

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1080883	(X3) Date Survey Completed 10/31/2024
Name of Provider or Supplier Primary Pediatrics Of Wr	Street Address, City, State 6082 Lakeview Road, Warner Robins, GA	
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 performed on October 31, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL: D2016 - Successful Participation CONDITION 493.803(a)(b)(c) D6000 - Moderate Complexity Laboratory Director CONDITION 493.1403
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 review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the laboratory failed to achieve a satisfactory performance for Specialty Hematology, Subspeciality Monocyte (Mono) for 2023,</p>

	<p>event 1, and event 3, and for the 1st event of 2024. This is a Condition Level Citation REFERENCE: D2130 - Hematology 493.851(f)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the laboratory failed to achieve a satisfactory performance for Specialty Hematology, subspeciality Monocyte (Mono) for 2023, event 1, and event 3, and also for 2024 event 1. Findings: 1. On review of the API PT evaluation reports for the Specialty of Hematology, for 2023 and 2024. the laboratory received the following scores: 2023 - Event 1, subspeciality Mono, the laboratory scored 60% Event 3, subspeciality Mono, the laboratory scored 40% 2024 - Event 1, subspeciality Mono, the laboratory scored 60% 2. Interview with the Laboratory Manager on 10/31/2024 at approximately 12 pm in the breakroom, confirmed the statements as listed above.</p>
D6000	<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 review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the Laboratory Director failed to provide overall management and direction. The laboratory failed to achieve a satisfactory performance for Specialty Hematology, Subspeciality Monocyte (Mono) for 2023, event 1, and event 3, and for 2024 event 1. This is a Condition Level Citation Reference: D6016 - Laboratory Director Responsibilities. 493.1407(e)(H)(i)</p>
D6016	<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 review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the Laboratory Director(LD) is responsible for the overall operation and administration of the laboratory. The LD failed to ensure that</p>

the proficiency testing samples are tested as required. The laboratory failed to achieve a satisfactory performance for Specialty Hematology, Subspeciality Monocyte (Mono) for 2023, event 1, and event 3, and for event 1 of 2024 Findings: 1. On review of the API PT evaluation reports for the Specialty of Hematology, for 2023 and 2024. the laboratory received the following scores: 2023 - Event 1, Subspeciality Mono, the laboratory scored 60% 2023 - Event 3, Subspeciality Mono, the laboratory scored 40% 2024 - Event 1, Subspeciality Mono, the laboratory scored 60% 2. Interview with the Laboratory Manager on 10/31/2024 at approximately 12 pm in the breakroom, confirmed the statements as listed above. .