

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2042238	(X3) Date Survey Completed 01/14/2021
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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by staff the laboratory failed to evaluate 1 of 1 new testing persons twice the first year of potassium hydroxide testing. Findings include: 1. Moderate complexity test person B lacked documentation of semiannual competency the first year of KOH testing. 2. In an interview conducted on 01/14/2021 at approximately 12:00 P.M., staff confirmed they did not have semi annual documentation of competency evaluations for testing person B.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to evaluate 1 of 1 moderate complexity test person annually after the first year of testing in 2019 and 2020. Findings include: 1. Test person C lacked documentation of competency evaluations in 2019 and 2020 for potassium hydroxide testing. 2. In an interview conducted on 01/14/2021 at approximately 12:00 P.M. staff confirmed test person C did not have a competency evaluation in 2019 or 2020.</p>

<p>D6128</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to evaluate 2 of 2 testing personnel semiannually for the first year of histopathology testing. Findings include: 1. The laboratory lacked documentation 2 of 2 new dermatologists were evaluated twice the first year of histopathology testing in 2019 and 2020. 2. In an interview with staff on 01/14/2021 staff confirmed high complexity testing personnel were not evaluated for competency semiannually the first year they performed testing.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of dermatology board certification documentation and lack of training documentation for Mohs Micrographic surgical specimen frozen section histopathology testing, two of three histopathology testing personnel failed to qualify as high complexity histopathology testing personnel. (See D6171)</p>
<p>D6171</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60</p>

semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with staff, two of two new histopathology testing personnel failed to have documentation to perform histopathology frozen section testing, (testing personnel B and C). Findings include: 1. Testing person B lacked a copy of dermatology board certification and Mohs micrographic frozen section training and testing person C lacked documentation they received training for micrographic frozen section histopathology specimen testing received during their dermatology residency. 2. In an interview conducted on 01/14 /2021 testing person C stated the syllabus contained Mohs survey frozen section histopathology diagnosis and resolution training. Such documentation was not received for testing persons B or C.