GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Brian P. Kemp, Governor

Frank W. Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

November 27, 2019

Dr. Janet Lefkowitz, Laboratory Director
Planned Parenthood Southeast, Savannah
720 E. 71st Street
Savannah, GA 31405

CLIA No.: [redacted]

Dear Dr. Lefkowitz:

Thank you for submitting your plan of correction outlining the measures you have taken to assure that deficiencies noted during the CLIA survey are corrected.

The plan is acceptable and will become a part of the record and files of your laboratory. As the agency having responsibility for recommending certification, we must insist that this plan of correction be carried out.

If we can be of assistance during this time, please let us know.

[redacted]
Christel Benn-Griffith, Director
Diagnostic Services Unit
Healthcare Facility Regulation Division

CBG/cbm

Rec'd 11/21/2019

PRINTED: 11/06/2019
FORM APPROVED
OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	11D2027914	A. BUILDING _____ B. WING _____	10/22/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST, SAVANNAH	720 E 71ST STREET SAVANNAH, GA 31405

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS	D 000		
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)	D5403	1. What corrective action(s) have been taken for patients found to be affected by the deficient practice?	11/20/19
120M 130M	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		No patients were affected after review of our 2018-2019 internal laboratory logs, incident reporting system, American Proficiency Institute results, yearly laboratory evaluation, and yearly provider competency review. 2. How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective action(s) have been taken? No patients were affected after review of our 2018-2019 internal laboratory logs, incident reporting system, American Proficiency Institute results, yearly laboratory evaluation, and yearly provider competency review. 3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur? Planned Parenthood Southeast's Laboratory Manual has been updated to reflect the following in the Quality Control Wet Mount section: *Check the expiration date for the reagent prior to use and document in the Wet Mount and KOH Log. Review common wet mount findings, such as the images shown below or through review of API images.*	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	CNO/CNO	11/20/19

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D5403	Continued From page 1 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.	D5403	All health centers have received the revision. The staff have signed the signature log for the Laboratory Manual. 4. How the corrective action(s) is being monitored to ensure the deficient practice does not recur? The Lab Manual will continue to be reviewed during on boarding and annually with all staff. The Quality Control section regarding wet mounts and the procedure itself in the In-House Non-Waived tests section of the Lab Manual will be highlighted during these reviews.	11/20/19
D5449 120M 130M	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--	D5449		

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D5449	Continued From page 2 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.	D5449	1. What corrective action(s) have been taken for patients found to be affected by the deficient practice? No patients were affected after review of our 2018-2019 internal laboratory logs, incident reporting system, American Proficiency Institute results, yearly laboratory valuation, and yearly provider competency review. 2. How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective action(s) have been taken? No patients were affected after review of our 2018-2019 internal laboratory logs, incident reporting system, American Proficiency Institute results, yearly laboratory evaluation, and yearly provider competency review.	11/20/19
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	D6053	3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur? The Wet Mount Log was updated to include the following: *Reagent Expiration and Quality Control Images Reviewed.* All health centers have received the revision. The log is attached to this document. 4. How the corrective action(s) is being monitored to ensure the deficient practice does not recur? Planned Parenthood Southeast's Health Center	

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D6053	Continued From page 3 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.	D6053	Managers will continue to document review of the Wet Mount Log on their Monthly Checklist. Any discrepancies will be brought to the attention of the Lab Director immediately. 1. What corrective action(s) have been taken for patients found to be affected by the deficient practice? No patients were affected after review of our 2018-2019 internal laboratory logs and incident reporting system. 2. How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective action(s) have been taken? The laboratory determined that no patients were found to be affected after review of our 2018-2019 incident reporting system. 3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur? The Director of Compliance, Risk, and Quality Management will work with the Health Center Manager on a schedule to ensure that the lab evaluations are completed. 4. How the corrective action(s) is being monitored to ensure the deficient practice does not recur? The Lab Director will review quarterly the competency documents to make sure that when staff have been signed off on additional skills that the next lab evaluation will be completed within the required timeframe.	11/20/19

Wet Prep and KOH Log
Planned Parenthood Southeast, Inc. 404.688.9300

Instructions: The Reagent Expiration and Review of the Control Image must be done **once** daily by each family planning provider.

Control Image Source: API 2019 Hematology/Coagulation-2nd Event

Image 1 (VA-02):

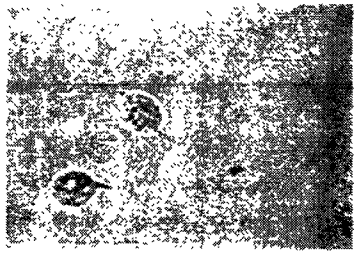

Image 2 (VKP-02):

Date	Reagent Expiration	Control Image 1	Control Image 2	Encounter Number	NP/MD Initials	Whiff	Clue Cells	Yeast	Trich	WBC#	Lactobacilli	pH Comma
Example: 11/20/2019	*1.20.20 (KOH)/12.15.19 (Saline)*	*No trich, clue cells, or yeast seen*	*No trich, clue cells, or yeast seen*	*xxxxx*	*XX*	*Neg*	*Neg*	*Neg*	*Neg*	*Neg*		

PPSE Form 164 Log
Revised 1/17; 12/17; 11/19

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November 06, 2019

Dr. Janet Lefkowitz, Laboratory Director
Planned Parenthood Southeast, Savannah
720 E. 71st Street
Savannah, GA 31405

CLIA No.: 11D2027914

Dear Dr. Lefkowitz:

The Diagnostic Services Unit of the Healthcare Facility Regulation Division conducted a certification/recertification survey of your laboratory on October 22, 2019. Enclosed is the **Statement of Deficiencies** which outlines the violations found during the survey **(CMS Form 2567)**.

Please return the 2567 form with your Plan of Correction on the right side of the form. An acceptable plan of correction should include (example enclosed):

- The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited;
- The procedure for implementing the acceptable plan of correction for the specific deficiency cited
- The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;
- The title of the person responsible for implementing the acceptable plan of correction and completion date.

Please return the form CMS 2567 and any other forms left for your completion, dated and signed by the director, **no later** than **11/16/2019. Please note that failure to return the Plan of Correction within the specified time frame may result in suspension or limitation of your CLIA Certificate (42 CFR 493.1816)**. If you have any questions, please call 404-657-5450.

[redacted]

Christel Benn-Griffith, Director
Diagnostic Services Unit
Healthcare Facility Regulation Division

CBG/cbm

Laboratory Name: Planned Parenthood Southeast, Inc. Savannah

Laboratory Test and Equipment List

Section Name/Specialty	Test Performed	Annual Test Volume	Instrument /Kit	Supervisor /PH#
Immunohematology	Rh testing	597	Eldon Cards	Janet Lefkowitz/ 860-922-5110
Mycology KOH	237	474		
Parasit. Wet Prep	237			

Delaware County Memorial Hospital and
The Crozer-Keystone Health System

certify that

Janet Beth Lefkowitz, DO

has faithfully and satisfactorily performed the duties of

Intern

within the Crozer-Keystone Health System

From June 25, 2001 to June 23, 2002

[redacted]

President, System Hospitals
CKHS

[redacted] MBA
Director, Osteopathic Medical Education
CKHS