

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2308467	<b>(X3) Date Survey Completed</b> 05/29/2025
<b>Name of Provider or Supplier</b> Lighthouse Dermatology & Skin Cancer Specialists	<b>Street Address, City, State</b> 26901 Harper, Saint Clair Shores, MI	
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 record review and interview with the laboratory director (LD), the laboratory failed to establish a competency assessment policy for personnel (LD) for 2 (April 2025 to May 2025) of 2 months reviewed. Findings include: 1. A review of the laboratory policies and procedures revealed a lack of a competency assessment policy. 2. An interview with the LD on May 29, 2025, at 1:15 pm confirmed that a competency assessment policy had not been developed.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the</p>

laboratory failed to indicate the required demographic information on the patient test report for 9 (1-9) of 9 patients reviewed. Findings include: 1. A record review of 9 patient test reports revealed the following demographic information was missing from the patient test report: a. Patient name or unique identifier b. Name and address of the laboratory location c. Test report date d. Test performed e. Specimen Source f. Test Result g. Laboratory Director signature 2. A record review of patient reports missing the above demographic information are as follows: a. Patient 1: 04/01/2025 b. Patient 2: 04/04/2025 c. Patient 3: 04/30/2025 d. Patient 4: 05/07/2025 e. Patient 5: 05/12/2025 f. Patient 6: 05/14/2025 g. Patient 7: 05/16/2025 h. Patient 8: 05/19/2025 i. Patient 9: 05/22/2025 3. An interview on 05/29/2025 at 1:15 pm with the LD confirmed the demographics were missing on the patient test reports.