Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2027914	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Southeast, Inc	720 E 71st Street, Savannah, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 22, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 policy and procedure manual (SOP), the laboratory failed to include required quality control (QC) policies and procedures. Findings include: 1. SOP review revealed there was not a policy and procedure for QC for

	Potassium Hydroxide (KOH) and Wet Mount (Parasitology) laboratory testing. 2. An interview with the clinic office manager in the breakroom on October 22, 2019, at approximately 1:30 p.m. confirmed the lack of a QC policy and procedure for KOH and Wet Mount in the laboratory SOP.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient logs and staff interview, the laboratory failed to perform qualitative quality control (QC) on each day of patient testing as required. Findings include: 1. Review of patient logs revealed Potassium Hydroxide (KOH) and Wet Preparation (Parasitology) QC was not performed for 2018 (February through December) and 2019 thus far. 2. An interview with the clinic office manager in a breakroom on 10/22/2019 at approximately 2:00 p.m. confirmed the lack of aforementioned QC for 2018 and 2019.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document TP competency for moderate complexity testing at least semiannually during the first year of TP laboratory testing as required. Findings include: 1. TP competency document review revealed there was no six-month competency performed on Staff #5 (CMS 209) in 2019. 2. An interview with the clinic office manager in the breakroom on 10/22/2019 at approximately 1:15 p.m. confirmed a six- month competency was not performed for the aforementioned TP in 2019.