Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0916496	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clear Dermatology & Aesthetics Center	8406 E Shea Blvd, Ste 100, Scottsdale, AZ	

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
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: Based on review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to perform and document the annual preventative maintenance of the microscope used in patient testing under the sub-specialty of Histopathology. Findings include: 1. During the survey conducted on April 13, 2023, no documentation was presented for review from 2021 and 2022 to indicate the laboratory performed and documented annual preventative maintenance on the microscope used for reading patient slides. 2. The facility personnel interviewed on April 13, 2023 at 10:15am confirmed that there was no documentation of annual preventative maintenance from 2021 and 2022 for the microscope used by the laboratory to read patient slides under the sub-specialty of Histopathology. 3. The laboratory's established policy states, "All microscopes should be serviced as needed or once a year for calibration and maintenance." 4. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 422.
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 lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for Mohs testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 422. 2. No documentation of the Hematoxylin & Eosin (H&E) stain acceptability was presented for review for testing that occurred on April 27, 2022. Approximately 7 patients were tested on that date. 3. The facility personnel interviewed on 4/13/23 at 10:05am confirmed the laboratory failed to document the H&E stain acceptability on 4/27/2022, as indicated above.