

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2057222	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier Rheumatology & Pulmonary Clinic	Street Address, City, State 421 Carriage Drive, Beckley, WV	
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	An initial certification survey was conducted at Rheumatology & Pulmonary Clinic on September 23, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, lack of documentation, review of TERIS (instrument software) patient reports, and interview with the general supervisor (GS), the laboratory failed to have the laboratory director (LD) sign, date, and approve 13 of 13 policies and procedures related to Immunology testing on the Dynex DSX instruments before beginning patient testing in 2025. Findings: 1. Review of the policies and procedures for testing performed in the Immunology laboratory revealed 13 of 13 new policies and procedures were signed, dated, and approved by the technical supervisor (TS) in May and June 2025. 2. No signature, date, and approval by the LD could be located for 13 of 13 policies and procedures related to Immunology testing on the DSX instruments. 3. Review of 2025 TERIS final patient reports for Immunology testing on the Dynex DSX instruments identified the first patient results released 6/9/2025. 4. During an interview, 9/23/25 at 12:20 PM, the GS stated the policies and procedures had been signed, dated, and approved by the technical supervisor and not the laboratory director because the LD had delegated that responsibility.</p>