

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D1049854	<b>(X3) Date Survey Completed</b>  08/19/2025
<b>Name of Provider or Supplier</b>  Preferred Pediatrics At Lee Hill	<b>Street Address, City, State</b>  10600 Spotsylvania Avenue, Fredericksburg, VA	
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>	<p>An announced CLIA recertification survey was conducted at Preferred Pediatrics at Lee Hill on August 19, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Preferred Pediatrics at Lee Hill was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2016 - 42 CFR. 493.803 Condition: Successful Participation D6000 - 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing records and interview, the laboratory failed to successfully participate for the Hematocrit analyte. The laboratory had unsatisfactory scores for the first and second Hematology events of 2025, resulting in an initial unsuccessful PT performance. Refer to D2130.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) 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 a pre-survey review of the Center for Medicaid and Medicare Services CASPER 0155 report (CMS 0155), Proficiency Testing (PT) records, and interview, the laboratory failed to attain a score of at least 80% for the analyte Hematocrit (HCT) for two (2) consecutive hematology module testing events resulting in an initial unsuccessful PT performance as reviewed on the date of the inspection on August 19, 2025 (review timeframe October 2023 through August 2025). The findings include: 1. A pre-survey review of the CMS 0155 report revealed the laboratory received an unsatisfactory score of 60% for the regulated analyte #0785, HCT, in the 2025 Hematology-1st Event and 2025 Hematology-2nd Event. 2. Review of the laboratory's American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) PT evaluations on August 19, 2025 revealed HCT scores of less than 80% for the following 2 consecutive hematology PT events: AAB-MLE 2025 Hematology Event 1: HCT scored 60% ; AAB-MLE 2025 Hematology Event 2: HCT scored 60%; resulting in an initial unsuccessful PT performance. 3. In an interview with the Laboratory Manager on August 19, 2025 at 12:30 PM, the above findings were confirmed.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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 a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p>

This STANDARD is not met as evidenced by:

Based on a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. Refer to D2130.