

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0956346	<b>(X3) Date Survey Completed</b>  11/27/2018
<b>Name of Provider or Supplier</b>  Carter Abel Md Llc	<b>Street Address, City, State</b>  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>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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: Based on surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2017 and 2018. The finding includes: 1. A review of the BA records revealed that the slides submitted for BA were submitted with the LD diagnosis on them. 2. The LD confirmed on 11/27/18 at 3:00 pm that BA was not performed.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the reagents and interview with the Laboratory Director (LD), the laboratory had expired material for Histopathology tests from 11/29/16 to the date of survey. The findings include: 1. Reagents were expired as follows: a. Platinum Eosin Y Lot 1509-703 expired 4/8/17 b. EKI Acid Decolorizer 1% Lot 1534505 expired 12/16/17 c. Scott's Tap Water Substitute Lot 1532337 expired 11/29/16 2. Approximately four patients were stained each day of testing. 3. The LD confirmed on 11/27/18 at 2:50 pm that the laboratory had expired reagents.</p>

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to ensure BA was performed accurately in the calendar years 2017 and 2018. The findings include: 1. The laboratory submitted slides with a diagnosis. 2. There was no evaluation of the LD to ensure accuracy. 3. The LD confirmed on 11/27/18 at 3:00 pm that BA was not performed.