

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D0947644</p>	<p>(X3) Date Survey Completed</p> <p>02/10/2020</p>
<p>Name of Provider or Supplier</p> <p>North Point Pediatrics</p>	<p>Street Address, City, State</p> <p>3180 North Point Parkway, Suite 410, Alpharetta, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 10, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and an interview with the office manager, the laboratory failed to include the six required competency assessment criteria when evaluating annual competency on all testing personnel for the specialty of Microbiology in 2018 and 2019. The findings include: 1. Review of testing personnel competency assessment records (TP #s 2 to 7 CMS 209) for 2018 and 2019 revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. An interview with the office manager in the break room on February 10, 2020 at approximately 12:50 PM confirmed that annual competency assessments for testing personnel (TP#s 2 to 7 CMS 209) did not contain the (6)six required criteria by CLIA in 2018 and 2019.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to</p>

identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of Quality Controls (QC) records, maintenance records, procedure manual (SOP) and an interview with the office manager, the laboratory director who is also the Technical Consultant (TC) failed to provide overall Quality Assurance management and direction of the laboratory as required. Findings include: 1.)

Laboratory maintenance records review revealed the following: freezer, (QC), refrigerator, and incubator temperature logs were not reviewed for accuracy by the Technical Consultant (TC) who was also the Laboratory Director in 2018 and 2019.

2.) An interview with the office manager, at approximately 12:45 PM, on February 10, 2020, in the break room, confirmed the aforementioned laboratory logs were not reviewed by the (TC) or Laboratory Director as part of overall Quality Assurance in 2018 and 2019.