Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1049784	04/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Los Angeles	2690 Pacific Ave, Ste 340, Long Beach, CA	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, lack of a laboratory safety procedure, and interview with testing personnel (TP); the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the survey on April 9, 2025, at approximately 1:00p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. The TP confirmed by interviews April 15, 2025, at approximately 1:30p.m., that the laboratory lacked written safety policy and procedures based on the laboratory's risk assessment. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 4 /15/2025, the laboratory processed and reported approximately 222,072 patients' test samples.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on the lack of a Quality Assurance plan (QA), review of the laboratory's policies and procedures, and interview with the laboratory's staff; the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings include: 1. Based on the day survey on April 15, 2025, at approximately 12:30 p.m., no documentation could be retrieved by the laboratory to show that a written QA plan was in place for the years 2023, 2024, and 2025. 2. Laboratory staff reviewed and documented monthly patient tracers. The laboratory staff randomly selected 3 patients and reviewed the requisition, final report, test results, QC, and preventive maintenance. However, no written QA plan was found at the time of the survey. 3. The laboratory staff confirmed by interview on April 15, 2025, at approximately 1:00 p.m., that the laboratory did not establish a QA plan to follow written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on April 15, 2025, signed and dated by the laboratory director, the laboratory performed annually 222,072 bacteriology molecular tests and diagnosis without an established written QA plan.
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 the surveyor's review of policies and procedures, lack of a written procedure for the molecular detection of Chlamydia trachomatis and Neisseria Gonorrhroae, interviews with the laboratory's staff, and review of four (4) randomly chosen patient records; the laboratory failed to establish required written test procedures. Findings included: 1. Review of the standard operating procedures and policies revealed lack of a formal operating procedure for the molecular detection of Chlamydia trachomatis and Neisseria Gonorrhroae approved and signed by the laboratory director. 2. During interviews with the laboratory staff on April 15, 2025, at approximately 1:30 p.m., the laboratory staff confirmed the lack of a required written procedures for the molecular detection of Chlamydia trachomatis and Neisseria Gonorrhroae as listed in 1 above. 3. According to the submitted laboratory declaration of test volume, the laboratory tested

	and reported 222,072 bacteriology molecular samples for which there is a lack of a written procedure for the detection of Chlamydia trachomatis and Neisseria Gonorrhroae.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on interviews with the laboratory's staff on the day of the survey (April 15, 2025), the laboratory director failed to ensure that an approved, signed, and dated, procedure manual reflecting the current practice, a written Quality Assurance Plan, and a laboratory Safety Plan are available to all personnel in the laboratory. Findings include: D3011, D5291 and D5403.