

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1090401	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Novant Health New Garden Medical Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2019 and 2020 quality assessment records, and interview with the TC (technical consultant) 6/9/21, the laboratory director failed to ensure that the quality assessment plan was followed to assure the quality of laboratory services provided. The laboratory's "Quality Assessment Plan" states "... V. PROCESSES / PROGRAM COMPONENTS Quality Assessment Activities 1. Quality Assessment Activities, also known as monitors, will be completed by the testing personnel throughout each year in moderately and highly complex laboratories. 2. Each activity (monitor) will include instructions for completion and reporting. 3. All laboratory personnel must be familiar with and follow the written quality assessment plan and safety policies. ..." The plan includes monitors for each quarter (1st, 2nd, 3rd, 4th) and an "Annual General Laboratory Assessment". The monitors for each quarter include different items to monitor the preanalytic, analytic, and postanalytic portions of the testing process. Review of 2019 and 2020 quality assessment records revealed: 1. For 2019, the 1st Quarter "General Laboratory Assessment" and a "Year End Summary" monitor were the only records available. Both were signed by the TC 5/10/19, but neither was signed by the laboratory director. It was unclear whether the Year End Summary monitor was for 2018 or 2019. 2. For 2020, the "Annual General Laboratory Assessment" signed by the TC 12/30/20 was the only record available. The comments section of the "Annual</p>

General Laboratory Assessment" included the following notation by the TC "QA monitors will be reeducated and reinstated for 2021". During interview at approximately 11:20 a.m., the TC confirmed that quality assessment monitors were not completed by testing personnel as required in the quality assessment plan.