Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2060605	12/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
St Luke's Clinic Dermatology & Mohs Surgery	714 N College Rd Ste B (Rome Building), Twin Falls, 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
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 and an interview with the laboratory compliance officer on 12/2/2021, the laboratory failed to document humidity as required for operation of the Leica cryostats while performing Mohs procedures. The findings include: 1. A review of the manuals for the Leica CM1520 and CM1950 cryostats identified that the operational humidity is less than 60%. 2. A review of the laboratories daily QC log identified that the laboratory failed to document humidity. 3. An interview with the laboratory compliance officer confirmed that the laboratory fail to document humidity. 4. The laboratory reports performing 1,000 Mohs procedures annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory compliance officer on 12/2/2021, the laboratory failed to perform maintenance on the Leica CM1520 cryostat as defined by the manufacturer and with at least the minimum specified frequency. The findings include: 1. The Leica CM1520 cryostat manual states that the instrument must have the plastic coupling oiled and the specimen cylinder lubricated weekly. 2. A record review of the daily QC log identified that the laboratory failed to document weekly maintenance required by the manufacturer on the Leica cryostat CM1520. 3. An interview with the laboratory compliance officer on 12/2/2021 at 1:30 pm confirmed that the laboratory had not document performance of weekly maintenance on the Leica cryostat CM1520. 4. The laboratory reports performing 1000 Mohs procedures annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review and and interview with the laboratory compliance officer on 12/2/2021, the laboratory failed to document corrective actions when temperatures were outside the operating parameters for the Leica CM1520 cryostat. The findings include: 1. A review of the laboratories daily QC log identified that the laboratory did not document corrective actions when the operating temperature for the Leica CM1520 was out of the established operating range of -22 to -27C. The laboratory failed to document corrective actions for out of range temperatures 9 of 11 days in June 2021, 6 of 6 days in July 2021, 8 of 13 days in August 2021, 6 of 11 days in September 2021, 8 of 10 days in October 2021, 9 of 10 days in November 2021 and 1 of 1 days in December 2021. 2. An interview with the laboratory compliance officer on 12/2/2021 at 10:19 am confirmed the above findings. 3. The laboratory reports performing 1,000 Mohs procedures annually.
D5805	TEST REPORT CFR(s): 493.1291(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.

	This STANDARD is not met as evidenced by: Based on a review of laboratory patient reports and an interview with the laboratory compliance officer on 12/2/2021, the laboratory failed to identify the name and address of the laboratory performing the reported Mohs procedures. The findings include: 1. A review of laboratory patient test reports identified that the laboratory failed to include the correct name and address of the the laboratory performing and reporting patient Mohs procedures. 2. An interview with the laboratory compliance officer on 12/2/2021 at 10:40 am confirmed that the laboratory failed to correctly identify the name and address of the performing laboratory. 3. The laboratory reports performing 1,000 Mohs procedures annually.