Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0534672	06/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Albuquerque Dermatology Associates &	5310 Homestead Rd Ne, Ste 301, Albuquerque, NM	

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
D0000	Based upon the onsite recertification survey conducted on 06/27/2022, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 42 CFR Part 493.41 Condition: Laboratories performing high Complexity testing; testing personnel
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's packaging instructions, and interview with laboratory staff, the laboratory failed to monitor, document, and define the room temperature to ensure long-term, proper preservation of the histopathology slides, paraffin blocks, and paraffin embedding medium in 2 of 2 storage supply rooms. Findings included: 1. During a tour of the laboratory on June 27, 2022 at 9:06 am, there were 2 storage supply rooms used to store the histopathology slides from 2019 to 2022, paraffin blocks from 2012 to 2016, and 1 of 1 box/case of paraffin embedding medium. The laboratory failed to provide documentation to show that temperature was monitored. 2. Review of the manufacturer's packaging for the paraffin (embedding medium from Leica-Surgipath Paraplast), revealed that the storage requirement is 15C to 30C. 3. During an interview on 06/27/2022 at 09:15 am the laboratory's lead histotechnologist confirmed that they had not been monitoring and documenting the temperature or the humidity of the 2 storage supply rooms.
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 the review of the laboratory's policies, the peer review documents, and interview with the laboratory staff, the laboratory failed to perform the twice a year verification of the gross examination (the process by which tissue is measured, dyed, cut, and mounted on glass slides) and microscopic evaluation (used to diagnose or determine the effectiveness of the surgery) for 2 of 2 assessments in 2019, and for 2 of 2 assessments in 2020. Findings included: 1. Review of the laboratory's policies revealed the laboratory failed to have a written policy regarding the twice a year verification process for the gross examination and the microscopic evaluation of frozen sections. 2. The peer review documents from the American Society for Mohs Surgery (ASMS) revealed the laboratory failed to perform the twice a year verification of the gross examination and microscopic evaluation of frozen tissue sections for 1 of 2 verifications for 2019, 1 of 2 verifications for 2020, and 1 of 2 verifications for 2021. 3. During an interview on 06/27/2022 at 12:45 pm, the laboratory's lead histotechnologist was asked if the laboratory performed the twice a year verification of test system/processes, she stated that she was not aware that it needed to be done twice a year. This confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the facility's procedure for Mohs surgery, the Slide Stainer Logs, and confirmed in staff interview, the laboratory failed to define the intended reactivity for the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for 6 of 12 months reviewed in 2019, 2020 and 2021. Findings included: 1. Review of the Mohs procedure titled "Specimen and Map Arrival in Moh's Lab", revealed the laboratory had no written policy/procedure regarding the H&E Quality Control (QC) slide, the intended reactivity, and its predicted staining characteristics 2. In review of 6 months of 2019 (July through December), 6 months of 2020 (July through December), 6 months of 2021 (July through December) labeled "Frozen Lab Stain Line (H&E)" and "Paraffin Lab Stain Line (H&E)", revealed only the initials of the person that made the H&E QC slide but failed to define the specific staining characteristics. The Lab reported 7765 Mohs cases for 2019 and 8056 for 2020. 3. During an interview on 06/27/2022 at 2:16 pm, the laboratory's lead histotechnologist confirmed the above findings.
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 the review of the CMS-209 form, personnel credentials, and interview with laboratory staff, the laboratory failed to ensure 1 of 3 (TP#1) Testing Personnel met qualification requirements to perform high complexity testing. Refer to 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 the review of the CMS-209 form, personnel credentials, continuing education, training records, and interview with laboratory staff, the laboratory failed to ensure 1 of 3 (TP#1) Testing Personnel met qualification requirements to perform high complexity testing. Findings included: 1. Review of the CMS-209 form listed a total of 3 (TP#1-TP#3) testing personnel. 2. Review of the personnel credentials, college/university transcripts, and training records provided during survey and via email on 07/05/2022 and 07/08/2022, revealed that testing person #1 failed to meet the 60 hour educational requirement necessary to perform high complexity testing. 3. Continuing education and training records provided on 7-08-2022 revealed that TP#1 did not have at least 3 months of documented laboratory training in performing the gross examination portion of the Histopathology specialty as required under 493.1489 (b)(2)(ii)(B)(2). 4. During phone interviews on 07-11-2022 at 11:23 am, the Histotechnologist, and TP#1 confirmed that TP#1 performed the gross examinations for the surveyed laboratory.