

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0237483	<b>(X3) Date Survey Completed</b>  06/26/2019
<b>Name of Provider or Supplier</b>  Atrium Health Wfb Family Medicine Laboratory	<b>Street Address, City, State</b>  1920 West First Street, Winston Salem, 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><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 policies and procedures and interview with the TC (technical consultant) 6/26/19, the laboratory director failed to ensure the establishment and maintenance of a comprehensive quality assessment program designed to identify and correct problems and assure the quality of laboratory services provided throughout all phases of the testing process (preanalytic, analytic, and postanalytic). Review of the laboratory's policies and procedures revealed there were no written quality assessment policies or procedures available. During interview at approximately 2:45 p.m., the TC stated they routinely review quality control and proficiency testing records and document corrective action when needed, but she did not think there was a quality assessment program in place when she transferred to this location in September 2018.</p>