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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>31D0956346   | <b>(X3) Date Survey Completed</b><br>05/24/2021 |
| <b>Name of Provider or Supplier</b><br>Carter Abel Md Llc  | <b>Street Address, City, State</b><br>1465 Route 31 South, Annandale, NJ |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5209</b>              | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES<br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on one of one Testing Personnel (TP) in the calendar years 2019 and 2020. The OM confirmed on 5 /18/21 at 10:50 am that CA was not performed on TP in 2019 and 2020.</p>  |
| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2020. The finding includes: 1. A review of the BA records revealed that in 2020 slides were submitted once for BA on 7/29/2020. 2. The OM confirmed on 5/18/21 at 10:00 am that the laboratory did not verify the accuracy of Histopathology testing twice a year in 2020.</p> |
| <b>D5413</b>              | 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:

a. Based on surveyor review of the Procedure Manual (PM), Temperature Log and interview with Office Manager (OM), the laboratory failed to monitor and document Room Temperature (RT) and Humidity where Histopathology tests were performed from 1/1/21 to the date of survey. The OM confirmed on 5/18/21 at 10:20 am that the laboratory did not document RT and Humidity. b. Based on surveyor review of the Cryostat log, PM and interview with the OM the laboratory failed to record the temperature of the Leica Cryostat every day of patient testing from 1/1/21 to the date of the survey. The OM confirmed on 5/18/21 at 10:25 am that approximately 24 patients were tested in the time frame above, but the Cryostat Temperature was not recorded.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the reagents and interview with the Office Manager (OM), the laboratory had expired material for Histopathology tests from December 2019 to the date of the survey. The findings include: 1. Reagents were expired as follows: a. Fisher Permunt Lot 17647 expired 12/2019 b. Gill-3 Hematoxylin Lot 074608 expired 6/1/2020 c. Eosin Y Stain Solution 10% Lot 1829205 expired 10/23 /2020 2. Approximately 24 patients were stained with expired material. 3. The OM confirmed on 5/18/21 at 8:50 am that the laboratory had expired reagents. Note: This was cited on the previous survey performed 11/27/18.

**D5429**

MAINTENANCE AND FUNCTION CHECKS  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Maintenance Records (MR) and interview with the Office Manager (OM), the laboratory failed to perform and document weekly cleaning and maintenance as specified by the manufacturer on the Leica Cryostat used in

Histology Testing from 1/1/21 to the date of the survey. The OM confirmed on 5/18/21 at 10:30 am weekly maintenance and cleaning was not performed.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing from 1/11/21 to the date of the survey. The findings include: 1. The laboratory did not document H&E stain QC reactions during the time period stated above. 2. The laboratory read and reported approximately 40 patients slides in the above time period. 3. The OM confirmed on 5/18/21 at 10:30 am that the laboratory did not document H&E QC stain reaction.