

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2042238	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Utah Valley Dermatology	Street Address, City, State 680 E Main St Suite 201, Lehi, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on patient test record review, patient specimen slide review, and interview with staff, the laboratory failed to establish and follow a procedure that ensures positive identification of patients specimens from the time of collection through completion of testing and reporting of results. Findings include: 1. Patient test records review failed to include the case number or a unique identification for Mohs surgical specimens to connect the specimen to the map to the test report for patient's with record numbers: 258997 collected on 06/09/2016, 324100 collected on 10/27/2016, 333206 collected on 03/29/2017, 251214 collected on 11/13/2017, 282856 collected on 02/15/2018, and 283676 collected on 03/29/2018, 2. Mohs specimen slide review included documentation the slides were labeled with the patient name, date of birth, date of service, stage, cut and Mohs surgical case number. 3. Mohs map review are labeled with the Mohs case number, patient's name and date of surgery. 4. Patient test reports failed to include the case number for patients: 333206, 251214, 282856, and 283676 . 4. In an interview conducted on 04/19/2018 at approximately 1:30 P.M., staff confirmed the laboratory failed to ensure the Mohs testing process uniquely linked the patient identity to the Mohs specimen, with the Mohs map with the patient specimen slide with the patient test report.</p>
D5315	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c)</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.

This STANDARD is not met as evidenced by:

Based on patient test reports review, lack of documentation, and interview with staff, the laboratory failed to ensure the laboratory performing gross analyses was CLIA certified for 2 of 8 histopathology formalin fixed, paraffin embedded biopsy specimen reports reviewed. The laboratory reported approximately 600 to 800 biopsies per year. Findings include: 1. Patient test report review included the statement that gross analyses were performed at Independent Histology for patient 10426 for specimen M18-0250 and patient 322258 for specimen M18-0538. 2. Independent Histology lacks a CLIA certificate for histopathology testing. 3. In an interview conducted on 04/19/2018 at approximately 1:00 P.M., laboratory staff stated they were not aware a CLIA certificate is required for performing gross analysis. testing

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with staff, the technical consultant failed to ensure competency evaluations for 1 of 1 testing person was performed annually for 1 of 2 years of testing reviewed (2017) for potassium hydroxide (KOH) preparation testing. The laboratory performed approximately 25 to 30 KOH tests per year. Findings include: 1. The laboratory failed to document they evaluated moderate complexity testing person annually in 2016 for KOH testing competency. 2. In an interview conducted on 04/19/2018 at approximately 12:45 P.M. staff confirmed the laboratory technical consultant failed to evaluate KOH testing personnel competency in 2016.