specifically, "Direct observations of routine patient test performance" for 11 out of 11 TP for two out of two years reviewed (2023, 2024). Findings included: 1. Review of the laboratory's written policies and procedures reveal the laboratory failed to include all 6 components of the competency assessments. 2. Review of testing personnel files reveals that competency records lack the requirement for direct observations of routine patient test performance component as required by 42 CFR 493.1413. 3. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(ii)

(b)(8)(ii) Monitoring the recording and reporting of test results;

This STANDARD is not met as evidenced by:

Based on records review and staff interview, the TC failed to evaluate employee competency with all 6 components of competency assessment, specifically "Monitoring the recording and reporting of test results" for 11 out of 11 TP for two out of two years reviewed (2023,2024). Findings included: 1. Review of the laboratory 's wriitten policies and procedures reveals the laboratory' s failure to include all 6 components of competency assessment. 2. Review of the "Annual Employee Competency Evaluation" form lacks monitoring the recording and reporting of test results component as required by 42 CFR 493.1413. 3. In an

	<p>interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.</p>
<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;</p> <p>This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the TC failed to evaluate the employee's competency with all 6 components of competency assessment, specifically "Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records" for 11 out of 11 TP for two out of two years reviewed (2023, 2024). Findings included: 1. Review of the laboratory procedure manual reveals the failure of the laboratory to provide a written procedure to evaluate all 6 components of competency assessment as required by 42 CFR 493.1413. 2. Review of the "Annual Employee Competency Evaluation" form reveals a lack requirement for review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records". 3. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.</p>
<p>D6050</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;</p> <p>This STANDARD is not met as evidenced by: Based on records review, employee files, and staff interview, the TC failed to evaluate employee competency with all 6 components of competency assessment, specifically "Direct observations of performance of instrument maintenance and function checks" for 11 out of 11 TP for two out of two years reviewed (2023,2024). Findings included: 1. Review of the laboratory procedure manual reveals the laboratory's failure to provide a written procedure to evaluate all 6 components of competency assessment. 2. Review of the "Annual Employee Competency Evaluation" form reveals a lack requirement for direct observations of performance of instrument maintenance and function checks. 3. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.</p>
<p>D6051</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and</p> <p>This STANDARD is not met as evidenced by: Based on records review, employee files, and staff interview, the TC failed to evaluate employee competency with all 6 components of competency assessment, specifically</p>

"Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples" for 11 out of 11 TP for two out of 2 years reviewed (2023,23024). Findings included: 1. Review of laboratory procedure manual reveals the laboratory's failure to provide a written procedure to evaluate all 6 components of competency assessments as required by 42 CFR 493.1413. 2. Review of CMS 209 laboratory personnel report lists 11 TP, 1 Laboratory Director (LD), and 1 Technical Consultant (TC). 3. Review of the "Annual Employee Competency Evaluation" form reveals a lack requirement for assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 4. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:
Based on records review, employee files and staff interview, the TC failed to evaluate employee competency with all 6 components of competency assessment, specifically "Assessment of problem-solving skills" for 11 out of 11 TP for two out of two years reviewed (2023,2024). Findings included: 1. Review of the laboratory procedure manual reveals the laboratory's failure to provide a written procedure to evaluate all 6 components competency assessment as required by 42 CFR 493.1413. 2. Review of the "Annual Employee Competency Evaluation" a lack of requirement for the assessment of problem-solving skills. 3. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.

D6053

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

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on records review, employee files, and staff interview, the TC failed to document TP competency evaluations at 6-months in the first year of employment for 11 out of 11 TP for two out of two years reviewed (2023,2024). Findings included: 1. Review of the laboratory's procedure for employee competency evaluation reveals a requirement for competency evaluation at 6-months in the first year of employment. 2. Review of TP competency records reveals the laboratory's failure to provide written procedure to evaluate new employees at 6-months in their first year of employment as required by 42 CFR 493.1413. 3. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.

D6054

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

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on records review, employee files and staff interview, the TC failed to ensure the documentation of annual competency for 11 out of 11 TP for two out of two years reviewed (2023, 2024). Findings included: 1. Review of the "Employee Competency Evaluation" reveals the laboratory's procedure for employee competency evaluation which states "Employees will be evaluated for proficiency in the following areas six months after hire date and then annually". 2. Review of employee competency documentation reveals the laboratory failed to follow the written procedure for evaluating TP at 6-months after hire date and annually as required by 42 CFR 493.1413. 3. Review of employee competency records reveals a lack of annual competency evaluations for 11 out of 11 TP. 4. In an interview with the OM on February 26, 2025, at 10:00am in the laboratory office, the findings were confirmed.