

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0525211	(X3) Date Survey Completed 08/31/2022
Name of Provider or Supplier Lone Peak Dermatology	Street Address, City, State 11760 S 700 E Suite 210, Draper, 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
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 with the Laboratory Director, the laboratory failed to verify the accuracy for potassium hydroxide (KOH) preparations twice a year. The laboratory performs approximately 50 mycology tests annually. Finding include: 1. During laboratory record review, the laboratory failed to produce records of accuracy verification since last survey was conducted on 11/01/2019. 2. Interview with the laboratory director on 08/31/2022, at 1:45 PM confirmed the laboratory failed to verify the accuracy of KOH two times per year.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with testing personnel, the laboratory failed to ensure that the StatLab tissue marking dyes were not used past their expiration date. The laboratory performs approximately 26 histopathology tests annually. Findings: 1. Direct observation of StatLab tissue marking dyes on 08/31/2022 at 2:08 PM revealed that 4 of 5 StatLab tissue marking dyes had expirations dates of 2019-11-30, 2019-10-31, 2022-01-31, and 2021-21-31. 2. Interview with the testing personnel on 08/31</p>

/2022 at 2:10 PM confirmed the StatLab tissue marking dyes were being utilized for patient testing past their expiration date.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with Laboratory Director, the laboratory failed to perform control procedures each day patient specimens are examined potassium hydroxide (KOH) preparations. The laboratory performs approximately 50 mycology test annually. Findings include: 1. A review of laboratory records failed to include records of positive and negative control procedures being performed for KOH preparations since the last survey on 11/01/2019. 2. An interview on 08/31/2022, at 1: 50 PM, with the LD confirmed the laboratory failed to perform control procedures each day patient specimens are examined for KOH preparations.