

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0953747	<b>(X3) Date Survey Completed</b>  09/17/2020
<b>Name of Provider or Supplier</b>  St Luke's Dermatology	<b>Street Address, City, State</b>  920 E First St Ste 201, Duluth, MN	
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:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document temperatures for the cryostat for multiple dates in 2018, 2019 and 2020. Findings are as follows:: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a visual observation of the laboratory on 9/17/20 at 10:00 a.m. 2. The Leica CM1850 Cryostat was observed as present and available for use during a visual observation of the laboratory. 3. Based on a review of the Mohs patient log, daily temperatures for the above equipment were not documented on the following dates on which Mohs surgery patients were tested: Date # of Mohs cases performed 7/24/18 4 9/6/18 3 12/3/18 5 12/4/18 5 12/20/18 4 10/30/19 4 10/31/19 5 11/19/19 4 2/03/20 3 2/25/20 5 7/28/20 3 4. The laboratory was unable to provide the cryostat temperature documentation upon request. 5. In an interview on 9/17/20 at 12:45 p.m., the MT confirmed the above findings. .</p>
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the</p>

manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to document Histopathology quality control (QC) performance.

Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a visual observation of the laboratory on 9/17/20 at 10:00 a.m. 2. A patient case (M20-114) from 4/30/2020 was reviewed. 3. Documentation of 04/30/20 QC slide performance was not included in the written log. 4. In an interview on 9/17/20 at 12:45 p.m., the MT confirmed the above findings. .