

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D1038865	(X3) Date Survey Completed 08/27/2020
Name of Provider or Supplier Western Wyoming Dermatology	Street Address, City, State 62 Redmond St, Jackson, WY	
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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation and interview with staff, the laboratory failed to retain 1 of 1 reference laboratory report for Mohs case #M19-139. The laboratory performed approximately 200 Mohs frozen section cases per year. Findings include: 1. Mohs map for case M19-139 included the diagnosis for the original biopsy from the right lateral upper lip, specimen number C19-11193 for basal cell carcinoma. 2. In an interview with staff on 08/27/2020 at approximately 11:30 A. M., staff confirmed the laboratory failed to retain the test report for at least 10 years from the date of reporting.</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 lack of documentation and interview with staff, the laboratory failed to verify histopathology frozen section analysis to determine the persistence or absence of tumor cells for 1 of 2 years of testing reviewed from August 27, 2018 to August 27, 2020. The laboratory performed approximately 200 frozen section tests per year.</p>

	<p>Findings include: 1. The laboratory failed to document histopathology of Mohs frozen section histopathology test accuracy twice in 2019. 2. In an interview conducted on 08/27/2020 at approximately 1:30 P.M., staff confirmed the laboratory failed to verify histopathology testing at least twice annually in 2019.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview with staff, the current laboratory director failed to sign and date as approved the current laboratory procedure manual. Findings include: 1. The laboratory procedure manual failed to include the current director's signature and date of approval. 2. In an interview conducted on 08/27/2020 at approximately 12:45 P.M., office staff confirmed the procedure manual failed to include the current director's signature and date of approval.</p>
<p>D5409</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and confirmation by staff the laboratory failed to document the dates mycology testing potassium hydroxide (KOH) and dermatophyte cultures were discontinued. Findings include: 1. The procedure manual included procedures for KOH and dermatophyte cultures. 2. The laboratory no longer performed KOH and dermatophyte culture testing. 3. In an interview conducted on 08/27/2020 at approximately 12:30 P.M., laboratory staff confirmed the procedure manual failed to document the date the testing was discontinued.</p>