Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0674401	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medical Center Clinic Dermatology	8333 N Davis Hwy, Pensacola, 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	An announced CLIA recertification survey was conducted at Medical Center Clinic Dermatology in Pensacola, FL on 12/04/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that records documenting all analytic systems activities were failed to be retained for 6 of 24 months reviewed. The findings include: Analytic records for the secondary laboratory area for January 2024 to June 2024 were requested. However, no records were presented for review. Staff A and Staff B, both histology technicians, confirmed during an interview on 12/4/2024 at 3:05 PM that the analytic records for the secondary laboratory area for January 2024 to June 2024 could not be located.
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 record review and interview, it was determined the laboratory failed to verify the Hematoxylin and Eosin (H&E) test staining materials for intended reactivity for two of two years reviewed (2023-2024). The findings include: The laboratory Standard Operating Manual was approved by the Laboratory Director on 11 /19/2024. The procedure for H&E testing included directions for Quality Control. The procedure failed to require qualified testing to versify the H&E staining materials for intended reactivity. The Laboratory Personnel Report signed by the Laboratory Director on 12/2/2024 listed two testing personnel (Testing Personnel (TP) A & B) qualified to perform H & E testing. A review of the 2023-2024 H&E Quality Control records documented the H&E test staining materials for intended reactivity was not documented by either testing personnel (TP A & B).
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 record review and interview, it was determined the laboratory director failed to ensure the competency for Testing Personnel B for two of two years (2023-2024). The findings include: The laboratory Operating Manual was approved by the Lab Director on 11/19/2024. The Competency Testing Policy stated personnel were to be evaluated upon initial employment, 3 months of employment, 6 months of employment, and annually thereafter. The Laboratory Personnel Report signed by the Laboratory Director on 12/2/2024 listed two testing personnel, himself and Testing Personnel B (TP B). A review of the delegation of duties documented TP B had been employed by the laboratory at least since October 2022. No documentation of competencies were presented for review for TP B for the years of 2023 and 2024. The Laboratory Director confirmed on 12/4/2024 at 2:10 PM that he had not ensured the competency of TP B for these years.