Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1011557	06/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Francis A Caban Md Pa D/B/A Caban Skin Institute	4164 N Armenia Ave, Tampa, 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 Francis A. Caban MD PA DBA Caban Skin Institute on 6/3/25. 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 Testing
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 ensure the defined cryostat temperature was monitored for the Histopathology testing performed by the laboratory for two (10/2023 and 3/2025) months of three (10/2023, 6/2024, and 3 /2025) months reviewed (See D5413); the Laboratory failed to document the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for three (10/2023, 6/2024, and 3/2025) of three months reviewed (See D5473); the Laboratory failed to document corrective action when the cryostat temperature was out of range for two (10/2023 and 3/2025) months of three (10/2023, 6/2024, and 3/2025) months reviewed (See D5781).
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 interviews, the Laboratory failed to ensure the defined cryostat temperature was monitored for the Histopathology testing performed by the laboratory for two (10/2023 and 3/2025) months of three (10/2023, 6/2024, and 3 /2025) months reviewed. Findings included: 1. The temperature defined for acceptable limits for the cryostat was documented on the temperature log for 3/2025 as -21 to -30 (C) degrees Celsius and for 10/2023 as-20 to -30 C. The laboratory manual was last reviewed by the Lab Director 8/15/24 and included a Quality Control procedure indicating the acceptable cryostat temperature range was -20 to -25 C. 2. The 3/2025 cryostat temperatures were documented outside of defined acceptable limits as -18 C on 03/06/25, -19 C on 03/13/25, -18 C on 03/20/25, -19 C on 03/27/25 and for 10 /2023, documented as -19 C on 10/10/23. There was no indication the unacceptable temperatures had been identified. 3. The Lab Director confirmed on 06/03/2025 at 11: 25 AM the unacceptable documented cryostat temperatures for 10/2023 and 03/2025 and that the unacceptable temperatures had not been identified or any corrective actions taken.
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 three of three months reviewed (10/2023, 06/2024, and 03/2025). Findings included: 1. The Laboratory Procedure Manual reviewed and approved by the Laboratory Director on 08/15/2024 included a Quality Control procedure which stated the first specimen of the day would be examined to ensure staining accuracy and was to be recorded in the Histopathology Worksheet. The Lab Director was the only Testing Person listed on the CMS-209 signed by the Lab Director 06/02/2025. 2. The MOHS Slides Quality Control Log for 03/2025 and 10/2024 did not document quality of the H&E staining for any of the testing days at this laboratory. There was no MOHS Slides Quality Control Log for 06/2024 provided for review. 3. The Lab Director confirmed on 06/03/2025 at 11:25 AM there were no documentation of the H&E Histopathology staining materials for intended reactivity for three of three months reviewed 10/2023, 06/2024, and 03/2025.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to document corrective action when the cryostat temperature was out of range for two (10/2023 and 3/2025) months of three (10/2023, 6/2024, and 3/2025) months reviewed. This is a repeat deficient practice from the 03/16/2023 recertification survey. Findings included: 1. The accepted Plan of Correction (PoC) for the recertification survey on 03/16/2023, was signed by the Lab Director on 04/04/2023 and indicated the completion date was 03/26/2023. The PoC showed the cryostat would be checked prior to operating it and in the event the temperature was not in range, the cryostat would not be used. The Histotech and the Doctor (Lab Director) were to monitor the temperature. 2. As cited at D5413, the laboratory failed to ensure the defined cryostat temperature was monitored for the Histopathology testing performed by the laboratory for two (10/2023 and 3/2025) months of three (10/2023, 06/2024, and 03/2025) months reviewed. 3. The Monthly Assurance Checklist for 03/2025 signed by the Lab Director 3/13/25, stated all temperatures were reviewed and documented. There was no evidence the Laboratory had followed the accepted plan of correction to ensure corrective actions were taken and documented for unacceptable cryostat temperatures. There was no Monthly Assurance Checklist for 10/2023 provided for review. 4. The Lab Director confirmed on 06/03/2025 at 11:25 AM, there was no documentation the Laboratory Quality Assurance had identified or corrected the ongoing deficient practice from the recertification survey dated 03/16/2023.
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 that the quality control for three of three months reviewed (10/2023, 6/2024, and 3/2025) and quality assessment programs for two (10/2023 and 3/2025) months of three (10/2023, 6/2024, and 3/2025) were established and maintained to assure the quality of Laboratory services provided and to identify failures in quality as they occur for the Histopathology testing (See D6093), and the Laboratory Director failed to specify, in writing, the responsibilities and duties of the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Person engaged in the performance of the preanalytic, analytic, and postanalytic phases of Histopathology testing (See D6107).

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 on record review and interview, the Laboratory Director failed to ensure that the quality control for three of three months reviewed (10/2023, 6/2024, and 3/2025) and quality assessment programs for two (10/2023 and 3/2025) months of three (10 /2023, 6/2024, and 3/2025) were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for the Histopathology testing. Findings included: 1. The Laboratory Director failed to ensure there was documented corrective action when the cryostat temperature was out of range for two (10/2023 and 03/2025) months of three (10/2023, 06/2024, and 03 /2025) months reviewed. This is a repeat deficient practice from the 03/16/2023 recertification survey. (See D5781) 2. The Laboratory Director failed to ensure the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for three of three months reviewed (10/2023, 06/2024, and 03/2025). (See D5473) 3. The Laboratory Director confirmed on 06/03/2025 at 11:25 AM there was no documentation the Laboratory Quality Assurance had identified or corrected the ongoing deficient practice from the recertification survey dated 03/16/2023 as cited at D5781 or the failure to document the quality control of the Histopathology stains as cited at D5473.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to specify, in writing, the responsibilities and duties of the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Person engaged in the performance of the preanalytic, analytic, and postanalytic phases of Histopathology testing. Findings included: 1. The Laboratory manual last reviewed by the Laboratory Director on 08/15/2024, failed to include written specific responsibilities and duties of the Lab Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Person engaged in the performance of the preanalytic, analytic, and postanalytic phases of Histopathology testing. 2. The Laboratory Director confirmed on 06/03/2025 at 11:25 AM there was no written specific responsibilities and duties of the Lab Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Person engaged in the performance of the preanalytic, analytic, and postanalytic phases of Histopathology testing.