

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1042129	(X3) Date Survey Completed 05/24/2021
Name of Provider or Supplier Philadelphia Womens Center	Street Address, City, State 777 Appletree Street, Philadelphia, PA	
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
D6033	<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 review of personnel qualification records and interview with Testing Personnel (TP)#1., the laboratory failed to have a technical consultant who meets the qualification requirements for Rh factor assay (moderate complexity) from 01/7/2019 to the date of survey. Refer to D6035. * Repeat deficiency</p>
D6035	<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</p>

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's 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 review of personnel qualification records and interview with Testing Personnel (TP)#1., the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for Rh factor assay (moderate complexity) from 01/07/2019 to the date of survey. Findings include: 1. A review of Competency Assessment (CA) records revealed that TP#1 performed and signed off the CA records of 5 of 6 TP from 01/07/2019 to 05/24/2021 as a Technical Consultant. 2. On the date of survey, 05/24/2021 at 09:20 a.m., a reviewed of personnel qualifications revealed that the TC (TP#1) did not meet the qualifications (493.1411) to be a Technical Consultant for the RH factor assay. 3. TP#1 confirmed during an interview on 05/24/2021 around 09:25 a.m. that she has a Bachelors of Science in Human Resources and is currently going to school for a nursing degree. * Repeat deficiency