Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1012626	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Fort Myers Dermatopathology Pa	12580 University Dr Ste 200, Fort Myers, 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 Fort Myers Dermatopathology PA on 4/09/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure documentation of immunohistochemical stains for positive and negative reactivity each time of use for two of two years (2023-2025). Findings included: 1. The CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certifications signed 12/6/22 and 3/25/2025 both included immunohistochemical stains (IHC). 2. The Immuno Stain Process Quality Control log for 2/2025 and 6/2024 was signed monthly by Testing Personnel A (TP-A) who was the only testing personnel reading slides. The date of signing was not documented. There was no documentation available for review documented by TP-A of the IHC controls reactivity each time of use. 3. Testing Personnel B confirmed on 4/09/2025 at 12:10 PM there was no documentation by the Testing Personnel performing the IHC test (the reading of the slides) of the positive and negative reactivity each time of use, and the laboratory had never documented this before.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy,

	precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on documentation review and interview, the Laboratory Director failed to ensure the verification of the immunohistochemical (IHC) testing performed procedures were adequate to determine accuracy, precision, and other pertinent performance characteristics of the method from 1/10/2024 to 4/09/2025. Findings included: 1. The IHC processor, Intellipath, was installed 12/19/23 and the date of the first patient testing was 1/10/2024. The documentation of verification of operation for the newly installed Intelllipath failed to include review and approval of use by the Lab Director. 2. The laboratory Procedure and Policy Manual signed as approved by the Laboratory Director 9/22/2023 and 1/15/2024 included a list of the Laboratory Director's responsibilities. One of the listed responsibilities was to ensure "Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method." 3. Testing Personnel B on 4/09/2025 at 12:10 PM confirmed there was no documentation of the Lab Director ensuring the verification of the immunohistochemical (IHC) testing performed on the Intellipath from 1/10/2024 to 4/09/2025.