Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2068472	09/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Alpine Dermatology Clinic Pc	780 Bridgeport Rd, Idaho Falls, ID	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, a lack of documentation and an interview with the lead histotechnician on 9/9/2024, the laboratory failed to follow written procedures to assess testing personnel's competency for Mohs mechanical procedures. The findings include: 1. A lack of competency assessment records identified four testing personnel listed on the CMS 209 that failed to have documentation of training and competency assessments for Mohs mechanical procedures including inking in 2023 and 2024. 2. An interview with the lead histotechnician on 9/9/2024 at 2:15 pm confirmed the above finding. 3. The laboratory reports performing 200 Mohs slide examinations annually. 4. This is a repeat deficiency from the previous inspection on 11/29/2022.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of Mohs peer review documents and an interview with the office manager on 9/9/2024, the laboratory failed to verify the accuracy of Mohs slide examinations at least twice annually in 2023 and 2024. The findings include: 1. A

	record review of peer review documents for Mohs slide examinations identified that the laboratory failed to verify the accuracy of Mohs slide examinations at least twice annually in 2023 and 2024. 2. An interview with the office manager on 9/9/2024 at 2: 42 pm confirmed that the laboratory did not verify the accuracy of Mohs slide examination twice annually for 2023 and 2024. 3. The laboratory reports performing 200 Mohs slide examinations annually. 4. This is a repeat deficiency for failure to perform biannual verification for Mohs slide examinations from surveys performed on 9/19/2018 and 2/25/2024.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a direct observation of laboratory equipment, a review of maintenance records, and an interview with the office manager on 9/9/2024, the laboratory failed to perform maintenance as required by the manufacturer for one of two cryostats. Findings include: 1. A direct observation in the laboratory identified two cryostats; a Leica CM 1510S and an Avantik QS12. 2. A review of the cryostat maintenance log identified that the laboratory failed to have a maintenance log and document maintenance for both of the cryostats in 2024. 3. An interview with the office manager on 9/9/2024 at 3:52 pm confirmed the lack of documentation for the Leica CM 1510S cryostat maintenance. 4. The laboratory reports performing 200 Mohs slide examinations annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of temperature logs and an interview with the office manager on 9/9/2024, the laboratory failed to document corrective actions when temperatures were out of the established ranges in 2023 and 2024. The findings include: 1. A review of the cryostat temperature logs for 2023 and 2024 identified that the laboratory failed to document corrective actions for 119 of 124 days in 2023 and 125 of 125 days in 2024 when the temperature was out of the established range of -20_-26 C. 2. A review of the room temperature logs for 2023 and 2024 identified that the laboratory failed to document corrective actions for 20 of 210 days in 2023 and 26 of 146 days in 2024 when the room temperature was out of the established range of 68_80 F. 3. An

	interview with the office manager on 9/9/2024 at 3:50 pm confirmed the above findings. 4. The laboratory reports performing 200 Mohs slide examinations annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, educational documents, laboratory logs, a lack of documentation and interviews with the lead histotechnician and office manger on 9/9/2024, the laboratory director failed to provide direction and management to the laboratory. See D6079, D6096 and D6102.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, a lack of competency assessment and training records and an interview with the lead histotechnician on 9/9/2024, the laboratory director failed to ensure adequate training of new testing personnel and competency of testing personnel in 2023 and 2024. The findings include: 1. A review of the CMS 209 form identified five testing personnel of which two were new since the previous inspection (11/29/22). 2. A review of competency assessment and training records identified the laboratory director failed to have documentation of initial training for two of two new testing personnel performing Mohs mechanical procedures including inking. 3. A review of competency assessment records identified the laboratory director failed to document annual competency for two of two testing personnel performing Mohs mechanical procedures in 2023 and 2024. 4. An interview with the lead histotechnician on 9/9/2024 at 2:15 pm confirmed the above findings. 5. The laboratory reports performing 200 Mohs slide examinations annually.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and

	documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of temperature logs and an interview with the office manager on 9/9/2024, the laboratory director failed to ensure corrective actions were taken when temperatures were out of the established ranges in 2023 and 2024. The findings include: 1. A review of the cryostat temperature logs for 2023 and 2024 identified that the laboratory director failed to ensure corrective actions were taken for 119 of 124 days in 2023 and 125 of 125 days in 2024 when the temperature was out of the established range of -20_-26 C. 2. A review of the room temperature logs for 2023 and 2024 identified that the laboratory directo failed to ensure corrective actions were taken for 20 of 210 days in 2023 and 26 of 146 days in 2024 when the room temperature was out of the established range of 68_80 F. 3. An interview with the office manager on 9/9/2024 at 3:50 pm confirmed the above findings. 4. The laboratory reports performing 200 Mohs slide examinations annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, a lack of documentation and an interview with the lead histotechnician on 9/9/2024, the laboratory director failed to ensure educational requirements were met for three of five testing personnel. The findings include: 1. A review of the CMS 209 form identified four testing personnel performing Mohs mechanical procedures including inking. 2. Lack of educational documents identified that the laboratory director failed to ensure minimal educational requirements were met for three of four testing personnel performing Mohs mechanical procedures including inking of patient tissue. 3. An interview with the lead histotechnician on 9/9/2024 at 2:15 pm identified that three of four histotechnician's performing Mohs mechanical procedures failed to have minimum qualifications for high complexity testing. 4. The laboratory reports performing 200 Mohs slide examinations annually.
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 a review of documentation, a lack of documentation and an interview with the lead histotechnician on 9/9/2024, the laboratory failed to have documentation of

	the minimum educational requirements for three of four testing personnel performing Mohs mechanical procedures. See D6171
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 on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, a lack of documentation and an interview with the lead histotechnician on 9/9/2024, the laboratory failed to have documentation of educational requirements for three of four testing personnel. The findings include: 1. A review of the CMS 209 form identified four testing personnel performing Mohs mechanical procedures including inking. 2. A lack of educational documents identified that the laboratory failed to have documentation of minimal educational requirements to qualify three of four testing personnel performing Mohs mechanical procedures including inking of patient tissue. 3. An interview with the lead histotechnician on 9/9/2024 at 2:15 pm identified that three of four histotechnicians performing Mohs mechanical procedures failed to have minimum qualifications for high complexity testing. 4. The laboratory reports performing 200 Mohs slide examinations annually. 5. This is a repeat deficiency from the previous inspection on 11/29/2022. The laboratory failed to follow their Allegation of Compliance from the previous inspection.