

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0933599	(X3) Date Survey Completed 01/27/2022
Name of Provider or Supplier St Luke's Clinic - Dermatology Wood River	Street Address, City, State 100 Hospital Dr Ste 201, Ketchum, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the laboratory lead on 1/27/2022 the laboratory failed to verify the accuracy of potassium hydroxide (KOH) testing for 2021. The findings include: 1. A review of the laboratory records identified that the laboratory failed to verify the accuracy for KOH testing at least biannually for 2021. 2. An interview with the laboratory lead on 1/27/2022 at 12:01 pm confirmed that the laboratory failed to verify the accuracy of KOH testing for 2021. 3. The laboratory reports performing 60 KOH tests annually.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory lead on 1/27/2022, the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1451(b)(7)(8) for 2021. The findings include: 1. A review of competency assessment records</p>

identified one (1) of two (2) testing personnel listed on the CMS 209 failed to have documentation of annual competency for mapping and tissue grossing which included the six parameters as listed in 493.1451(b)(8) for 2021. 2. A review of competency assessment records identified two (2) of two(2) testing personnel listed on the CMS 209 failed to have documentation of annual competency for KOH testing which included the six parameters as listed in 493.1451(b)(8) for 2021. 3. An interview with the laboratory lead on 1/27/2022 at 11:58 confirmed the above findings. 4. The laboratory reports performing 573 KOH and histopathology tests annually.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:
Based on a record review of laboratory logs, cryostat manual and an interview with the laboratory lead on 1/27/2022, the laboratory failed to document humidity and room temperature as required for operation of the Avantik cryostats while performing Mohs procedures. The findings include: 1. A review of the manual for the Avantik cryostats identified that the operational humidity is less than or equal to 60% and the operating temperature is 5-35 C. 2. A review of the laboratories logs identified that the laboratory failed to document humidity and room temperature for 2021. 3. An interview with the laboratory lead confirmed that the laboratory fail to document humidity room temperature. 4. The laboratory reports performing 513 Mohs procedures annually.