

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2193220	(X3) Date Survey Completed 08/31/2021
Name of Provider or Supplier Tooele Dermatology	Street Address, City, State 2321 N 400 E, #200, Tooele, UT	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview with the office manager/histotech, quality assessment activities were not documented. The laboratory performs approximately 150 Mohs tests annually. Findings include: 1. A procedure titled "Remedial Actions" was included in the laboratory procedure manual. 2. The Remedial Actions procedure requires the use of a corrective action form to investigate and document corrections to any incidents, complaints, or quality failures. 3. No corrective action form was found in the documents. 4. In an interview on 8/31/2021 at approximately 3:30 pm, the office manager/histotech confirmed that a corrective action form has not been created or put in use.</p>
D5413	<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>

This STANDARD is not met as evidenced by:

Based on record review, direct observation, and interview with the office manager /histotech, temperature and humidity of the laboratory were not monitored. The laboratory performs approximately 150 Mohs tests annually. Finding include: 1. Record review included boxes to document room temperature and humidity on the maintenance log. 2. The boxes for room temperature and humidity were checked on days that Mohs testing was performed. 3. No thermometer or hygrometer was present in the laboratory during observation. 4. Hematoxylin stain manufacturer requires storage at 15 - 30 degrees C. 5. In an interview on 8/31/2021 at approximately 3:30 pm, the office manager/histotech confirmed that room temperature and humidity was not monitored.