Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2024003	11/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mid Florida Dermatology Associates Pa	7350 Futures Dr Ste 12a, Orlando, FL	

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	A Recertification survey was conducted on November 15, 2022. Mid Florida Dermatology Associates PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document quality control information including the lot numbers, expiration dates, and open dates for all reagents used in their Sakura Tissue-Tek VIP 5 (Vacuum Infiltration Processor) and their Automated Leica Stainer, and the laboratory failed to have documentation of the preparation of the reagents used on the Sakura Tissue-Tek VIP 5 from 11/01/2020 to 11/18/2022. Findings: Review of the "Sakura VIP - 5 Processor #1 Maintenance" and the "Sakura VIP - 5 Processor #2 Maintenance" logs showed they did not list the lot numbers, expiration dates, and open dates of the reagents used on the processor. The Tissue Tek VIP used the following reagents: 10% Neutral Buffered Formalin, 70% Reagent Alcohol, 80% Reagent Alcohol, 95% Reagent Alcohol, 100% Reagent Alcohol, Xylene and Paraffin. The laboratory prepares the 70% Reagent Alcohol and 80% Reagent Alcohol. There was no log reflecting the preparation of the 70% Reagent Alcohol and 80% Reagent Alcohol solution used on the Tissue Tek VIP. Review of the "Automated Leica Stainer Maintenance" log showed the Hematoxylin stain and the Eosin Stain lot numbers and open dates were listed on the maintenance logs. The automated stainer log also showed that the Periodic Acid and Schiff's Reagent lot numbers and open dates were listed on 15 of 25 logs examined. The laboratory used the Automated Leica Stainer to stain tissue slide for the Hematoxylin

	& Eosin stain (H&E) and Periodic Acid Schiff stain (PAS). The Automated Leica Stainer used the following reagents: Xylene, 100% Reagent Alcohol, 70% Reagent Alcohol, Hematoxylin Vintage stain, Define MX-aq, Blue Buffer 8, 95% Reagent Alcohol, Eosin-Y Vintage stain, Periodic Acid 5% Aqueous Solution, and Schiff's Reagent. Review of the laboratory's quality control records revealed there was no other reagent log. On 11/15/2022 at 1:30 PM, Testing Personnel C acknowledged not all the reagent lot numbers, expiration dates, and open dates were recorded and there was no log listing the lot numbers, expiration dates, and open dates of the reagents used to prepare the 70% and 80% Reagent Alcohol solutions.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain the documentation of the initial training and failed to perform a competency evaluation semiannually during the first year on 1 (C) of 2 (B-C) Testing Personnel who performed grossing (macroscopic physical examination/description) in the histopathology laboratory. Findings: Review of the histopathology laboratory's procedure "Competency Assessment" noted "After initial training and before working independently, a new employee's competency is assessed, and the assessment is documented on the training documentation." The procedure also noted "6 months after an employee has been deemed competent to work independently, competency is assessed, and the assessment is documented on competency assessment documentations." Review of the competency assessments for Testing Personnel C revealed the initial training competency assessment documentation was missing and the six-month competency assessment was performed on 11/30/2021. On 11/15/2022 at 12:55 PM, Testing Personnel B stated she was unable to locate the initial training competency assessment performed on Testing Personnel C and the six-month review was performed on 11/30/2021. On 11/15/2022 at 12:57 PM, Testing Personnel B stated Testing Personnel C started working in the laboratory on 11/02/2020.