

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0525866	<b>(X3) Date Survey Completed</b> 01/30/2018
<b>Name of Provider or Supplier</b> Southwest Skin And Cancer	<b>Street Address, City, State</b> 383 S 300 E, St George, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to verify 4 of 4 test's accuracy for 2 of 2 years of testing reviewed (2016 and 2017) for Potassium Hydroxide (KOH), Dermatophyte Test Media, (DTM), formalin fixed paraffin embedded skin biopsy diagnosis, and frozen section Mohs micrographic section skin biopsy determination for presence or absence of tumor cells. The laboratory performed approximately 50 KOH, 40 DTM, 6000 skin biopsies, and 650 frozen section tests per year. Findings include: 1. The laboratory failed to document KOH, DTM, paraffin embedded biopsy, and frozen section biopsy specimens were verified for test accuracy twice a year in 2016 and 2017. 2. In an interview with the director on 01/30/2018 at approximately 5:00 P.M. the director confirmed the lab had not documented the numerous verifications they perform for biopsy specimens and that they failed to have a system to verify KOH and DTM test accuracy twice a year.</p>
<b>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> 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 semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation and interview with staff, the</p>

technical supervisor failed to document competency evaluations for three of three new testing personnel performing gross analysis testing in for 1 of 1 year of testing (2017). Findings include: 1. Direct observation of the specimen processing laboratory and interview with the director on 01/30/2018 at approximately 5:00 P.M., the director stated the laboratory brought in gross analysis and slide preparation testing in 2017. Three testing personnel were brought in and received on-site training to perform the gross description and measurements. 2. The laboratory confirmed they failed to document competency evaluations for the 3 testing personnel

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

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.

This CONDITION is not met as evidenced by:

Based on lack of documentation and confirmation by staff, the laboratory testing personnel failed to document qualifications for 3 of 6 high complexity testing personnel to perform histopathology specimen gross analysis for dermatology specimens received for 1 of 2 years of testing reviewed (2017). The laboratory performed approximately 6000 histopathology specimen gross analyses per year. Findings include: 1. Three testing personnel performing gross analysis failed to document they met educational benchmarks to qualify as gross analysis testing personal of at least an associates degree in bacteriology, chemistry, physical science or medical technology or laboratory science. 2. In an interview with the director on 01/20/2018 at approximately 5:00 P.M. the director confirmed the staff did not have documentation for the 3 gross analysis testing personnel for the on-site survey. The laboratory brought gross analysis test performance on site in 2017.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(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 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 confirmation by staff, three of three testing personnel failed to document they met educational benchmarks to qualify to perform high complexity gross analysis testing for dermatology specimens for 1 of 1 year of testing reviewed (2017). Findings include: 1. Testing personnel D, E and F failed to have documentation of at least an associates degree in biology, chemistry, physical science or medical technology/ medical laboratory science as qualification to perform gross analysis testing in 2017. 2. In an interview with the director on 01/30/2018 at approximately 5:00 P.M. the director confirmed they did not have educational documentation for the 3 histotechnicians on site.