Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2178013	02/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Dermatology	106 S Inglewood, Suite B, Russellville, AR	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through a review of Room Temperature Logs for January 2020 through January 2021, lack of documentation, and an interview with laboratory staff, it was determined the laboratory failed to document room temperature on eleven of fourteen days of operation in June 2020. Survey findings follow: A. In a review of the Room Temperature Log for June 2020, it was revealed that on eleven of fourteen days the room temperature was documented by a "check mark". Actual laboratory temperature is not documented on the eleven days of operation. B. At 11:27 a.m. on 2/5/2021, laboratory employee #8 (as listed on the Employee Identification Form) confirmed the lack of documented room temperatures on the eleven days of operation in June 2020.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

	reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Through a review of the Cryostat Maintenance Logs and Microscope Maintenance Logs for January 2020 through January 2021, patient logs for Mohs and frozen sections, Frozen (Excision) Pathology Reports for two patients, and through interviews with laboratory staff, it was determined the laboratory failed to document maintenance on the microscope and cryostat in December 2020 on two of two days that the laboratory was in operation. Survey findings include: A. Cryostat Maintenance Logs and Microscope Maintenance Logs are used to document all daily cleaning and maintenance of the cryostat and microscope used for histopathology in Mohs surgical cases and frozen section biopsies. B. The surveyor reviewed patient logs for Mohs and biopsies with frozen sections and determined patients were reported on two days in December. Two patient final reports were reviewed for Frozen (Excision) Pathology. Pathology # RV20-323 was received and reported on 12 /14/2020 and Pathology # RV 20-331 was received and reported on 12/28/2020. C. There is no documented daily cleaning or maintenance of the microscope or cryostat on 12/14/2020 or 12/28/2020 when patients were tested. D. At 11:27 a.m. on 2/5/2021 laboratory employee #8 (as listed on the Employee Identification Form) confirmed the lack of documented maintenance in December 2020.
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: Through a review of the monthly Quality Control Log: Daily Worksheets for Toluidine Blue stain, a review of patient test records for December, and interviews with laboratory staff, it was determined the laboratory failed to document stain quality on one of two days in which patient histopathology slides were stained and examined. Survey finding include: A. Quality Control Log: Daily Worksheets for Toluidine Blue stain are used to document the daily stain quality and any corrective actions taken if the stain is not acceptable. B. Through a review of patient test logs for December 2020, it was determined that patient slides were stained and examined on 12/14/2020 and 12/28/2020. C. A review of the Quality Control Log: Daily Worksheets for Toluidine Blue stain revealed that stain quality was not documented on 12/14/2020 when two patients had slides stained and examined. D. In an interview, at 11:27 on 2/5 /2021, laboratory employee #8 (as listed on the Personnel Identification Worksheet) confirmed the stain quality was not documented on 12/14/2020 when patient slides were stained and examined.