

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2280400	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Clear Creek Dermatology Fredericksburg	Street Address, City, State 205 W Wincrest Suite 340, Fredericksburg, 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	An onsite recertification survey conducted February 5, 2026, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. Standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 laboratory policy, review of temperature and humidity charts, and interview with laboratory personnel, the laboratory failed to record the temperature and humidity of the laboratory for one of five testing dates in 2024. The findings included: 1. The laboratory policy "Quality Control Program" stated the following: "Daily room temperature and humidity values will be documented on days that the Mohs lab is in use. These will be signed off by the Mohs tech and physician." 2. Based on review of the laboratory temperature and humidity charts for 2024, there were no temperature or humidity levels recorded on October 1, 2024. A review of the Mohs Specimen Log indicated that Mohs testing was performed on October 1, 2024. The following patient specimens were tested on 10/01/2024: MS24-043 MS24-044 MS24-045 MS24-046 MS24-047 MS24-048 MS24-049 MS24-050 MS24-051 MS24-052 3. In an interview at 10:29 hours on February 5, 2026, in the reception area, the Practice Manager confirmed the findings.</p>

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:

Based on laboratory policy, review of stain quality control records, and interview with laboratory personnel, the laboratory failed to record the acceptability of the stain used in Mohs testing for one of five testing dates in 2024. The findings included: 1. The laboratory policy "Quality Assurance Manual" stated the following: "The Laboratory Director will ensure that quality control of Mohs slides is evaluated every Mohs day at least twice a year." 2. Based on review of the laboratory Mohs quality control charts for 2024, there were no stain acceptability levels recorded on October 1, 2024. The following patient specimens were tested on 10/01/2024: MS24-043 MS24-044 MS24-045 MS24-046 MS24-047 MS24-048 MS24-049 MS24-050 MS24-051 MS24-052 3. In an interview at 10:35 hours on February 5, 2026 in the reception area, the Practice Manager confirmed the findings.