Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1013827	05/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Brian G Fabian Md Pa	26800 S Tamiami Trl Ste 390, Bonita Springs, 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 on 05/12 /25 - 05/13/25. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6076 493.1441 Condition: Laboratory Director High Complexity
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to document the room temperature and humidity to ensure correct operating conditions for Histopathology testing for two of ten patient testing days in March 2025 (See D5413), and the laboratory failed to document the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for two of ten patient testing days in March 2025 (See D5473).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to document the room temperature and humidity to ensure correct operating conditions for Histopathology testing for two of ten patient testing days in March 2025. This is a repeat deficient practice from the 03/29/2023 recertification survey. Findings included: 1. The accepted Plan of Correction signed by the Laboratory Director with a correction date of 04/24/2023 for the recertification survey completed 03/29/2023 showed the Laboratory Director would review all Quality Control and Temperature logs (which includes the room temperature and humidity). A monthly review was to be conducted for completeness with corrective action taken for any omissions. 2. The Laboratory Procedure Manual reviewed and approved by the Laboratory Director 12/2024 and 04/31/2025 included a Quality Control procedure, which stated the temperature and humidity of the laboratory would be maintained and documented in a written log. 3. The MOHS Histology Quality Control Log Record for March 2025 documented room temperature and humidity for 3/5/25, 3/10/25, 3/12/25, 3/17/25, 3/19/25, 3/24/25, 3/26/25, and 3/31/25 at this laboratory. The Practice Manager stated 5/12/25 at 12:45 PM the MOHS Histology Quality Control Record provided 5/12/25 at the laboratory documented the room temperature and humidity for all patient testing days for this laboratory. 4. The Patient MOHS log documented patient testing was performed on 03/03/2025 and 03/06/2025. There was no documentation provided of the room temperature and humidity being monitored and documented for these two days. On 05/12/2025 at 12:45 PM, the Practice Manager stated the Patient MOHS log was for this laboratory and a sister laboratory. The Practice Manager confirmed the lack of documentation of room temperature and humidity for 03/03/2025 and 03/06/2025.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to document the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for two of ten patient testing days in March 2025. Findings included: 1. The Laboratory Procedure Manual reviewed and approved by the Laboratory Director 12/2024 and 04/31/2025 included a Quality Control procedure which stated the first specimen of the day would be reviewed by the Laboratory Director for quality of the H&E staining and would be maintained in a written log. 2. The MOHS Histology Quality Control Log Record for March 2025 documented quality of the H&E staining for 03/05/2025, 03/10/2025, 03/12/2025, 03/17/2025, 03/19/2025, 03/24/2025, 03/26/2025, and 03/31/2025 at this laboratory. The Practice Manager stated on 05/12/2025 at 12:45 PM the MOHS Histology Quality Control Record provided on 05/12/2025 documented the quality of the H&E staining for all patient testing days. 3. The Patient

	MOHS log documented patient testing was performed on 03/03/2025 and 03/06/2025. There was no documentation provided of the quality of the H&E staining for 03/03 /2025 and 03/06/2025. On 05/12/2025 at 12:45 PM, the Practice Manager stated the Patient MOHS log was for this laboratory and a sister laboratory. The Practice Manager confirmed the logs did not specify where the patient testing was done and confirmed the lack of documentation for 03/03/2025 and 03/06/2025 for either laboratory.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the documentation of the room temperature and humidity to ensure correct operating conditions for Histopathology testing and failed to ensure the documentation of the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity (See D6079).
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, the Laboratory Director failed to ensure documentation of the room temperature and humidity to ensure correct operating conditions for Histopathology testing for two of ten patient testing days in March 2025 (See D5413), and the Laboratory Director failed to ensure documentation of the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for two of ten patient testing days in March 2025(See D5473).