

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0673123	(X3) Date Survey Completed 11/18/2019
Name of Provider or Supplier Limmer Dermatology	Street Address, City, State 4630 N Loop 1604 West, Suite 316, San Antonio, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's accuracy assessment records from 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for MOHS testing in 2018. Findings include: 1. A review of the laboratory's accuracy assessment records from 2018 revealed the laboratory had documentation of performing the assessment only once in 2018. The accuracy assessment for 2018 was performed: 7/11/2018 2. The laboratory was asked to provide documentation of performing the required twice annual accuracy</p>

assessments. No documentation was provided. 3. An interview with the laboratory director on 11/18/19 at 9:40 a.m. in the consultation room, after her review of the records, confirmed the above 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:

Based on a review of the manufacturer's instructions for the Leica CM1510S Cryostat, review of the MOHS Laboratory Temperature Logs from 2018 and 2019, and staff interview, it was revealed the laboratory failed to maintain the room temperature according to the manufacturer's stated temperature requirements. Findings include: 1. A review of the manufacturer's instructions for the Leica CM1510S Cryostat (V1.0 08 /2003) under the section titled "Installation site requirements" revealed the following: "The place of installation must meet the following requirements: Room temperature maximum 22C." 2. The laboratory recorded the room temperature in Fahrenheit. 22C is equivalent to 71.6F. 3. A review of the MOHS Laboratory Temperature Logs from January 2018 to October 2019 revealed the following days where the documented maximum room temperature exceeded the manufacturer's requirement of 22C (71.6F): a) April 3, 2018 73F b) June 5, 2018 72F c) October 25, 2018 72F d) October 26, 2018 72F e) October 29, 2018 72F f) November 16, 2018 72F g) March 15, 2019 72F F 4. An interview with the laboratory director on 11/18/19 at 9:40 a.m. in the consultation room, after review of the records, confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED ON 11 /2017.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 1 of 2 testing personnel for moderately complex testing in 2018. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/18/19), revealed the laboratory identified 2 testing personnel. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing competency assessments for 1 of 2 testing personnel for moderately complex testing for the speciality Mycology in 2018. The testing personnel with no

documentation of competency assessments: Testing person #2 3. An interview with the laboratory director on 11/18/19 at 9:40 a.m. in the consultation room, after review of the records, confirmed the above findings.