

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2152412	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Mohs-Tek, Inc	Street Address, City, State 1342 Bell Ave Ste 3h, Tustin, CA	
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
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> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's analytical records for temperature monitoring with laboratory personnel (LP), it was determined that there were not written documentation metrics for room temperature and testing support implementation. CLIA regulations require that testing conditions be monitored and documented. Findings include: 1. On 11/3/2021, an inspection was conducted between 9:00 a.m. and 10:30 a.m. 2. During a review of the laboratory operations and analytical support instruments, it was noted that there was not written documentation to validate instrument temperatures for devices used directly to support instrument testing 3. The following instruments are used for testing directly or indirectly: -Room temperature thermometer -Refrigerator -Freezer -Embedding wax dispenser - Embedding cold plate -Oven -Water bath 4. The LP affirmed that there were not documented temperatures..</p>