

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0954867	(X3) Date Survey Completed 02/03/2021
Name of Provider or Supplier Aspen Dermatology	Street Address, City, State 114 E 800 N, Spanish Fork, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on histopathology frozen section slide review, slide labeling procedure review, and interview with staff, the laboratory failed to follow procedures for the labeling process to follow for multiple sections of specimens for one case for 1 of 11 cases reviewed. Findings include: 1. Histopathology slides for case EM19-04-08 review included 47 slides. The slides were reviewed failed to include the letter for the specimen section and the number of the slide made for each section for stage IV of the case. 2. Procedure review for Mohs frozen section surgery case slide included instruction to labeled each stage with the section number as A, B, C. and each cut from the section as 1,2,3...etc. 3. In an interview with staff on 02/03/2021 at approximately 12:10 P.M. staff confirmed the procedure was not followed for labeling each stage of testing for case EM19-04-08.</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>

This STANDARD is not met as evidenced by:

Based on direct observation and confirmation by staff the laboratory failed to ensure histopathology tissue marking dyes were not used past their expiration dates for 2 of 4 marking dye stains available for use on 02/03/2021 at approximately 9:15 A.M. The laboratory performed approximately 15 to 20 frozen section histopathology cases per week. Findings include: 1. Direct observation of marking dyes lot number 066247 (black) expiration date 05- 2020 and lot number 67796 (orange) expiration date 2020-06-01. 2. In an interview conducted on 02/03/2020 staff at approximately 12:20 P.M. confirmed the tissue marking dyes were expired.