

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2105418	<b>(X3) Date Survey Completed</b>  11/02/2021
<b>Name of Provider or Supplier</b>  Lakes Dermatology	<b>Street Address, City, State</b>  14305 Southcross Dr W #110, Burnsville, 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 instrument temperatures for a cryostat for 2 of 66 dates on which Mohs surgery was performed. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing as confirmed by the Histotechnician (HT) during the entrance interview on 11/02/21 at 12:35 p.m. 2. A Leica model CM-1860 (S/N: C840214712TV0057/08/15) Cryostat was observed as present and available for use during a tour of the lab. 3 A requirement to record the operating temperature of the cryostat each day of patient testing was established in the Procedure: "Tissue Processing in Mohs Micrographic Surgery" / Section A, located in the Laboratory Manual. 4. During a review of the Cryostat Daily / Weekly / Monthly QA Log, cryostat temperature documentation was not found in laboratory records for 2 of 66 days on which Mohs surgery was performed during the time period reviewed, 11/19/19 through 11/02/21. Date of service 12/03/19 9/21/21 5. The laboratory was unable to provide the missing records upon request. 6. During an interview on 11/02/21 at 3:15 p.m., the HT confirmed the above findings. .</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 document review and interview with laboratory personnel, the laboratory failed to ensure a solution used for Microbiology microscopic examinations was not used after the expiration date had been exceeded in 2020 and 2021. Findings are as follows: 1. The laboratory performed fungal microscopic examinations under the Microbiology specialty as confirmed by the Histotechnician (HT) during the entrance interview on 11/02/21 at 12:35 p.m. 2. Expired Potassium Hydroxide (KOH) solution was used for testing patient specimens in 2020 and 2021 as indicated on the KOH /Stain Reagent Log provided by the laboratory. See below for detailed information. Solution: KOH Lot #: 191616 Expiration Date: 4/15/20 Dates used: 7/20/20 - 5/5/21 # of fungal microscopic examinations performed during this time period: 26 3. During an interview on 11/02/21 at 3:15 p.m., the HT confirmed the above findings. NOTE: This is a repeat deficiency from the 11/05/19 survey. .

**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 observation, document review and interview with laboratory personnel, the laboratory failed to document required maintenance on equipment used for Histopathology testing. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing as confirmed by the Histotechnician (HT) during the entrance interview on 11/02/21 at 12:35 p.m. 2. A Leica model DM-750 (S/N:2212/01. 2016) Microscope was observed as present and available for use during a tour of the lab. 3. Requirements for daily maintenance of the microscope were established in the Laboratory Manual. 4. Documentation of daily maintenance for the microscope was not found during review of laboratory records for 3 of 66 days on which Mohs surgery was performed during the time period reviewed, 11/19/19 through 11/02/21. . Date of service: 12/03/19 1/12/21 2/9/21 5. The laboratory was unable to provide the missing records upon request. 6. During an interview on 11/02/21 at 3:15 p.m., the HT confirmed the above findings. .

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the 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 document review and interview with laboratory personnel, the laboratory

failed to document Histopathology quality control (QC) performance for Hematoxylin and Eosin (H&E) staining for 1 of 66 dates on which Mohs surgery was performed. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing as confirmed by the Histotechnician (HT) during the entrance interview on 11/02/21 at 12:35 p.m. 3 A requirement to record the H&E stain quality each day of patient testing was established in the Procedure: "Tissue Processing in Mohs Micrographic Surgery" / Section G, located in the Laboratory Manual. 3. Documentation of H&E stain quality was not included in the H&E Stain Quality log for 1 of 66 dates on which Mohs surgery was performed. Date of service 6/29/21 4. The laboratory was unable to provide the missing records upon request. 5. During an interview on 11/02/21 at 3:15 p.m., the HT confirmed the above findings. .

**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 document review and interview with laboratory personnel, the laboratory failed to ensure corrective actions were taken when an equipment operating temperature fell outside the established parameters. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing as confirmed by the Histotechnician (HT) during the entrance interview on 11/02/21 at 12:35 p.m. 2. A Leica model CM-1860 (S/N: C840214712TV0057/08/15) Cryostat was observed as present and available for use during a tour of the lab. 3 A requirement that the operating temperature of the cryostat be in the range of -22 to -28 degrees Celsius was established in the Procedure: "Tissue Processing in Mohs Micrographic Surgery" / Section A, located in the Laboratory Manual. 4. The cryostat temperature was outside the established temperature range for 7 of 66 days on which Mohs surgery was performed during the time period reviewed, 11/19/19 through 11/02/21. Date of service 11/17/20 12/01/20 12/4/20 12/8/20 2/23/21 5/25/21 6/1/21 5. The laboratory was unable to provide the missing corrective action records upon request. 6. During an interview on 11/02/21 at 3:15 p.m., the HT confirmed the above findings. .