Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1042129	06/12/2025
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
D0000	A routine recertification survey was conducted by the Pennsylvania State Agency for Philadelphia Women's Center on 06/12/2025. The laboratory was found out of compliance with the following conditions: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and interview with Testing Personnel # 2)TP) , the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples for 5 of 5 AAB-MLE Nonchemistry D (RH) Typing PT events for 2023, 2024, and 2025. Findings: 1. On the day of survey 6 /12/2025 at 9:30 am, review of AAB-MLE records for Rh testing revealed the laboratory failed to test PT samples the same number of times that it routinely tests patients samples for the following 5 of 5 AAB-MLE PT events performed in 2023, 2024 and 2025: - Nonchemistry M3 2023: D (RH) Typing - Nonchemistry M1 2024: D (RH) Typing - Nonchemistry M2 2024: D (RH) Typing - Nonchemistry M3 2024: D (RH) Typing - Nonchemistry M1 2025: D (RH) Typing 2. During interview, 6/12 /2024 at 12:00 pm, TP #2 confirmed multiple TP will perform each PT sample with results being compared for consensus before submitting the PT results to AAB-MLE.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency

	testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the laboratory's American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interview with testing personnel (TP) #2, the laboratory failed to provide 6 of 6 AAB-MLE PT attestation statements signed by the analyst for Non Chemistry testing events performed in 2023 through 2025. Findings include: 1. On the day of survey, 6/12/2025 at 9:30 am, the laboratory failed to provide attestation statements signed by the analysts for the following 6 of 6 AAB-MLE Nonchemistry PT events for Rh testing: - Nonchemistry 3rd Event 2023, 1st, 2nd, 3rd Event 2024, and 1st, 2nd Event 2025. 2. TP #2 confirmed the finding above on 6/12/2025 at 12:10 pm.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: A Based on record review and interview with testing personnel #1 (TP), the laboratory director (LD) failed to ensure laboratory policies were followed for 1 of 1 hematology test (Hemoglobin) required pre procedure for all patients from 12/1/2024 to 12/31 /2024.. Findings include: 1. The laboratory's Lab Quality Assurance Plan stated, " All patients who plan to have an abortion will receive the following tests: Rh factor, Hemoglobin (Hgb), and EPT pregnancy testing less than or equal to 7.0 weeks gestational age." 2. Further review of the laboratory's Standing Test Orders for Lab Technicians revealed the LD approved the following standing test orders on 11/11 /2022: Pre procedure tests: Blood Tests: Rh factor, Hemoglobin. 3. On the day of the survey, 06/12/2025 at 11:00 am, review of a sample of patient test results revealed that the laboratory failed to perform and document pre procedure Hgb testing as required per laboratory policy for the following from 12/01/2024 to 12/31/2024: -5 of 8 patients performed on 12/19/2024. 4. TP #1 confirmed the findings above on 06/12 /2025 at 12:00 pm. B. Based on review of personnel records and interview with testing personnel #2 (TP), the laboratory failed to ensure a General Supervisor (GS) who met the state (PA) requirement was on the laboratory premises during all hours in which tests were performed from 06/27/2023 through the day of the survey. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 06/12//2025, review of the laboratory personnel report (PA State) and personnel credentials revealed the laboratory failed to ensure a qualified supervisor was on site in the laboratory during all hours of patient testing from 06/27 /2023 to 06/12/2025. 3. TP #2 confirmed the findings above on 06/12/2025 at 12:00 pm.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to monitor and document refrigerator temperatures to ensure reagent stability and proper operating conditions for immunohematology reagents stored for 229 of 716 days from 6/27/2023 to 6/12/2025. Findings include: 1. On the day of survey, 6/12/2025 at 11:30 am, review of laboratory temperature records revealed the laboratory failed to monitor and document refrigerator temperatures when the laboratory was closed to ensure reagent stability and proper operating conditions for Albaclone Anti-D Blend reagents (immunohematology) for 229 of 716 days from 6/27/2023 to 6/12/2025. 2. Further review of the manufacturers information for Albaclone Anti-D Blend reagent revealed the reagent should be stored at 2-8 degrees Celsius. 3. The OM confirmed the findings above on 6/12/2025 at 11:45 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the Office Manager (OM), the laboratory failed to ensure that 2 of 4 patient controls for RhD determinations were not used beyond their expiration dates from 4/4/2025 to 6/12/2025 . Findings include: 1. The Laboratory's Policy for Storage of Blood Specimens for RH Controls states that "Rh+ and RH- blood specimens for use in control testing may be stored in the refrigerator for 90 days. Blood tubes must be marked with an expiration date and initialed." 2. On the day of survey, 6/12/2025 at 11:45 am, during the tour of the laboratory, the surveyor observed 2 of 4 patient controls that were collected 1/4/2025 with an expiration date of 4/4/2025 stored in the refrigerator for use from 4/4/2025 to 6 /12/2025. 3. The OM confirmed the findings above on 6/12/2025 at 12:00 pm.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Office Manager (OM), the laboratory director (LD) failed to ensure a quality control (QC) and Quality Assurance (QA) program was established and maintained to assure the quality of services provided and to identify failures in quality as they occur for 2 of 2 years from 6/27/2023 to 6/12/2025. Findings Include: 1. The Lab Quality Assurance Plan stated " The Lab Director will perform the Lab Quality Assessment and will complete and sign off on the Quarterly Lab Quality Assessment Plan." 2. The laboratory's Quality Control Testing with Anti-D Blend policy stated, "Quality controls are run everyday on Anti-D reagent prior to the start of patient care. Controls are a known positive blood sample from a staff member and a known negative blood sample from a staff member." 3. On the day of the survey, 06/12/2025 at 10:00 am, the laboratory failed to provide documentation for the quarterly assessments completed and signed off by the LD for 6/27/2023 to 6/12/2025. 4. Further review of the laboratory's QC records revealed the laboratory failed to document the known negative blood sample control each day of patient testing from 06/27/2023 to the date of the survey. 5. The OM confirmed the findings above on 6/12/2025 at 10:45 am.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), personnel qualification records, and interview with the Office manager (OM), the laboratory failed to ensure 3 of 3 testing personnel (TP) that performed RhD typing examinations for determining recipient compatability met the minimum requirements of 493.1489 to perform high complexity testing from 1/29 /2025 to 6/12/2025. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry,

	biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records, and interview with the office manager (OM), the laboratory failed to ensure 3 of 3 testing personnel (TP) that performed RhD typing examinations for determining recipient compatability met the minimum requirements of 493.1489 to perform high complexity testing from 1/29/2025 to 6/12/2025. Findings include: 1. On the day of survey, 6/12/2025 at 10:00 am, review of personnel qualification records revealed 3 of 3 testing personnel (TP) (CMS 209 personnel #2-4) did not meet the minimum qualifications to perform RhD typing examinations for determining recipient compatability (high complexity) from 1/29/2025 to 6/12/2025. 2. Competency assessment records revealed TP # 2, #3, and #4 (CMS 209) performed RhD typing examinations for determining recipient compatability from 6/27/2023 to 6 /12/2025. 3. The laboratory failed to provide documentation for the evaluation of credentials for TP #3 (CMS 209) that received their diploma from a foreign institution to determine the equivalency of their education to an education obtained in the United States (U.S.). 4. The OM confirmed the findings above on 6/12/2025 at 10:45 am.