| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>46D0523585 | (X3) Date Survey Completed<br>05/01/2023 |
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| **Name of Provider or Supplier**<br>Uuhc Midvalley Dermatology - Mohs Laboratory | **Street Address, City, State**<br>243 East 6100 South, Murray, 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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the Clinic Manager, the laboratory failed to establish a written policy to assess personnel competency for practitioners who conducted (potassium hydroxide) KOH testing as specified in subpart M since the last survey on 11/19/2020. Findings include: 1. Review of laboratory policies and procedures revealed the laboratory failed to establish and perform competency assessment as specified in subpart M for 27 of 27 testing personnel who were practitioners conducting KOH testing. 2. On 05/01/2023 at approximately 3:00 PM, the Clinic Manager confirmed there was no competency assessment policy established or performed for practitioners conducting KOH testing. |
| **D5609** | HISTOPATHOLOGY<br>CFR(s): 493.1273(e)(f)<br><br>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review and interview by the Operations Manager, the laboratory failed to document the lot numbers and expiration dates of Hematoxylin and Eosin (H&E) stains in use since the last survey on 11/19/2020. The laboratory performed |

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| | approximately 2400 histopathology tests annually. Findings include: 1. Histopathology staining records review failed to include the lot number and expiration dates of H&E stains the laboratory used to stain histopathology controls and specimens since the last survey on 11/19/2020. 2. In an interview conducted on 05/01 /2023 at approximately 4:30 PM, the Operations Manager confirmed the histopathology staining records failed to include the lot number and expiration dates of H&E stains. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on personnel records and interview with the testing personnel, the laboratory failed to employ qualified testing personnel that met the educational requirements for high complexity grossing examination in histopathology testing. (Refer to D6171) |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on an interview with the testing personnel and review of education records, the laboratory failed to employ qualified personnel to perform gross examinations for high complexity histopathology testing. The laboratory performed approximately 2400 histopathology tests annually. Findings include: 1. Review of education records for one of five histotechnician testing personnel revealed educational requirements were not met for high complexity grossing examination in histopathology testing. 2. In an interview with the testing personnel on 05/01/2023 at approximately 3:06 PM it was confirmed one of five testing personnel did not meet the high complexity educational requirements for grossing histopathology specimens. |