

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0672884	<b>(X3) Date Survey Completed</b> 10/31/2024
<b>Name of Provider or Supplier</b> Skin Cancer Centre, Pa	<b>Street Address, City, State</b> 1409 North Fant Street, Anderson, SC	
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>	An announced onsite CLIA recertification survey was conducted on October 31, 2024, at the clinical laboratory of the Skin Cancer Centre of Anderson, SC by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the Standard level deficiencies cited: Sent to enforcement 04/03/2025.
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy review, documentation review, and staff interview, the laboratory director (LD) failed to ensure that testing personnel receive proper training and competency evaluations. Findings included: 1. Review of laboratory policy reveals "Pathologists and Section Leader evaluate the competency of all testing personnel and assure that they maintain their competency to perform test procedures promptly, accurately and proficiently." 2. Review of testing personnel competency documentation reveals a lack of annual competency evaluation for testing personnel (TP1). 3. Review of personnel competency documentation reveals a single competency evaluation for TP1 for 2020. 4. In an interview on October 31, 2024, at 1:00pm with TP1 in the laboratory, the findings were confirmed.</p>

<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy review, documentation review, and staff interview, the technical consultant (TC) failed to evaluate competency of testing personnel and assure testing personnel maintain their competency to perform testing procedures. Findings included: 1. Review of laboratory policy reveals "Pathologists and Section Leader evaluate the competency of all testing personnel and assure that they maintain their competency to perform test procedures promptly, accurately and proficiently." 2. Review of testing personnel competency documentation reveals a lack of annual competency evaluation for testing personnel (TP1). 3. Review of personnel competency documentation reveals a single competency evaluation for TP1 for 2020. 4. In an interview on October 31, 2024, at 1:00pm with TP1 in the laboratory, the findings were confirmed.</p>
<p><b>D6053</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy review, documentation review, and staff interview, the technical consultant (TC) failed to evaluate and document performance of TP responsible for moderate complexity testing at least semiannually during the first year the TP tests patient specimens. Findings included: 1. Review of laboratory policy reveals "Pathologists and Section Leader evaluate the competency of all testing personnel and assure that they maintain their competency to perform test procedures promptly, accurately and proficiently." 2. Review of testing personnel competency documentation reveals a lack of semiannual competency evaluation for testing personnel (TP1). 3. Review of personnel competency documentation reveals a single competency evaluation for TP1 for 2020. 4. In an interview on October 31, 2024, at 1:00pm with TP1 in the laboratory, the findings were confirmed.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy review, documentation review, and staff interview, the technical consultant (TC) failed to evaluate and document the performance of TP</p>

responsible for moderate complexity testing at least annually. Findings included: 1. Review of laboratory policy reveals "Pathologists and Section Leader evaluate the competency of all testing personnel and assure that they maintain their competency to perform test procedures promptly, accurately and proficiently." 2. Review of testing personnel competency documentation reveals a lack of annual competency evaluation for testing personnel (TP1). 3. Review of personnel competency documentation reveals a single competency evaluation for TP1 for 2020. 4. In an interview on October 31, 2024, at 1:00pm with TP1 in the laboratory, the findings were confirmed.