

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2258312	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Clear Creek Dermatology	Street Address, City, State 904 Ford St, Llano, TX	
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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy and procedure, manufacturer's instructions, presurvey paperwork, maintenance records, and interview, the laboratory failed to follow its own procedure to perform annual preventative maintenance on the Tanner Scientific TN50 cryostat used in Mohs testing for one of one years' reviewed.</p>

Findings follow. A. Review of the laboratory's policy and procedure titled "Quality Control Program," approved 06/23/2022, under "Equipment Quality Control for Cryostats" stated, "10) Preventative maintenance and grounding check are done yearly." B. Review of the Tanner Scientific Operating Instructions for the Cryostat TN50, 03/2020, at chapter 10.3 Recommended Maintenance and Service Schedule stated "Yearly Complete Service (performed by authorized Tanner Scientific service technician) check all functions complete defrost removing of microtone oiling of movable parts check of cooling system check of driving system complete disinfection /cleaning/drying". C. Review of the presurvey paperwork titled "Annual Test Volume & Proficiency Testing Programs Worksheet" showed the laboratory began Mohs testing on 06/23/2022 (elapsed time 2 years). D. Annual preventive maintenance records were requested on 07/29/2024 at 1300 hours but not provided. E. Interview with the Mohs histotech on July 29, 2024 at 1300 hours in the office confirmed the findings. II. Based on review of the laboratory's policy and procedure, manufacturer's instructions, presurvey paperwork, maintenance records, and interview, the laboratory failed to define preventative maintenance frequency for the Accu-Scope 3000-LED Microscope used in Mohs testing for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled "Quality Control Program," approved 06/23/2022, did not define the frequency of preventative maintenance on the microscope. B. Review of the Accu-Scope 3000-LED Manual under Care and Maintenance stated "5. Accu-Scope microscopes are precision instruments which require periodic preventative maintenance to maintain proper performance and to compensate for normal wear. An annual schedule of preventative maintenance by qualified personnel is highly recommended. Your authorized Accu-Scope distributor can arrange for this service." C. Review of the presurvey paperwork titled "Annual Test Volume & Proficiency Testing Programs Worksheet" showed the laboratory began Mohs testing on 06/23/2022 (elapsed time 2 years). D. Preventive maintenance records were requested on 07/29/2024 at 1300 hours but not provided. E. Interview with the Mohs histotech on July 29, 2024 at 1300 hours in the office confirmed the findings.

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:
I. Based on review of the laboratory's policy and procedure, temperature logs, Mohs logs, and interview, the laboratory failed to ensure the Tanner Scientific TN50 cryostat was within range for 35 of 84 days of Mohs testing reviewed over 18 1/2 months. Findings follow. A. Review of the laboratory's policy and procedure titled "Quality Control Program," approved 06/23/2022, under "Equipment Quality Control for Cryostats" stated, "1) Temperature is checked and recorded daily and documented. Temperature range is -23 degrees Celsius to -28 degrees Celsius. 3) Corrective action is taken and documented if temperature exceeds range." B. Review of the Cryostat Temperature Record from 01/05/2023 - 07/18/2024 stated "Specified Temp Limits

-23 to -28 degrees Celsius revealed out of range temperatures on the following dates with the cryostat temperature in Celsius: Mohs Test Date Cryostat Temperature in Celsius 1. 01/26/2023 -22 2. 02/16/2023 -22 3. 02/23/2024 -20 4. 04/02/2023 -22 5. 03/21/2023 -22 6. 04/20/2023 -22 7. 04/27/2023 -21 8. 05/02/2023 -21 9. 05/04/2023 -19 10. 05/11/2023 -21 11. 05/18/2023 -20 12. 05/25/2023 -19 13. 05/27/2023 -21 14. 06/05/2023 -20 15. 06/06/2023 -20 16. 06/08/2023 -20 17. 06/15/2023 -20 18. 06/20/2023 -21 19. 06/27/2023 -20 20. 06/29/2023 -18 21. 06/30/2023 -19 22. 07/06/2023 -20 23. 07/13/2023 -21 24. 07/25/2023 -20 25. 07/27/2023 -20 26. 08/03/2023 -21 27. 08/10/2023 -19 28. 08/17/2023 -19 29. 08/24/2023 -19 30. 08/25/2023 -20 31. 08/31/2023 -19 32. 09/07/2023 -20 33. 09/21/2023 -20 34. 10/05/2023 -19 35. 10/12/2023 -19 C. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 606 blocks. D. Interview with the Mohs histotech on July 29, 2024 at 1140 hours in the office confirmed the findings after a review of the findings. II. Based on review of manufacturer's instructions, temperature logs, Mohs logs, presurvey paperwork, and interview, the laboratory failed to ensure the Mohs laboratory room temperature was within range of the operating specifications for the Tanner Scientific TN50 cryostat for five of 23 days of Mohs testing reviewed. Findings follow. A. Review of the Tanner Scientific Operating Instructions for the Cryostat TN50, 03/2020, at chapter 5. Specifications TN50 stated "Temperature range during operation +10 to +25 degrees Celsius." B. Review of the Temperature Record Mohs Lab Room from 01/04/2024 - 07/18/2024 showed the room temperature acceptable range was 5 to 35 degrees Celsius. Review of the documented room temperature on the logs showed the room temperature exceeded 25 degrees Celsius on the following Mohs testing days, as listed by date and room temperature in Celsius: Mohs Test Date Room Temperature in Celsius 1. 01/04/2024 25.2 2. 01/25/2024 25.5 3. 03/14/2024 25.8 4. 03/21/2024 25.2 5. 04/04/2024 25.2 The log had the incorrect acceptable room temperature range of 5 to 35 degrees Celsius. C. Random sampling of the dates revealed the number of Mohs cases performed: 1. 03/14/2024 14 cases D. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 606 blocks. E. Interview with the Mohs histotech on July 29, 2024 at 1240 hours in the office confirmed the findings after a review of the 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:

I. Based on review of the laboratory's policy and procedure, temperature logs, Mohs logs, corrective action, and interview, the laboratory failed to perform and document corrective action when the Tanner Scientific TN50 cryostat was out of range for 35 of 84 days of Mohs testing reviewed over 18 1/2 months (see D5413 I). Findings follow. Review of documentation of corrective action showed none for the cryostat. Interview with the Mohs histotech on July 29, 2024 at 1140 hours in the office confirmed the

findings. II. Based on review of manufacturer's instructions, temperature logs, Mohs logs, presurvey paperwork, corrective action and interview, the laboratory failed to perform and document corrective action when the Mohs laboratory room temperature exceeded the operating specifications for the Tanner Scientific TN50 cryostat for five of 23 days of Mohs testing reviewed (see D5413 II). Findings follow. Review of documentation of corrective action showed none for the room temperature. Interview with the Mohs histotech on July 29, 2024 at 1240 hours in the office confirmed the findings.