

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2003619	<b>(X3) Date Survey Completed</b>  08/04/2021
<b>Name of Provider or Supplier</b>  Novant Health Northwest Family Medicine	<b>Street Address, City, State</b>  7607 - B Highway 68 North, Oak Ridge, 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>D6021</b>	<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 quality assessment records, and interview with the TC (technical consultant) 8/4/21, 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 quality assessment records revealed the laboratory had completed monitors for 2019 and 2021, but there were no records available for 2020. During interview at approximately 12:10 p.m., the TC confirmed that quality assessment monitors were not completed by testing personnel during 2020 as required in the quality assessment plan.</p>