

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2060139	<b>(X3) Date Survey Completed</b>  09/29/2025
<b>Name of Provider or Supplier</b>  Skin Surgery Centre Llc	<b>Street Address, City, State</b>  1615 Metairie Rd, Suite 101, Metairie, 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>D0000</b>	A Recertification survey was performed at Skin Surgery Centre, LLC, CLIA ID 19D2060139, on September 29, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<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 the laboratory's policies and interview with personnel, the laboratory failed to establish a complete written competency assessment policy for testing personnel. Findings: 1. Review of the laboratory's "Training and Information" and "Proficiency Testing Competency and CLIA competency assessment" policies revealed the laboratory did not include the following: a) written procedures related to initial training for doctors who serve as testing personnel b) documentation utilized for semi-annual competency assessment for new testing personnel 2. In interview on September 29, 2025 at 11:00 am, the Operations Manager confirmed the laboratory's written competency assessment policy did not include the identified information.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

	<p>This STANDARD is not met as evidenced by:  Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on September 29, 2025 at 9:44 am revealed the following expired item: Tissue Marking Dye, yellow, Lot 160944, Expiration date: 2024-11-30, Quantity: one (1) bottle 2. In interview on September 29, 2025 at 9:49 the Mohs lab tech confirmed the identified marking dye was expired.</p>
<p><b>D5793</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b>  CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:  Based on observation by surveyor, review of the laboratory's quality assessment forms, and interview with personnel, the laboratory failed to ensure their established monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Monthly Quality Assurance Checklist" revealed the laboratory monitors the following: a) "Patient Test Management System" b) "Quality Control Policies" which includes, but not limited to, "All reagents, controls, kits, etc. that exceeded their expiration date were discarded" c) "Laboratory Safety Policies" d) "Proficiency Testing Policies" e) "Personnel Policies" f) "Quality Assurance Program" 2. Observation by surveyor and interview with personnel revealed the laboratory's monitors did not identify the following issue within the analytic system: a) The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by:  Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
<p><b>D6093</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p>

	<p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were maintained to assure the quality of laboratory testing. Refer to D5793.</p>
<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were established. Refer to D5209.</p>
<p><b>D6112</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Refer to D5417.</p>