

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0955309	(X3) Date Survey Completed 12/05/2024
Name of Provider or Supplier Palmetto Pediatric & Adolescent Clinic	Street Address, City, State 1970 Augusta Hwy, Lexington, 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	The following deficiencies are the result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of Certification and Survey Provider</p>

	<p>Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) 2024 records, the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Chemistry for the Bilirubin (Bili), Total analyte. Refer to 2096 and D2097.</p>
<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: During a PT Desk review survey performed on 12/05/2024, based on review of CASPER report 155D and graded proficiency reports from API, it was revealed that the laboratory failed to achieve a satisfactory score of 80% for Bili, Total on two consecutive proficiency testing events. Findings include: 1. The CASPER 155D report revealed the following scores for the laboratory's Bili, Total: a. 2024, Event 2: 60% b. 2024, Event 3: 0% 2. The scores were confirmed by review of the graded API results. Scores less than 80% for the analyte indicate failure or unsatisfactory performance. A failure of the analyte for two out of three testing events is scored as unsuccessful.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: During a PT Desk review performed on 12/05/2024, based on review of the CASPER 155D and graded report from API, it was determined that the laboratory failed to achieve satisfactory performance for Bili, Total in two consecutive testing events (2024, Event 2 and 3) See D2087.</p>
<p>D2097</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and API Proficiency Testing 2024 records (Events 2, and 3), the laboratory failed to achieve an overall satisfactory performance for Routine Chemistry for two consecutive testing events. Findings included: 1. A review of the CASPER 0155 report revealed the following results: Routine Chemistry 2024-2nd Event the laboratory received an unsatisfactory score of 60% for overall Chemistry. Routine Chemistry 2024-3rd Event</p>

	<p>the laboratory received an unsatisfactory score of 0% for overall Chemistry. 2. A review of the API Proficiency Testing 2024 records confirmed the laboratory received the above results.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and API 2024 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer 6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and API Testing 2024 records, the laboratory director failed to ensure that the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096.</p>