| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D0860084 | 12/02/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Michael J Haiken Md Pa | 8841 Cody Lee Road, 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 |
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| **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 Conditions were cited: D5400-Analytic Systems-493.1250 D6076-Laboratory Director High Complexity-493.1441 |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the laboratory failed to retain records documenting all analytic systems activities for at least 2 years (2023-2024) for Anti-Human Cytokeratin 5 (CK5) Histopathology testing. Findings included: Review of patient logs from January 2023 to November 2024 revealed the CK5 test was performed for 94 days from 1/4/2023 to 11/12/2024. Review of analytic testing systems records showed no documentation for the CK5 testing. On 11/25/2024 at 3:15 PM, Histotech A and the Laboratory Director confirmed there were no records for 2023-2024 of the CK5 analytic activity. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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 |

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| | 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review, observation, and interview, the laboratory failed to have an approved policy and procedure for the Anti-Human Cytokeratin 5 (CK5) immunohistochemical (IHC) stain (see D5401), the laboratory failed to monitor and document the storage temperature for CK5 IHC stain reagents (see D5413), the laboratory failed to test staining materials to verify the intended reactivity of Hematoxylin and Eosin (H&E) Histopathology slides on each day of use (see D5473), the laboratory failed to check the CK5 IHC stains for positive and negative reactivity each time of use (see D5475), and the laboratory failed to have an established mechanism to identify problems in the analytic system (see D5791). |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>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 testing for two of two years (2023 and 2024). Findings included: Review of the laboratory's policy and procedure manual, reviewed by the Laboratory Director on 9/7/2024, revealed no policy and procedures for CK5. Interview with the Laboratory Director on 11/25/2024 at 2:00 PM confirmed the lab was performing CK5 testing for 2023-2024 and had no approved policy and procedures for this IHC stain testing. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review. and interview, the laboratory failed to monitor and document the storage temperature for Anti-Human Cytokeratin (CK5) immunohistochemical (IHC) stain reagents for Histopathology testing for two of two years reviewed (2023 and 2024). Findings included: Review of the CK5 reagent manufacturer's instructions, dated May 2022, revealed the product should be stored at 2-8 degrees Celsius. On 11/25/2024 at 2:35 PM, a refrigerator was observed in the cutting room of the laboratory. No documentation of refrigerator temperature |

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| | monitoring was available for review of 2023-2024. Interview with Histotech A and the Laboratory Director on 11/25/2024 at 2:35 PM confirmed the lab stored the CK5 reagent in the observed refrigerator and does not monitor or document the temperature of the refrigerator. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to test staining materials to verify intended reactivity of Hematoxylin and Eosin (H&E) Histopathology slides on each day of use for one (4/2024) of three months reviewed (2/2023, 4/2024, and 9 /2024) and two (11/20/24 and 11/21/24) of eleven days (11/5/24, 11/6/24, 11/7/24, 11 /11/24, 11/12/24, 11/13/24, 11/14/24, 11/18/24, 11/19/24, 11/20/24, and 11/21/24) in 11/2024. Findings included: Review of the 4/2024 H&E Staining Quality Control Worksheet revealed no documentation by Testing Personnel that verified the expected reactivity of the H&E daily Quality Control (QC) slide for fifteen of fifteen testing days (4/1/24, 4/3/24, 4/4/24, 4/8/24, 4/10/24, 4/11/24, 4/15/24, 4/16/24, 4/17/24, 4/18 /24, 4/22/24, 4/23/24, 4/24/24, 4/29/24, and 4/30/24). Review of the 11/2024 H&E Staining Quality Control Worksheet revealed no documentation by Testing Personnel to verity the expected reactivity of the H&E daily Quality Control (QC) slide for two days, 11/20/24 and 11/21/24, out of 11 testing days. On 11/25/24 at 2:30 PM, Histology Tech A confirmed the lack of documentation of verification of intended reactivity for H&E QC slides for all testing days in 4/2024 and for 11/20/24 and 11/21 /24. |
| **D5475** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(3)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, 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: Review of the CMS (Centers for Medicare and Medicaid Services) Form 116, Clinical Laboratory Improvement Amendments Application, signed by the Laboratory Director on 11/9/24 showed the laboratory performed non-waived CK5 IHC testing using the Novodiax test system Review of the package insert for Novodiax CK5 showed positive and negative controls should be run simultaneously with patient samples. On 11/25/24 CK5 Quality Control records for 2023-2024 were requested and not provided. On 11/25/24 at 3:15 PM, Histology Tech A and the Laboratory Director |

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| | confirmed there was no documentation of positive and negative reactivity for the CK5 testing performed. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, observation, and interview, the laboratory failed to have an established mechanism to identify problems in the analytic system for three of three months reviewed (2/2023, 4/2024, and 9/2024). Findings included: Review of the laboratory Quality Assurance Control procedure, approved by the Laboratory Director on 9/20/2024, revealed the laboratory used a "Monthly Quality Control Worksheet" to identify problems/concerns. Review of the "Monthly Quality Control Worksheet" for 2 /2023, 4/2024, and 9/2024 failed to identify any of the issues identified with the analytic systems during the recertification survey. During an interview on 11/25/24 at 3:15 PM the Laboratory Director and Histotech A confirmed the laboratory's quality assurance plan had not identified the deficient practices found (see D5401, D5413, D5473, and D5475). |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview and record review, 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 establish a quality assessment program to identify failures (see D6094) and failed to establish and maintain acceptable levels of analytic performance for the Anti-Human Cytokeratin 5 (CK5) test and Hematoxylin and Eosin (H&E) histopathology test (see D6095) for two of two years (2023 and 2024). |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, observation, and interview the Laboratory Director failed to ensure that the quality assessment program identified failures in quality as they |

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| | occurred for two of two years (2023-2024). Findings included: Review of the laboratory procedure for Quality Assurance Control, approved by the Laboratory Director on 9/20/2024, revealed a checklist titled "Monthly Quality Control Worksheet" to document failures in the laboratory systems. Review of the "Monthly Quality Control Worksheets for 2/2023, 4/2024, and 9/2024 failed to identify any of the issues found during the survey (see D5791) On 11/25/24 at 3:15 PM, the Laboratory Director confirmed the quality assurance plan had not identified the failure to have an approved policy and procedure for the Anti-Human Cytokeratin 5 (CK5) immunohistochemical (IHC) stain (see D5401), failure to monitor and document the storage temperature for CK5 IHC stain reagents (see D5413), failure to use test staining materials to verify the intended reactivity of Hematoxylin and Eosin (H&E) Histopathology slides for each day of testing (see D5473), and failure to check the CK5 IHC stains for positive and negative reactivity each time of use (see D5475). |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, observation, and interview the Laboratory Director failed to establish and maintain acceptable levels of analytic performance for the test Anti-Human Cytokeratin 5 (CK5) and Hematoxylin and Eosin (H&E) Histopathology for two of two years (2023 and 2024). Findings included: 1. The Lab Director failed to ensure analytic quality control records for CK5 were documented and retained (see D3031). 2. The Lab Director failed to ensure the lab monitored and documented the storage temperatures for CK5 stain reagents (see D5413). 3. The Lab Director failed to ensure for each day of use test staining materials was verified for intended reactivity of H&E Histopathology slides (see D5473). 4. The Lab Director failed to ensure the lab performed positive and negative controls for CK5 each time of use (see D5475). |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the Technical Supervisor failed to evaluate the competency of one (Testing Personnel B) of two Testing Personnel from 7/2023 to 11 /2024. Findings included: Review of the Laboratory Personnel Report signed by the Laboratory Director on 11/9/24, showed a new hire, Testing Personnel B (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. On 11/25/24 at 3:05 PM, the Laboratory Director (who is |

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| | also the Technical Supervisor) confirmed the lack of documentation of competency for TP B from 7/2023 to 11/2024. |