

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2287799	<b>(X3) Date Survey Completed</b> 03/21/2024
<b>Name of Provider or Supplier</b> Clear Creek Dermatology Marble Falls	<b>Street Address, City, State</b> 507 W 2147 Suite 204, Marble Falls, TX	
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>D0000</b>	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.
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Mohs test report and interview, the laboratory failed to include the name and address of the facility on the Mohs map for eight of eight cases for a period of five months reviewed. Findings follow. A. Review of the Mohs maps showed no name and address of the facility where the testing was performed. The following reports were reviewed as listed by case number and date of service: 1. 09/18/2023 M23-026 2. 10/02/2023 M23-058 3. 10/23/2023 M23-091 4. 11/14/2023 M23-144 5. 01/08/2024 M24-010 6. 01/29/2024 M24-039 7. 02/12/2024 M24-075 8. 03/04/2024 M24-113 B. Interview with the histotechnologist on March 21, 2024 at 1040 hours acknowledged she had removed the name and address on the Mohs maps when they added facility locations for ease of document revisions.</p>
<b>D6127</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p>

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedures, pre-survey paperwork, laboratory records, and interview, the technical supervisor failed to evaluate the competency at least semi-annually during the first year the individual tested patient specimens for one of one new hires that performed Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance Manual (no origination/approval date), stated, "It is the policy of this laboratory that all personnel implicitly adhere to the policies and procedures as published by this laboratory. Personnel assessment of competency is required semiannually for the first year and annually thereafter." And, under Personnel Assessment stated, "If the laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competency in job performance." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209), began Mohs testing on 8/22/2023 (elapsed time: 7 months). C. Review of the laboratory records showed no semi-annual competency evaluation performed. A competency evaluation was requested on 3/21/2024 at 1040 hours but not provided. D. Interview with the histotechnologist on March 21, 2024 at 1040 hours confirmed they had not performed a competency evaluation.