Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0668196	01/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Se Pennsylvania	1144 Locust 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
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: A. 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 the Director of Clinical Services (DCS), the laboratory failed to provide 3 of 3 AAB-MLE attestation statements for Provider Performed Microscopy (PPM) PT testing events performed in 2023. Findings include: 1. On the day of survey, 01/21/2025, the laboratory failed to provide attestation statements for the following 3 of 3 AAB-MLE Chemistry PT events for PPM examinations (vaginal wet mount/potassium hydroxide prep) performed in 2023: - Chemistry M1 2023 - Chemistry M2 2023 - Chemistry M3 2023 2. The DCS confirmed the findings above on 01/21/2025 at 12:10 pm. B. Based on review of the laboratory's proficiency testing (PT) policy, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records and interview with the Director of Clinical Services (DCS), the laboratory director (LD)/designee and testing personnel (TP) failed to attest to the routine integration of samples into the patient workload for 3 of 3 AAB-MLE Chemistry: Provider Performed Microscopy (PPM) PT events performed in 2024. Findings include: 1. The laboratory's proficiency testing policy states, "Assigned staff test samples, record results on the testing sheet and signs attestation. Completed form is given, faxed or scanned and emailed to the laboratory director for signature." 2. On

	the day of survey, 01/21/2025 at 9:42 am., review of the laboratory's AAB-MLE PT records revealed the LD/designee and TP failed to sign attestation statement forms for 3 of 3 AAB-MLE Chemistry PT events for PPM examinations (vaginal wet mount /potassium hydroxide prep) performed in 2024: - Chemistry M1 2024 - Chemistry M2 2024 - Chemistry M3 2024 3. The DCS confirmed the findings above on 01/21/2025 at 12:10 pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the laboratory's personnel policy, and interview with the Director of Clinical Services (DCS), the laboratory failed to follow established policies to assess the competency of 1 of 2 Technical Consultants (TC) for their supervisory responsibilities performed in 2023 and 2024. Findings include: 1. The laboratory's personnel policy states, "Technical Consultants must be privileged by the Lab Director and are assessed for competency at the completion of training, at 6 months, and annually." 2. On the day of the survey, 01/21/2025, the laboratory failed to provide competency records for 1 of 2 TC (CMS 209 personnel #3) for their supervisory responsibilities performed in 2023 and 2024. 3. The DCS confirmed the findings above on 01/21/2025 at 12:10 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Provider Performed Microscopy (wet prep/wet mount) procedure and interview with the Director of Clinical Services (DCS), the

	laboratory failed to provide a complete test procedure for the potassium hydroxide (KOH) prep and wet mount microscopic examinations performed from 07/01/2016 to 01/21/2025. Findings include: 1. On the day of the survey, 01/21/2025 at 11:00 am, review of the laboratory's Provider Performed Microscopy (wet prep/wet mount) procedure, effective as of July 1, 2016, revealed the procedure did not include the following: - Step-by-step performance to include interpretation of results. 2. The DCS confirmed the findings above on 01/21/2025 at 12:10 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records (credentials) and interview with the Director of Clinical Services (DCS), the laboratory failed to ensure that 1 of 2 Technical Consultants (TC) met the requirements to perform technical consultation for moderate complexity mycology and parasitology examinations performed from 04/16/2015 to 01/21/2025. 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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and

	(b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records (credentials) and interview with the Director of Clinical Services (DCS), the laboratory failed to ensure that 1 of 2 Technical Consultants (TC) met the requirements to perform technical consultation for moderate complexity mycology and parasitology examinations performed from 04/16/2015 to 01/21/2025. Findings include: 1. On the day of survey, 01/21/2025 at 11:21 am, review of the CMS 209 form revealed, Personnel #2 (CMS 209) was listed as a TC for mycology and parasitology. 2. On 01/21/2025, the laboratory provided the following documents for TC #1: - Planned Parenthood Federation of America/University of Pennsylvania School of Nursing Obstetrics/Gynecology Nurse Practitioner Program certificate completed in December of 1993. - Clinician Job description signed by TC #1 on 04/16/2015. 3. On 01/27/2025, the laboratory provided the following documents for TC #1: - Cape Cod Community College Associate of Science degree in Nursing granted on June 7, 1990. 4. Review of personnel credentials revealed the laboratory failed to ensure that 1 of 2 TC (CMS 209 personnel #2) met the education requirements to perform technical consultation for moderate complexity mycology and parasitology examinations (wet mount/KOH prep) performed from 04/16/2015 to 01/21/2025. 5. The DCS confirmed the findings above on 01/21/2025 at 12:10 pm.