

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2065828	<b>(X3) Date Survey Completed</b>  09/13/2022
<b>Name of Provider or Supplier</b>  Sills Dermatology	<b>Street Address, City, State</b>  1003 Windover Rd, Jonesboro, AR	
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>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: Through observation, review of Mohs surgery log, review of cryostat temperature records and interview with laboratory staff it was determined that the laboratory failed to document proper cryostat operating temperatures for 6 of 125 Mohs surgery procedures performed in 2022. Findings follow: A) During a tour of the laboratory on 9/13/22 at 12:50 p.m. two cryostats, designated QS11 and QS12, both with an acceptable temperature range of -21 degrees C. to -35 degrees C. were observed in the tissue processing area. B) Review of the Mohs surgery log for 2022 revealed that Mohs surgery procedures were performed on six patients (specimen numbers 22m-0274, 22m-0275, 22m-0276, 22m-0277, 22m-0278 and 22m-0279) on 7/19/22 C) Review of the cryostat temperature log for cryostat QS12 revealed that no operating temperature was recorded on 7/19/22. D) In an interview on 9/13/22 at 1:40 p.m. the laboratory staff member (#2 on the CMS 209 form) stated that she was not present on 7/19/22 and other personnel would have used cryostat QS11 to process Mohs surgery patients on that day and that temperature records for cryostat QS11 were hanging on the side of the instrument since that unit was rarely used. E) Review of the temperature records on the side of cryostat QS11 revealed that no operating temperature was recorded on 7/19/22. F) In an interview on 9/13/22 at 1:40 p.m. the laboratory staff member (#2 on the CMS 209 form) and the laboratory director</p>

confirmed that Mohs surgery was performed on 7/19/22 and there was no documentation of the proper cryostat operating temperature on that day.