

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2299882	<b>(X3) Date Survey Completed</b> 05/20/2025
<b>Name of Provider or Supplier</b> Pinehurst Medical Clinic Endocrinology	<b>Street Address, City, State</b> 200 Pavillion Way, Southern Pines, NC	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of laboratory records, absence of records, and interview with the Technical Consultant (TC) 05/20/2025, the laboratory failed to establish a policy for TC competency assessment and failed to assess the competency of the TC in 2024 and 2025. Findings: Review of laboratory records revealed no documentation of a policy for TC competency assessment. Review of laboratory records revealed no documentation of TC competency assessment for 2024 and 2025. During interview at approximately 10:10 a.m., TC confirmed no TC competency assessments available for 2024 and 2025.</p>
<b>D5613</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(a)</p> <p>(a) Cytology slide examination site. All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology. (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, and interview with the Laboratory Director (LD) 05/20/2025, the laboratory procedure manual was incomplete and not current for the testing performed. Findings: Review of laboratory's</p>

procedure manual revealed no written procedure for staining slides. During interview with LD at approximately 2:00 p.m., LD confirmed the absence of a written procedure for staining slides.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of personnel records for 2024 and 2025, and interview with the Technical Consultant (TC) 05/20/2025, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for the LD, Clinical Consultant (CC), TC, and Cytotechnologist (CT) involved in the daily operation of the laboratory. Findings: Review of personnel records revealed the absence of a job description for the following positions: 1. LD 2. CC 3. TC 4. CT During interview at approximately 11:07 a.m., TC confirmed no position descriptions available for LD, CC, TC, and CT.