Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1036214	12/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Brian G Fabian Md Pa	7560 Winkler Rd, 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 Brian G Fabian MD PA on 12/9/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview, failed to follow safety procedures to ensure protection from chemical hazards for two of two years (2023-2024). Findings included: On 12/9/2024 at 2:10 PM, primary chemical containers were observed stored in a cabinet under the laboratory sink. The safety labels for the 100% Reagent Alcohol and the Eosin Y Stain Solution showed the contents were flammable and should be stored appropriately. Histology Tech A confirmed on 12//9/24 at 2:10 PM, the laboratory did not store flammable chemicals in accordance with the chemical labels. Photographic evidence was obtained.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on record review and interview. the laboratory failed to verify at least twice annually Histopathology Hematoxylin and Eosin (H&E) testing for one (2023) of two years reviewed (2023 and 2024). Findings include: The Procedure manual, approved by the Lab Director 1/16/2023, 1/16/2024 and 12/2/2024, included a procedure titled Proficiency Testing, which stated at least twice annually the lab would verify the accuracy of the histology slides. Histology Tech A confirmed on 12/9/24 at 1:30 PM there failed to be twice annual verification of the accuracy of the H & E histology slides in 2023.
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, the laboratory failed to document the intended reactivity for Histopathology Hematoxylin & Eosin (H&E) tests for two of two years (2023-2024). Findings include: Review of the monthly MOHS Histology Quality Control Record forms for 2023-2024 documented H&E quality control was signed by histotechs. The laboratory Procedure manual, approved by the Lab Director 1/16 /2023, 1/16/2024, and 12/2/204, included a procedure for Quality Control, which showed the stain was to to be checked daily by the Mohs physician (the Lab Director). Histology Tech A and the Lab Director confirmed on 12/09/24 at 1:45 PM, no documentation of the intended reactivity for Histopathology Hematoxylin & Eosin (H&E) testing was completed for two of two years (2023-2024).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based record review and interview, the Laboratory Director failed to ensure that a quality assessment program was established to assure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years (2023-2024). Finding include: Review of the Procedure manual, approved by the Lab Director 1/16/2023, 1/26/2024, and 12/2/2024, did not include a quality assessment program. No Quality Assessment documentation for 2023-2024 was provided as requested. Histology Tech A stated on 12/9/2024 at 2:40 PM, the laboratory did not have an established quality assessment program and there was not documentation regarding quality assessment activity for 2023-2024.