

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2068472	(X3) Date Survey Completed 09/19/2018
Name of Provider or Supplier Alpine Dermatology Clinic Pc	Street Address, City, State 780 Bridgeport Rd, Idaho Falls, ID	
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 a record review and an interview with the operations manager, the laboratory failed to verify the accuracy of both microscopic examinations for histopathology specimens and the presence of fungal elements using potassium hydroxide (KOH) at least twice a year since the last survey on July 20, 2017. Findings: 1. A record review revealed the laboratory failed to document the accuracy of microscopic examinations for KOH, used for the detection of fungal elements on the skin and histopathology specimens at least twice a year since the last survey in 2017. 2. An interview on September 19, 2018 at 8:20 AM, with the operations manager, confirmed the laboratory failed to document the accuracy of fungal and histopathology examinations at least twice a year.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of quality control records and an interview with the operations manager, the laboratory failed to document the known reactivity of hematoxylin and eosin (H&E) stain used in the microscopic examinations of histopathology specimens for the dates reviewed from July through August 2018. Findings: 1. A review of the quality control worksheet in the laboratory revealed the reactivity of a known control slide for H & E stains failed to be documented on the following dates: July 24, 2018, July 31, 2018, and August 11, 2018. 2. An interview on September 19, 2018 at 9:00 AM, with the operations manager, confirmed the laboratory failed to document the quality control for the H & E stain for 24 patient results reported during the dates of review.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the operations manager, the laboratory failed to document the lot numbers of hematoxylin and eosin (H & E) stain since August 2016. Findings: 1. A record review of laboratory worksheets revealed the laboratory failed to document the lot numbers for the H & E stains used in the microscopic examinations of histopathology specimens since 2016. 2. An interview on September 19, 2018 at 9:05 AM, with the operations manager, confirmed the laboratory failed to document lot numbers for the H & E stains.

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 record and an interview with the operations manager, the technical consultant who is the laboratory director failed to evaluate the competency of 1 out of 1 testing personnel performing microscopic examinations of potassium hydroxide (KOH) since the last survey on July 20, 2017. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency of 1 physician assistant performing KOH exams since the last survey. 2. An interview on September 19, 2018 at 8:20 AM, with the operations manager, confirmed the technical consultant failed to assess and document the competency for one practitioner performing KOH examinations.