

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0880563	(X3) Date Survey Completed 08/28/2020
Name of Provider or Supplier Lake Dermatology Pa	Street Address, City, State 1132 E North Blvd, Leesburg, FL	
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	A recertification survey was conducted on August 28, 2020. Lake Dermatology PA clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) preparations for fungus and the wet mount preparations for scabies and parasites at least twice annually in 2019. Findings: Review of the "Semi-Annual KOH and Ova & Parasite Quality Assurance" log showed that peer review by split specimen evaluation was only performed once on 1/30/19 for parasites. There was no peer review for KOH in 2019. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/6/20, the laboratory had an estimated annual test volume of 100 mycology and parasitology tests per year. During an interview on 8/28/20 at 10:23 AM, the manager the split testing was only performed once during 2019.</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</p>

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 record review and interview, the laboratory failed to record the temperature and humidity of the room where testing was performed from 8/28/18 to 8/28/20.

Findings: Review of the operations manual for the laboratory's Leica CM 1850 cryostat noted that the room temperature maximum should be 35 degrees Celsius and the air humidity should not exceed 60%. A review of the laboratory's logs showed that the laboratory failed to record the room temperature and humidity of the room where testing was performed. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/6/20, the laboratory had an estimated annual test volume of 800 histopathology tests per year. During an interview on 8/28/20 at 10:43 AM, the Manager stated they did not record the temperature or the humidity of the laboratory.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory failed to ensure the Potassium Hydroxide (KOH) was not expired prior to patient testing. Findings: Observations made during a tour of the laboratory on 8/28/20 at 9:58 AM, showed that the bottle of Potassium Hydroxide 10% with DMSO (Dimethyl Sulfoxide) expired on Dec 2016. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/6/20, the laboratory had an estimated annual test volume of 100 mycology and parasitology tests per year. The laboratory performed the following tests: KOH preparations for fungus, and wet mount preparations for scabies and parasites. During an interview on 8/28/20 at 10:00 AM, the manager stated that KOH reagent was expired and that the expired KOH reagent was currently the only bottle at the facility.