

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0464721	<b>(X3) Date Survey Completed</b>  11/19/2025
<b>Name of Provider or Supplier</b>  Freedman Clinic Laboratory	<b>Street Address, City, State</b>  176 Versailles Blvd, Alexandria, LA	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Freedman Clinic of Internal Medicine, CLIA ID #19D0464721 on November 19, 2025. I. Based on review of the laboratory's Plan of Correction (POC), manufacturer's assay sheet, and the laboratory's policies; as well as interview with personnel, the laboratory failed to establish complete policies and procedures for erythrocyte sedimentation rate (ESR) testing. Findings: 1. Review of the laboratory's POC revealed "Clinic policy and procedure was reviewed and staff was re-educated on labeling ctrl materials with open expiration dates and expiration</p>

dates which follow the manufacturer's guidelines. Manufacturer's guidelines were printed out for each ctrl type and a sheet was made available to staff with current expiration times." 2. Review of the manufacturer's assay sheet for the "Streck ESR-Chex Whole Blood Assayed Hematology Control" quality control materials revealed "Open-vial stability 95 days." 3. Review of the laboratory's policy "Open QC Expiration Time" revealed "Streck ESR QC - Vial expiration." 4. In interview on November 19, 2025 at 10:54 a.m., Testing Personnel 1 stated she thought the vials were acceptable through the manufacturer's original expiration date on the vials. She further stated the laboratory was labeling the ESR QC with an opened expiration date of thirty (30) days. She confirmed the laboratory's policy and education of staff did not match the manufacturer's requirements. II. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete policies and procedures for establishing quality control (QC) means and ranges. Findings: 1. Review of the laboratory's policy "Analytic Processes" section "Quality Control" revealed instructions for establishing ranges for unassayed controls, but did not include the standard deviation used to determine acceptability and/or instructions for establishing QC ranges for assayed controls. 2. In interview on November 19, 2025 at 11:35 a.m., the Technical Consultant confirmed the policy did not include the standard deviation utilized to determine QC acceptability for established ranges and did not include assayed controls.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:  
 A Revisit survey was performed at Freedman Clinic of Internal Medicine, CLIA ID #19D0464721 on November 19, 2025. Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish complete policies and procedures for erythrocyte sedimentation rate (ESR) testing. Refer to D5403 I. 2. The laboratory failed to establish complete policies and procedures for establishing quality control (QC) means and ranges. Refer to D5403 II.