

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0685911	<b>(X3) Date Survey Completed</b>  03/07/2024
<b>Name of Provider or Supplier</b>  Skin And Cancer Associates Llp	<b>Street Address, City, State</b>  1460 North University Dr, Coral Springs, FL	
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 conducted on March 5, 2024. Skin and Cancer Associates LLP Clinical laboratory was not in compliance with 42 CFR 493, requirements for laboratories.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the correct temperature for the cryostat for 25 out of 25 months reviewed. Findings included: - Review of "CRYOSTAT TEMPERATURE LOG" records revealed that they stated the following "Normal Ranges are -18 to -28 Degrees C." - Review of "CRYOSTAT TEMPERATURE LOG" for 25 consecutive months from February of 2022 until February of 2024 revealed that all the recorded temperatures were missing the minus (-) sign for the recorded temperature that were registered in the range of 21 to 25 Celsius Degrees. During an interview on 03/05/2024 at 12:19 PM with Testing Person #A, she confirmed that the "CRYOSTAT TEMPERATURE LOG" records missed the minus sign for temperature recordings.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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.

This STANDARD is not met as evidenced by:

Based on observation, Quality Control policy review and interview, the laboratory failed to dispose expired reagents since December 2023. Findings included: -Review of content in the reagent storage cabinet during the laboratory tour on 03/05/2024 at 9:55 AM, revealed that the laboratory had four one-gallon sealed containers of 10% formalin with lot # 2132640 and expiration date 11/30/2023 stored with other lots in use which were within expiration date. -Review of "Quality Control" Policy, revealed that it stated on Section "Reagents" the following: " Reagents that have expired or are no longer suitable for use must be properly disposed." During an interview on 03/05/2024 at 9:41 AM, Testing Person #A admitted that expired reagents needed to be disposed but have not called to place the order.