

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0244462	(X3) Date Survey Completed 11/02/2023
Name of Provider or Supplier Novant Health Mintview Ob/Gyn Randolph	Street Address, City, State 1918 Randolph Road, Suite 300, Charlotte, 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
D6046	<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 upon review of competency documentation and interviews with the TC (Technical Consultant) on 11/2/23 and 11/8/23, the TC failed to assess the competency of 1 of 8 TP (Testing Personnel) performing non waived testing in the laboratory. Findings: Review of competency documents revealed the absence of any competency assessment of TP #8 for use of the BD Affirm analyzer. Competency assessments completed for TP #8 included only waived test systems. In interview at approximately 9:45 a.m. on 11/2/23, the TC confirmed the absence of any documentation to assess the competency of TP #8 utilizing the BD Affirm analyzer. The TC also stated that TP #8 only performs waived testing. In email on 11/8/23 at approximately 2:02 p.m., the TC confirmed that TP #8 has been performing patient testing utilizing the BD Affirm analyzer at this facility.</p>