

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2178760	<b>(X3) Date Survey Completed</b>  04/25/2022
<b>Name of Provider or Supplier</b>  Whole Woman's Health Of South Bend	<b>Street Address, City, State</b>  3511 Lincoln Way West, South Bend, IN	
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>D6033</b>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Repeat Deficiency Based on record review and interview, the laboratory failed to ensure two of three personnel (SP1 and SP3) performing the duties of a technical consultant (TC) were qualified as a technical consultant (refer to D6035).</p>
<b>D6035</b>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's</p>

degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Repeat Deficiency Based on record review and interview, the laboratory failed to ensure two of three (SP1 and SP3) personnel performing the duties of a technical consultant (TC) meet qualification requirements for a technical consultant. Findings include: 1. Review of the "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 4/21/2022, indicated SP4 (laboratory director) is the technical consultant. No other personnel were marked for this position. 2. Review of the initial training and semiannual competency assessment documentation for SP1 and SP5 (conducted in March 2020 and June 2020) indicated that SP3 signed off as the observer who was performing SP1's and SP5's competency evaluations. 2. Review of the initial training and semiannual competency assessment documentation for SP6 (conducted in November 2020 and February 2021) indicated that SP1 signed off as the observer who was performing SP6's competency evaluations. 3. On 4/25/2022 at 1:31 pm, SP1 indicated that SP3 was delegated to perform competency evaluations by the lab director. 4. Review of a delegation document, signed by the laboratory director on September 14, 2020, read "[SP3] has been properly trained to [SP4's] satisfaction to test RH factor and hemoglobin at Whole Women's Health". 5. Review of SP1's and SP3's education documentation indicated that they are high school graduates.