

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0353797	<b>(X3) Date Survey Completed</b>  03/12/2020
<b>Name of Provider or Supplier</b>  Indianapolis Women's Center	<b>Street Address, City, State</b>  1201 N Arlington, Indianapolis, 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: Based on document review and interview, the laboratory failed to ensure two of two individuals (SP2 and SP3), performing competencies for moderate complexity testing personnel, qualified as technical consultants (TCs). Refer to D6305.</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:

Based on document review and interview, the laboratory failed to ensure two of two individuals (SP2 and SP6), performing competencies for moderate complexity testing personnel, qualified as TCs. 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by SP1 (laboratory director) on March 9, 2020, indicated SP2 and SP6 were testing personnel (TP). 2. Review of competency documentation titled "Personnel Training for Laboratory Test" indicated the following: a) SP4 had an annual competency "instructed" and "performed" on January 6, 2020. The document was signed by SP6 as "head nurse" and SP1 "laboratory director". There was no date for either signature. b) SP4 had a six month competency "instructed" and "performed" on May 2, 2019. The document was signed by SP2 as "head nurse" and SP1 "laboratory director". There was no date for either signature. c) SP3 had a six month competency "instructed" and "performed" on May 2, 2019. The document was signed by SP2 as "head nurse" and SP1 "laboratory director". There was no date for either signature. 3. Review of personnel files indicated the following: a) SP2: Highest level of education is an associate's degree in health sciences. b) SP6: Highest level of education is a high school degree. 4. In interview on March 12, 2020, at 11:14 AM, SP2 confirmed it was their signature under "head nurse" on the competency for SP4 and SP3. SP2 indicated the form titled "Personnel Training for Laboratory Test" was utilized to document competency, and the laboratory director was not present during the competency, but sent the competency to sign at a later date. SP2 further confirmed that SP2's and SP6's education did not meet the qualification for a technical consultant. 5. Review of "Women's Med Laboratory Procedures Handbook" dated February 8, 2020, and signed SP1 (laboratory director), read, "The Laboratory Supervisor completes the Training for Laboratory Test form...."