

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1090401	<b>(X3) Date Survey Completed</b>  08/09/2018
<b>Name of Provider or Supplier</b>  Novant Health New Garden Medical Associates	<b>Street Address, City, State</b>  1941 New Garden Road, Suite 216, Greensboro, NC	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on review of personnel records and interview with the TC (technical consultant) 8/9/18, the laboratory failed to follow established policies for evaluating the competency of testing personnel. Review of personnel records for TP (testing personnel) #2 revealed TP #2 was trained in December 2017. Review of the semiannual competency documentation for TP #2 revealed the documentation was incomplete and did not include evaluation for the performance of instrument maintenance and for problem-solving skills. In addition, the documentation was not signed and dated by the technical consultant. During interview at approximately 11:15 a.m., the TC confirmed that the competency evaluation was incomplete. She stated that TP #2 had not completed all the requirements needed to complete the evaluation.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on review of personnel records 8/9/18 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 2 testing personnel (TP #2) met the minimum education requirements to perform moderate complexity testing.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the TC (technical consultant) 8/9/18, the laboratory failed to verify that 1 of 2 testing personnel (TP #2) met the minimum education requirements for performing moderate complexity testing. Review of personnel records for TP #2 revealed there were no education credentials available at the time of the survey. During interview at approximately 11:10 a.m., the TC stated that TP #2 had been asked to bring in her education records, and the TC confirmed the records were not available for review.