

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1023568	(X3) Date Survey Completed 09/27/2024
Name of Provider or Supplier Pinnacle Med Clinics & Grace Pediatric Clinics, Pa	Street Address, City, State 2401 Tuckaseegee Road, Charlotte, NC	
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
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 desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 API (American Proficiency Institute) proficiency testing results 9/27/24, the laboratory failed to achieve satisfactory performance for WBC (white blood cell) differential, RBC (red blood cell count), Hematocrit, Hemoglobin, WBC (white blood cell count), and platelets, and failed to achieve overall test event scores of satisfactory for Hematology on two consecutive testing events, resulting in unsuccessful participation in proficiency testing. Findings: See the deficiencies cited at D2130 and D2131.</p>

<p>D2130</p>	<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 desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 API proficiency testing results 9/27/24, the laboratory failed to achieve satisfactory performance for WBC differential, RBC, Hematocrit, Hemoglobin, WBC, and platelets on two consecutive testing events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for WBC differential, RBC, Hematocrit, Hemoglobin, WBC, and platelets on the 2023 Hematology/Coagulation 3rd event. 2. Desk review of CMS 153D and 155D and desk review of 2024 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for WBC differential, RBC, Hematocrit, Hemoglobin, WBC, and platelets on the 2024 Hematology/Coagulation 1st event.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(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 desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 API proficiency testing results 9/27/24, the laboratory failed to achieve an overall test event score of satisfactory performance for Hematology on two consecutive test events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for all analytes (WBC differential, RBC, Hematocrit, Hemoglobin, WBC, and platelets), resulting in an overall score of 0% for Hematology on the 2023 Hematology /Coagulation 3rd event. 2. Desk review of CMS 155D and 2024 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for all analytes (WBC differential, RBC, Hematocrit, Hemoglobin, WBC, and platelets), resulting in an overall score of 0% for Hematology on the 2024 Hematology /Coagulation 1st event.</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:</p>

Based on desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 API proficiency testing results 9/27/24, the laboratory director failed to provide overall management and direction to ensure successful proficiency testing participation. Findings: See the deficiency cited at D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:
Based on desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 API proficiency testing results 9/27/24, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: See the deficiencies cited at D2130 and D2131.