

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2120213	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Mountain Pine Dermatology	Street Address, City, State 4664 N Penngrove Way Ste 100, Meridian, 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 laboratory director, the laboratory failed to document the accuracy of dermatopathology and fungal microscopic examinations at least twice a year since the last survey on December 2016. Findings: 1. A document review revealed the laboratory failed to document the accuracy of dermatopathology and fungal microscopic examinations performed on skin and biopsy sections at least twice a year. 2. An interview on November 7, 2018 at 2:45 P. M., with the laboratory director, confirmed the laboratory failed to document the accuracy of the microscopic examinations at least twice a year.</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 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 a record review of laboratory worksheets and an interview with the</p>

laboratory director, the laboratory failed to monitor and document the room temperature where staining procedures for dermatopathology microscopic examinations are performed and failed to identify the temperature range for the Cryostat since December 2016. Findings: 1. A review of temperature record logs revealed the laboratory failed to monitor and document the room temperature in the laboratory where Hematoxylin and Eosin staining procedures for microscopic biopsies examinations are performed. 2. A review of temperature record logs revealed the laboratory failed to indicate the Cryostat temperature reference range on the laboratory worksheets 2. An interview on November 7, 2018 at 3:30 P.M., with the laboratory director, confirmed the laboratory failed to monitor and document the room temperature of the laboratory and failed to state the Cryostat temperature range.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on a record a review and an interview with the laboratory director, the laboratory failed to document maintenance activities and function checks for the microscope used for dermatopathology microscopic examinations and skin fungal examinations since December 2016. Findings: 1. A review of the procedure manual and documents in the laboratory revealed the laboratory failed to follow and use the microscope maintenance document to record function checks and maintenance activities on the microscope used for examinations of skin biopsies and skin fungal examinations. 2. An interview on November 7, 2018 at 3:45 P.M., with the laboratory director, confirmed the laboratory failed to document maintenance activities on the microscopes.

D5601

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

(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.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the laboratory director, the laboratory failed to document the stain reactivity of Hematoxylin and Eosin (H & E) each day of patient testing from December 15, 2016 to November 1, 2017. Findings: 1. A review of quality control records and a review of the procedure manual revealed the laboratory failed to document the quality control reaction for H & E stain every day of

patient testing as indicated in the procedure manual. 2. An interview on November 7, 2018 at 3:35 P.M., with the laboratory director, confirmed the laboratory failed to document the reactivity of a quality control slide for H & E stains every day of patient testing.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of personnel competency assessments and an interview with the laboratory director, the laboratory director who is the technical supervisor failed to evaluate the competency of 2 out of 3 testing personnel who perform microscopic examinations for the presence of fungal elements and microscopic examinations of dermatopathology specimens since the laboratory began patient testing in December 2016. Findings: 1. A review of personnel documents revealed the technical supervisor failed to evaluate the competency of 1 out of 1 mid-level practitioner who performs potassium hydroxide examinations and 1 out of 2 providers who examine microscopic dermatopathology specimens since 2016. 2. An interview on November 7, 2018 at 2:30 P.M., with the laboratory director, confirmed competency assessment for the providers was not performed.