Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1042129	11/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Philadelphia Womens Center	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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment record review and interview with the nursing director and testing personnel (TP) #1, the laboratory failed to document all general laboratory systems quality assessment activities that assesses the laboratories Preanalytical, Analytical and Postanalytical systems from 2017 to the time of survey. Findings include: 1. On the day of survey, 11/19/2018, the laboratory could not provide documentation of quality assessment activities from 2017 to 11/19/2018. 2. The nursing director and TP #1 confirmed the findings above on 11/19/2017 around 11:00 am.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: . Refer to: D6035

D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (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 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 the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Nursing Director and Technical Consultant (TC) #2, the laboratory failed to ensure that the technical consultant #2 was qualified from 11/19/2018 to the date of survey. Findings include: 1. The CMS 209 form signed by the Laboratory Director (11/14/2018), lists Individual #2 as a technical consultant and as a Testing Personnel (TP). 2. On the date of the survey, 11/9/2018, TC#2 mentioned it was their responsibility to sign off on 5 of 6 testing personnel's yearly competency assessment; review of their credentials revealed their degree of Bachelors of Science (BS) was in a major of Human Resource, which is not of the sciences. A BS in a science related field is required to be a TC for the complexity of testing performed on site. 3. The Nursing Director confirmed the finding above on 11/19/2018 around 10:15 AM.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)

	The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on, the review of personnel competency assessment records, American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the nursing director and testing personnel (TP) #1, the Technical Consultant (laboratory director) failed to assess the competency of 3 of 6 TP through internal blind testing samples or external PT samples for Anti D RH typing testing in 2017. Findings Include: 1. On the day of survey, 11/19/2018, review of competency assessment attestation records, revealed the laboratory did not assess test performance of 3 of 6 TP through internal blind testing samples or external PT samples for Anti D RH typing in 2017. 2. Only 3 of 6 TP performed in 2017 PT evaluations. 3. The nursing director and TP#1 confirmed the findings above on 11/19/2018 around 10:30 am
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Refer to DTAG: 6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the nursing director and testing personnel (TP) #1, the laboratory failed to ensure that each individual performing moderate complexity testing is qualified. Findings include: 1. On the CMS 209 form signed by the Laboratory Director (11/14/2018), Individual #6 is listed as a Testing Personnel. 2. On the day of survey, 11/19/2018, TP #1 provided a diploma from the Dominican Republic, which was in Spanish. The labortaory could not

	provide educational equivalency for the diploma. 3. The nursing director was emailed of this issue on 11/21/2018 around 4:15 pm.