

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2033975	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Springville Dermatology And Diagnostics	Street Address, City, State 732 N Main Street, Springville, 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 laboratory procedure manual review, direct observation of histopathology slides and interview with staff, the laboratory failed to followed their process for slide labeling for approximately 6 of 6 slides reviewed for specimens processed off -site from 12/27/2016 to 10/24/2017. Findings include: 1. The laboratory procedure manual stated biopsy slides labeling included: "...slides are then labeled with the following information: i. Accession number (ALP 123) 1. Followed by the numerical case of this specimen. A 1234 would represent the 1234th case. ii. Patient last name and 1st initial, collection date. 2. Histopathology slides reviewed for SD16-7989, SD17-0041, SD17-3157, SD17-4967, SD17-6683, and SD17-7108 were labeled with the specimen number only (for example 17-4967). 3. In an interview conducted on 03/29/2018 at approximately 4:30 P.M. staff stated the slides were labeled by the accredited laboratory the laboratory used during the time period between December 2016 to December 2017.</p>
D5315	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c)</p> <p>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.</p>

This STANDARD is not met as evidenced by:
Based on patient test reports review and interview with staff, the laboratory failed to ensure histopathology gross analysis testing was referred only to a CLIA certified laboratory for specimens examined for testing performed from December 2017 to March 29, 2018. The laboratory performed approximately 14,000 tests annually. Findings include: 1. The test reports for specimens SD18-097, biopsy performed on 01/04/2018 and SD18-1111 biopsy performed on 02/19/2018 included the statement that the gross analysis was performed at Histotech located in Murray, UT. 2. Histotech of Murray, UT does not have a CLIA certificate. 3. In an interview with laboratory staff on 03/29/2018 at approximately 3:00 P.M., staff stated that since December 31st of 2017 all biopsy specimens were sent to Histotech for slide preparation and gross analysis.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with staff, the laboratory failed to test hematoxylin and eosin staining material each day of use to ensure predictable staining characteristics for 2 of 2 days of testing reviewed since the laboratory changed the preparation laboratory used for specimen processing after January 1, 2018. The laboratory performed approximately 25 histopathology diagnoses from slides prepared off-site. Findings include: 1. The laboratory lacked documentation of H and E stain adequacy for each day slides were received from the preparation laboratory. 2. The laboratory lacked documentation the stains were monitored for expiration dates and dates in use. 3. In an interview with staff on 03/29/2018 at approximately 4:45 P. M. staff stated they would send documentation of stain quality control for each day of testing from the preparation laboratory. The quality control documentation was not received by fax by 04/09/2018.