

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 46D2133385 | (X3) Date Survey Completed 03/06/2018 |
| Name of Provider or Supplier Wasatch Dermatology | Street Address, City, State 5734 S 1475 E, Ste 300, South Ogden, 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 |
|---------------------------|--|
| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to retain documentation of reagent lot numbers, expiration dates, and record the dates reagents were placed in use for Hematoxylin and Eosin (H&E) staining of Mohs surgery tissue slides for 5 of 5 months of testing reviewed. The laboratory began patient testing in 09/2017 and had performed approximately 277 Mohs surgeries. Findings include: 1. The laboratory failed to retain records of each reagent lot number, dates reagents were in use, and reagent expiration dates for H&E reagents used to stain histopathology tissue slides. 2. Staff stated they had used multiple lot number of reagents since they began testing in 09/2018 and did not document which lots were in use and when they replaced their working reagents.</p> |