PRINTED: 11/15/2013
FORM APPROVED

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPL
	FL22012812	A. BUILDING: _____ B. WING _____	

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	8950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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) COMPLETE DATE
L 000	Initial Comments State License 800015659 A relicensure survey was conducted on 2013. Planned Parenthood of Southwest and Central Florida had three deficiencies found at the time of the visit.	L 000	L2523 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will notify all Health Center Mangers about the necessity of keeping all paperwork from the proficiency testing cycle in a binder that is clearly labeled. The email will instruct Health Center Managers that the proficiency testing paperwork must be kept for a minimum of two years from the date of the test cycle. • What corrective actions have been taken for patients found to be affected by the deficient practice? The laboratory determined that no patients were by the deficiency. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were Refer to following two bullet points for corrective actions. • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not recur? A memo was sent to all Health Center Managers reminding them of the necessity of keeping all paperwork from the proficiency testing company for a minimum of two years. The QMRM Director will require all Health Center Managers to scan the completed paperwork to a file on the shared drive after the proficiency test results have been returned by the testing company. This will allow the QMRM Director to confirm that the testing packet is complete.	12/2/13
L2523	59A-7.025(2)(e) PARTICIPATION IN PROFICIENCY TESTING (2) Testing of proficiency testing samples. (e) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples in the same manner as patient specimens. 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 proficiency testing program, signed by the clinical laboratory personnel examining the sample(s) 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 Statute or Rule is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain one of six proficiency testing event records (1st Event 2013) from 2011 through 2013. The findings are: Review of the laboratory's American Proficiency Institute proficiency testing records for Rh testing	L2523		

AHCA Form 3020-0001
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE: MD/Laboratory Director (X6) DATE: 11/22/13

STATE FORM 6899 0XHP11 If continuation sheet 1 of 4

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Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FL22012812	A. BUILDING: _____ B. WING _____	11/04/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	8950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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) COMPLETE DATE
L2523	Continued From page 1 from ... 2011 through ... 2013 indicated that the laboratory did not have the original testing records and attestation statement for the first testing event of 2013. Interview with the Director of Risk and Quality Management on ... at 10:51 AM confirmed that the laboratory had not retained the attestation statement and original testing records for the first event of 2013 for ... proficiency testing.	L2523	• How is the corrective action being monitored to ensure the deficient practice does not recur? The Director will be responsible for reporting results of the Proficiency Test Packet review to the Laboratory Director one month after the testing period ends.	
L2915	59A-7.029(2)(f) GENERAL QUALITY CONTROL REQUIREMENTS (2) The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports as required by CLIA. (f) Expired, substandard or unusable supplies shall be promptly removed from use and clearly labeled to indicate their status. Such supplies shall be ... from usable supplies until they are removed from the premises. This Statute or Rule is not met as evidenced by: Based on record review and staff interview, the laboratory failed to use ... positive and negative controls that had not exceeded their expiration date on 16 of 55 days of Eldon Card ... quality control reviewed. The findings are: Review of the Quality Control (QC) records ... that the laboratory used previously tested ... confirmed ... positive and ... negative personnel for their positive and negative controls for the Eldon Card ... test. The controls were	L2915	L2915 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will notify all Health Center Staff that work in the laboratory about the necessity of checking the expiration date of all ... controls prior to use. Staff will be informed not to use expired ... as a control. • What corrective actions have been taken for patients found to be affected by the deficient practice? The laboratory determined that no patients were impacted by the deficiency. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were Refer to #4 and #5 for corrective actions.	12/6/13

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	FL22012812	A. BUILDING: _____ B. WING _____	11/04/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	8950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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) COMPLETE DATE
L2915	Continued From page 2 used to assure that the Eldon Card gave accurate results each day of use. The logs showed that samples drawn from personnel expired four weeks following collection. The expiration date of the current controls were included in the QC records. Review of the Quality Control log for testing for daily quality control performed on 10/5/12 through 10/30/13 showed that the laboratory used expired positive controls on 14 out of 55 days and expired negative controls on 16 out of 55 days. The "STP [St. Petersburg] Health Center Log" indicated the following: A positive control with an expiration date of 12/2/12 was used on 12/28/12, 1/ and A positive control with an expiration date of 6/3/13 was used on 6/7/13, 6/14/13, 6/21/13, 7/5/13, and 7/12/13. A positive control with an expiration date of was used on and 10/9/13. A negative control with an expiration date of was used on 12/13/12, and A negative control with an expiration date of was used on 6/7/13, 6/14/13, 6/21/13, 7/5/13, and A negative control with an expiration date of was used on and Interview with the Director of Risk and Quality Management on 11/4/13 at 11:51 PM confirmed that the laboratory's records indicated that they should have drawn fresh positive and negative controls for testing when records showed that the controls had expired.	L2915	L2915 • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not recur? A memo sent to all Health Center staff that work in the laboratory reminding them of the necessity of checking the expiration date on the control The Health Center Manger will be responsible for checking the control expiration monthly and documenting the result on the monthly Quality Assurance Checklist. The QMRM Director will require all Health Center Managers to scan the completed QA Checklist to her for review. This will allow the ctor to confirm that the being used for running controls has not expired. • How is the corrective action being monitored to ensure the deficient practice does not recur? The Health Center Manger will send a copy of monthly Quality Assurance checklist to the Director of QMRM with the controls documented. The QMRM Director will report any deficiencies immediately to the Laboratory Director. L3111 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will assign the Clinical Director the responsibility for scheduling and monitoring the wet mount proficiency for all clinicians. The Clinical Director will be responsible for reviewing and signing off on all wet mount proficiency reports. This task will be added twice yearly to the QMRM calendar. This will be completed by December 8, 2013.	12/8/13
L3111	59A-7.031(5)(b) QUALITY ASSURANCE (5) Comparison of test results. (b) If a laboratory performs tests for which	L3111		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FL22012812	A. BUILDING: _____ B. WING _____	

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	8950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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) COMPLETE DATE
L3111	Continued From page 3 proficiency programs are not available, the laboratory must have a system for verifying the accuracy of its test results at least every six months. This Statute or Rule is not met as evidenced by: Based on record review and staff interview, the laboratory failed to assure that they documented the verification of accuracy for Wet Prep and KOH Prep testing at least every six months from 2011 through 2013. The findings are: Review of the laboratory's quality assurance documentation of peer review for twice annual verification of accuracy of Wet Prep and KOH Prep testing from 2011 through 2013 showed that the laboratory had performed the peer reviews on 1/10/12, then 11/ (10 months later), and then (11 months later) and there was no documentation to show any other verification of these tests. Interview with the Director of Risk and Quality Management on 11/4/13 at 12:45 PM confirmed that the laboratory had performed three peer reviews of Wet Prep and KOH Prep tests in the past two years and an additional peer review should have been performed and documented in the quality assurance records during that time.	L3111	L311 • What corrective actions have been taken for patients found to be affected by the deficient practice? The laboratory determined that no patients were by the deficiency. The clinician completed wet mount proficiency twice in 2012 and again in November 2013, at all times she was found to be proficient and has maintained the procedure for performing wet mounts throughout that time. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were impacted. Refer to following two bullet points for corrective actions. • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not recur? A memo was sent to all clinicians advising them of the change in practice. The Clinical Director will email all clinicians in and informing them that they must schedule their wet mount proficiency with another clinician for completion prior to June and of each year. Upon completion, the clinician is responsible for scanning a copy of the proficiency review to the Clinical Director for her review and signature. Discrepancies in results will be addressed by the Clinical Director in consult with the Laboratory Director. • How is the corrective action being monitored to ensure the deficient practice does not recur? The Clinical Director will twice yearly compare a list of all providers to the completed wet mount proficiency documents to ensure the all providers have completed. This information will be documented on the Quality Management/Risk Management annual calendar. Review of Wet Mount Proficiency will be added to the QMRM committee agenda for and of each ye	12/6/13

AHCA Form 3020-0001
STATE FORM

ation sheet 4 of 4

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

PRINTED: 11/13/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	10D0970415	A. BUILDING _____ B. WING _____	11/04/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	6950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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
D3037	493.1105(a)(4) RETENTION REQUIREMENTS The laboratory must retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain one of six proficiency testing event records (1st Event 2013) from 2011 through 2013. The findings are: Review of the laboratory's American Proficiency Institute proficiency testing records for testing from 2011 through 2013 indicated that the laboratory did not have the original testing records and attestation statement for the first testing event of 2013. Interview with the Director of Risk and Quality Management on 11/4/13 at 10:51 AM confirmed that the laboratory had not retained the attestation statement and original testing records for the proficiency testing for the first event of 2013.	D3037	D3037 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will notify all Health Center Mangers about the necessity of keeping all paperwork from the proficiency testing cycle in a binder that is clearly labeled. The email will instruct Health Center Managers that the proficiency testing paperwork must be kept for a minimum of two years from the date of the test cycle. • What corrective actions have been taken for patients found to be affected by the deficient practice? The laboratory determined that no patients were by the deficiency. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were impacted. Refer to following two bullet points for corrective actions. • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not occur? A memo was sent to all Health Center Managers reminding them of the necessity of keeping all paperwork from the proficiency testing company for a minimum of two years. The QMRM Director will require all Health Center Managers to scan the completed paperwork to a file on the shared drive after the proficiency test results have been returned by the testing company. This will allow the QMRM Director to confirm that the testing packet is complete. • How is the corrective action being monitored to ensure the deficient practice does not occur? The QMRM Director will be responsible for reporting results of the Proficiency Test Packet review to the Laboratory Director one month after the testing period ends.	12/6/13
D5217 120M 130M	493.1236(c)(1) EVALUATION OF PROFICIENCY TESTING PERFORMANCE At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to assure that they documented verification of accuracy for Wet Prep and KOH Prep testing twice annually from 2011 through 2013. The findings are:	D5217	OK 12/12/13	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: MD / Laboratory Director — (X6) DATE: 11/22/13

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.

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	10D0976415	A. BUILDING _____ B. WING _____	

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	8950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

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D5217	Continued From page 1 Review of the laboratory's documentation of peer review for twice annual verification of accuracy of Wet Prep and KOH Prep testing from 2011 through 2013 showed that the laboratory had performed the peer reviews on and Interview with the Director of Risk and Quality Management on at 12:45 PM confirmed that the laboratory had performed three peer reviews of Wet Prep and KOH Prep tests in the past two years and an additional peer review should have been performed during that time.	D5217	D5217 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will assign the Clinical Director the responsibility for scheduling and monitoring the wet mount proficiency for all clinicians. The Clinical Director will be responsible for reviewing and signing off on all wet mount proficiency reports. This task will be added twice yearly to the QMRM calendar. This will be completed by December 8, 2013.	12/8/13
D6417 510M	493.1252(d) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 record review and staff interview, the laboratory failed to use positive and negative controls that had not exceeded their expiration date on 16 of 55 days of Eldon Card quality control quality control reviewed. The findings are: Review of the Quality Control (QC) records showed that the laboratory used previously tested and confirmed positive and negative personnel for their positive and negative controls for the Eldon test. The controls were used to assure that the Eldon Card gave accurate results each day of use. The logs showed that samples drawn from personnel expired four	D5417	• What corrective actions have been taken for patients found to be affected by the deficient practice? The laboratory determined that no patients were by the deficiency. The clinician completed wet mount proficiency twice in 2012 and again in at all times she was found to be proficient and has maintained the same procedure for performing wet mounts throughout that time. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were impacted. Refer to following two bullet points for corrective actions. • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not recur? A memo was sent to all clinicians advising them of the change in practice. The Clinical Director will email all clinicians in and October informing them that they must schedule their wet mount proficiency with another clinician for completion prior to and of each year. Upon completion, the clinician is responsible for scanning a copy of the proficiency review to the Clinical Director for her review and signature. Discrepancies in results will be addressed by the Clinical Director in consult with the Laboratory Director. • How is the corrective action being monitored to ensure the deficient practice does not recur? The Clinical Director will yearly compare a list of all providers to the completed wet mount proficiency documents to ensure the all providers have completed. This information will be documented on the Quality Manager Management annual calendar. Review of Wet Mount Proficiency will be added to the QMRM committee agenda for and December	

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

11/13/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	10D0970415	A. BUILDING _____ B. WING _____	11/0 2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	3950 MARTIN LUTHER KING JR ST N STE 102 SAINT PETERSBURG, FL 33702

(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 DEFICIENCY)	(X5) COMPLETION DATE
D5417	Continued From page 2 weeks following collection. The expiration date of the current controls were included in the QC records. Review of the Quality Control log for Rh testing for daily quality control performed on 10/5/12 through 10/30/13 showed that the laboratory used expired positive controls on 14 out of 55 days and expired negative controls on 16 out of 55 days. The "STP [St. Petersburg] Health Center Log" indicated the following: A positive control with an expiration date of 12/2/12 was used on 12/13/12, 12/21/12, 12/26/12, 1/3/13, 1/4/13, and 1/31/13. A positive control with an expiration date of 6/3/13 was used on 6/7/13, 6/14/13, 6/21/13, 6/28/13, and 7/12/13. A positive control with an expiration date of was used on 10/6/13 and 10/9/13. A negative control with an expiration date of 12/6/13 was used on 12/13/12, 12/25/12, 12/28/12, 1/3/13, 1/11/13, and 1/31/13. A negative control with an expiration date of was used on 6/7/13, 6/14/13, 6/21/13, 6/28/13, 7/5/13, and 7/12/13. A negative control with an expiration date of 9/3/13 was used on 10/9/13 and 10/16/13. Interview with the Director of Risk and Quality Management on 11/6/13 at 11:51 PM confirmed that the laboratory's records indicated that they should have drawn fresh positive and negative controls for testing when records showed that the controls had expired.	D5417	D5417 • How will the deficient practice be corrected? Planned Parenthood of Southwest and Central Florida will notify all Health Center Staff that work in the laboratory about the necessity of checking the expiration date of all blood controls prior to use. Staff will be informed not to use expired as a control. • What corrective actions have been taken for patients found to be affected by the deficient practice? The determined that no patients were the deficiency. • How the laboratory has identified other patients having potential to be affected by the deficient practice and what corrective actions have been taken. The laboratory determined that no patients were impacted. Refer to #4 and #5 for corrective acti • What measures have been put in place or what systematic changes have been made to ensure that the deficient practice does not reoccur? A memo was sent to all Health Center staff that work in the laboratory reminding them of the necessity of checking the expiration date on the control blood. The Health Center Manger will be responsible for checking the control expiration monthly and documenting the result on the monthly Quality Assurance Checklist. The QMRM Director will require all Health Center Managers to scan the completed QA Checklist to her for review. This will allow the QMRM Dire to confirm that the blood being used for running controls not expired. • How is the corrective action being monitored to ensure the deficient practice es not recur? The Health Center Manger will send a copy of the monthly Quality Assurance checklist to the Director of QMRM with the controls documented. The QMRM Director will report any deficiencies immediately to the Laboratory Director.	12/6/13

AHCA
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

, 2013

Via facsimile to (727) 898-9710
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

Planned Parenthood of Southwest & Central FL
8950 Martin Luther King Jr St N Ste 102
Saint Petersburg, FL 33702

RE: Standard-Level Deficiency; CLIA # 10D0970415

Dear Laboratory Director:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. §263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. §493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Agency for Health Care Administration conducted a recertification and relicensure survey of your laboratory that was completed on , 2013. Enclosed is form CMS-2567, Statement of Deficiencies, and State Form - Statement of Deficiencies, listing the deficiency found during the survey. The deficiency statement references the CLIA regulations at 42 CFR 493 and State of Florida Regulations at Chapter 59A-7, Florida Administrative Code.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions for each tag on the right side of both forms, CMS-2567 and State Form, in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date." **Please return the completed forms, CMS-2567 and State Form, dated and signed by the director, within 10 days of receipt of this notice, to the Field Office indicated on the right below.**

Regulations at 42 CFR 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to CMS (renamed Centers for Medicare & Medicaid Services, or CMS) in content and time frames. Further, regulations at 42 CFR 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

Headquarters
2727 Mahan Drive
Tallahassee, FL 32308
http://ahca.myflorida.com

St. Petersburg Field Office
525 Mirror Lake Drive North, Suite 410 A
St. Petersburg, FL33701
Phone: (727) 552-2000

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 CFR 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

- Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the Agency for Health Care Administration at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions, please contact Vickie Hart, BSIII at (727) 552-2000.

Sincerely,

Vickie Hart
for

Patricia Reid Caufman
Field Office Manager

PRC/sb
Enclosure(s)