Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2123718	(X3) Date Survey Completed 12/02/2024
Name of Provider or Supplier Michael J Haiken Md Pa	**Street Address, City, State** 20171 Summerlin 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 Michael J. Haiken MD PA on 11/25/2024 to 12/02/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076-Laboratory Director High Complexity-493.1441
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 the laboratory failed to retain records documenting all analytic systems activities for Anti-Human Cytokeratin 5 (CK5) Histopathology testing for 2 of 2 years (2023-2024). Findings included: Review of patient logs from 03/01/2023 to 11/25/2024 revealed from 04/03/2023 to 11/14/2024 the CK5 test was performed 64 days. Review of analytic testing systems records failed to include any quality control documentation for the CK5 testing. On 11/25/24 at 3:15 PM Histology Tech A and the Laboratory Director confirmed there were no records for 2023-2024 of the CK5 analytic activity.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have an approved policy and procedure for the Anti-Human Cytokeratin 5 (CK5) immunohistochemical (IHC) stain for Histopathology for two of two years (2023 and 2024). Findings included: Review of the laboratories policy and procedure manual reviewed by the Lab Director on 9/7/2024 failed to include a policy and procedure for CK5. Interview with the Laboratory Director on 11/25/2024 at 2:00 PM confirmed there was no approved policy and procedure for the CK5 testing performed in 2023 and 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 monitor & document the storage temperature for Anti-Human Cytokeratin (CK5) immunohistochemical stain reagents for Histopathology two of two years reviewed (2023 and 2024). Findings included: A review of the CK5 manufacturer's instructions, dated May 2022, showed the product should be stored at 2-8 degrees Celsius. Quality Control records for 2023 and 2024 were reviewed. No documentation of refrigerator temperature monitoring could be found. Interview with Histotech A and the Lab Director on 11/25/2024 at 2:35 PM confirmed the CK5 reagent was stored in the refrigerator and no monitoring or documentation of the refrigerator temperature was maintained.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (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 check the Anti-Human Cytokeratin 5 (CK5) immunohistochemical (IHC) stains for positive and negative reactivity each time of use for two of two years (2023-2024). Findings included: The laboratory CMS (Centers for Medicare and Medicaid) Form 116, Clinical Laboratory Improvement Amendments Application for Certification, signed by the Laboratory Director on 11/9/24 documented the laboratory performed non-waived CK5 IHC testing using the Novodiax test system. The package insert for Novodiax CK5 stated positive and negative controls should be run simultaneously with patient samples. Quality Control records for 2023-2024 were requested on 11/25/24. On 11/25/24 at 3:15 PM Histology Tech A and the Laboratory Director

	confirmed there was no documentation of positive and negative reactivity for the CK5 testing performed. Review of patient logs from 03/01/2023 through 11/25/2024 revealed CK5 stains were performed 64 days for on a total of 92 patients.
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 provide overall management failing to fulfill their responsibilities for two of two years (2023 and 2024). The Laboratory Director failed to ensure the lab had an approved policy and procedure for Anti-Human Cytokeratin 5 (CK5) immunohistochemical stain for Histopathology (see D5401), failed to establish a quality assessment program to identify failures (see D6094), failed to establish and maintain acceptable levels of analytic performance for the CK5 test (see D6095), and the Lab Director, who is also the Technical Supervisor, failed to evaluate the competency of Testing Person B from 7/2023 to 11/2024 (see D6120).
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 on record review and interview, the Laboratory Director failed to establish a quality assessment program to identify failures for two of two years (2023 - 2024). Findings included: Review of the Policy and Procedure Manual, signed by the Laboratory Director 9/7/2024, failed to include a quality assessment program. Interview with the Laboratory Director on 11/25/2024 at 12:05 PM confirmed there was no quality assessment program.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director failed to establish and maintain acceptable levels of analytic performance for the test Anti-Human Cytokeratin 5 (CK5) for two of two years (2023 and 2024). Findings included: 1. The Laboratory director failed to ensure analytic quality control records for Anti-Human Cytokeratin 5 (CK5) were documented and retained (see D3031). 2. The Laboratory Director failed to ensure the lab monitored and documented the storage temperatures

	for CK5 stain reagents (see D5413). 3. The Laboratory Director failed to ensure the lab performed positive and negative controls for CK5 each time of use (see D5475).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview the Technical Supervisor failed to evaluate the competency of one Testing Personnel (TP B) out of two Testing Personnel (TP A, TP B) from 7/2023 to 11/2024. Findings included: Review of the Laboratory Personnel Report, signed by the Laboratory Director 11/9/24, showed a new Testing Personnel (TP B). On 11/25/24 at 3:00 PM, the Laboratory Director stated TP B was hired 7 /2023. No documentation of initial, semi-annual, or annual evaluation of competency for TP B was available for review. The Laboratory Director (who was also the Technical Supervisor) confirmed on 11/25/24 at 3:05 PM there was no documentation of evaluation of competency for TP B from 7/2023 to 11/2024.