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
	10D0970415	A. BUILDING _____ B. WING _____	

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
D2007	493.801(b)(1) TESTING OF PROFICIENCY TESTING SAMPLES The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing attestation sheets and interview with the Office Manager, the laboratory failed to perform proficiency testing in the same manner as patient specimens for 4 of 5 testing events reviewed. Findings Included: Review of API proficiency testing attestation sheets revealed that the same person (#E) was the only one performing proficiency testing for the 1st and 2nd testing events of 2014 and 2015. Review of the CMS 209 (signed and dated by the Laboratory Director on) revealed that there are 4 (#C-#F) testing personnel who perform the Type testing. During an interview on at 12:18 PM the Office Manager confirmed the proficiency testing was not being rotated among the Testing personnel who performed patient testing.	D2007	There was no patient harm because the remaining 3 personnel had alternative competancy testing by the Laboratory Director which found them to be proficient in testing. Effective / / testing personnel have been informed of a rotation schedule for performing the proficiency testing. This will be monitored by the Lab Director/ Director of Quality/ designee and reported quarterly at the CQRM Meeting to ensure ongoing Compliance.	11/19/15
D5200	493.1230 GENERAL LABORATORY SYSTEMS	D5200		
120M 130M	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and			

Plan of correction acceptable. MRE 12/23/15

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE La... ty D... 16 | (X6) DATE 2/15/15

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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D5200	Continued From page 1 evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy of wet mounts and KOH ( ) testing at least twice annually for 2 of 2 (2013-2015) years reviewed (See D5217 which is a repeat deficiency from the recertification survey).	D5200	Patients were not affected because both Clinicians successfully completed wet mount proficiencies in 2015 (attached). Clinician A became a clinician in 2015, and completed wet mount proficiency on / / . Clinician B completed one wet mount proficiency in 2014, and 2 proficiencies in 2015. Proficiencies for both clinicians have been reviewed and verfied by the Lab Director. Clinician B has been employed by affiliate for over 5 years, and has always been found to be competant in wet mount performance, so unlikely that missing single proficiency in 2014 affected patients. Effective / / Wet mount and KOH proficiency testing will be completed 3x/year to ensure an every six month testing. Additionally the Laboratory Director will review and sign verifying the accuracy of testing. This will be tracked by the director of quality/designee. The results of this will be reported during the quarterly CQRM meeting to ensure ongoing compliance.	11.15
D5211 510M	493.1236(a) EVALUATION OF PROFICIENCY TESTING PERFORMANCE The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing results and interview with the Office Manager, the Laboratory Director failed to review the proficiency testing results for 4 out of 5 testing events reviewed. Findings Included: Review of API proficiency testing results revealed that the Laboratory Director did not review the results in the 1st and 2nd testing events in 2015 and the 1st and 3rd testing event in 2014. During an interview on at 12:18 PM the Office Manager confirmed there was no documentation that the Laboratory Director reviewed the proficiency testing results.	D5211	This did not have an impact on patients because the results of API Proficiency testing results were correct. Effective / / the Laboratory Director has reviewed and verified API proficiency results for 2014 and 2015(attached) and moving forward will continue to review and sign verifying API proficiency results. This will be tracked by the director of quality and reported during the quarterly CQRM meeting to ensure compliance.	12/15/15

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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 interview with the Office Manager, the laboratory failed to verify the accuracy of wet mounts and KOH ( ) testing at least twice annually for 2 of 2 (2013-2015) years reviewed. This is a repeat deficiency from the recertification survey. Findings Included: Review of wet mount (subspecialty of) and KOH (subspecialty of) testing revealed no peer reviews that verified the accuracy of testing for 2 of 2 (2013-2015) years reviewed. Review of the recertification survey conducted on revealed that this is a repeat deficiency. According to the plan of correction (signed by the Laboratory Director on) the laboratory "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 , 2013." During an interview on at 12:18 PM the Office Manager confirmed that peer reviews were not being performed for wet mount and KOH testing.	D5217	Patients were not affected because both Clinicians successfully completed wet mount proficiencies in 2015 (attached). Clinician A became a clinician in 2015, and completed wet mount proficiency on / . Clinician B completed one wet mount proficiency in 2014, and 2 proficiencies in 2015. Proficiencies for both clinicians have been reviewed and verfied by the Lab Director. Clinician B has been employed by affiliate for over 5 years, and has always been found to be competant in wet mount performance, so unlikely that missing single proficiency in 2014 affected patients. Effective / , Wet mount and KOH proficiency testing will be completed 3x/year to ensure an every six month testing. Additionally the Laboratory Director will review and sign verifying the accuracy of testing. This will be tracked by the director of quality/designee. The results of this will be reported during the quarterly CQRM meeting to ensure ongoing compliance.	11/19/15
D5400	493.1250 ANALYTIC SYSTEMS	D5400		

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D5400	Continued From page 3	D5400	We do not believe the patients were affected because results were consistent both before and after results were expired. Effective / all testing personnel were -reducated (documentation of inservice attached) regarding performing Eldon control testing, and verifying expiration dates on controls each day and documenting appropriately. In addition, implementation of RN check list now includes verfication of controls run as well as expiration dates. The Director of Quality/designee will monitor this quarterly through review of the control log and reported during the quarterly CQRM meeting to ensure compliance.	11/11/15
510M	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to use positive and negative controls that had not exceeded their expiration date on 7 of 79 days of Eldon Card quality control reviewed (See D5417 which is a repeat deficiency from the recertification survey).			
D5417	493.1252(d) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT	D5417		
510M	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 interview with the Office Manager, the laboratory failed to use positive and negative controls that had not exceeded their expiration date on 7 of 79 days of Eldon Card quality control reviewed. This is a repeat deficiency from the recertification survey.		The Lab Director/Director of Quality/designee will monitor this quarterly through review of the RN control log and reported during the quarterly CQRM Meeting to ensure compliance. The current Director of Quality is a new hire effective 8/25/14 w credentials including MSN, BSN, RN	

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D5417	Continued From page 4 Findings Included: Review of quality control (QC) records from to (79 days) revealed expired positive and negative controls used on , , (controls expired on on these 3 days in), , , (controls expired on on these 3 days in), and (controls expired on this day). The controls were used to assure that the Eldon Card gave accurate results each day of use. Review of the recertification survey from revealed that this is a repeat deficiency. The plan of correction (signed by the Laboratory Director on) stated that "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 . The Health Center Manager will be responsible for checking the control expiration monthly and documenting the result on the monthly Quality Assurance Checklist. The QMRM (Quality Management, Risk Management) Director will require all Health Center Managers to scan the completed QA Checklist to her for review. This will allow the QMRM Director to confirm that the being used for running controls has not expired." During an interview on at 12:34 PM, the Office Manager confirmed that expired controls had been used.	D5417	We do not believe the patients were affected because results were consistent both before and after results were expired. Effective / all testing personnel were -reducated (documentation of inservice attached) regarding performing Eldon control testing, and verifying expiration dates on controls each day and documenting appropriately. In addition, implementation of RN check list now includes verfication of controls run as well as expiration dates. The Director of Quality/designee will monitor this quarterly through review of the control log and reported during the quarterly CQRM meeting to ensure compliance. The Lab Director/Director of Quality/designee will monitor this quarterly through review of the RN control log & reported during the Quarterly CQRM meeting to ensure compliance. The current Director of Quality is a new hire effective 5/05/14 w/credentials including MSM BSN RN	11/7/15
D6046	493.1413(b)(8) TECHNICAL CONSULTANT RESPONSIBILITIES (b) The technical consultant is responsible for–	D6046		

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D6046	Continued From page 5 (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the Laboratory Technical Consultant failed to perform competency evaluations on 6 of 6 (#A-#F) Testing Personnel for 2 of 2 (2013-2015) years reviewed. Findings Included: Review of the CMS 209 signed and dated on / / by the Laboratory Director (who is also the Technical Consultant) revealed that there were 6 (#A-#F) Testing Personnel. Review of employee competencies revealed that Testing Personnel #A, B, E, and F did not have any competency evaluations performed by the Technical Consultant for 2014 or 2015. Testing Personnel #C and D (who were both new) did not have any competency evaluations performed by the Technical Consultant for 2015. During an interview on at 1:00 PM the Office Manager confirmed that the Technical Consultant did not perform the competency evaluations.	D6046	We do not believe patients were negatively affected because on / / (C,D, E, and F) performed competency evaluations successfully with the Lab Director, and (A & B) have completed their competencies respectively. Effective immediately, prior to performing lab testing independently and twice per year, all testing personnel will perform Lab competencies, to ensure compliance. The Laboratory Director and Director of Quality/designee will audit this quarterly. This will be monitored during the CQRM quarterly meeting to ensure compliance. Meeting minutes will reflect plan of correction compliance.	12/15/15
D6063	493.1421 LABORATORY TESTING PERSONNEL The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in	D6063		

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D6063	Continued From page 6 §493.1425 for the volume and of tests performed. This CONDITION is not met as evidenced by: Based on review of CMS 209, review of Testing Personnel files, and interview with the Office Manager, the laboratory failed to verify the proof of education in 4 (#C-F) out of 6 (#A-F) Testing Personnel (See D6065).	D6063	Effective / the Quality Department initiated an Education Qualification Project which includes obtaining copies of all testing personnel proof of education, as of this date of submission, 4 of the 4 testing personnel have submitted their proof of education (attached). These documents will be tracked and placed in their personnel files. All new hire testing personnel will provide proof of education upon hire. Patients were not affected as all staff have now presented proof of education. The Laboratory Director and the Director of Quality/designee will audit quarterly for compliance. This will be monitored during the CQRM quarterly meeting. Meeting minutes will reflect plan of correction compliance. Pt not affected because the staff were Competent.	11/19/15
D6065	493.1423(b)(1)(2)(3)(4)(i) TESTING PERSONNEL QUALIFICATIONS (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to verify the proof of education in 4 (#C-F) out of 6 (#A-F) Testing Personnel.	D6065		

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D6065	Continued From page 7 Findings Included: Review of the CMS 209 (signed and dated on by the Laboratory Director) revealed that there were 6 (#A-F) Testing Personnel. Review of Testing Personnel files revealed no proof of education for Testing Personnel (#C-#F). Without proof of education, minimum education requirements could not be verified. During an interview on at 1:00 PM with the Office Manager confirmed that Testing Personnel #C-F did not have proof of education.	D6065	Effective / / the Quality Department initiated an Education Qualification Project which includes obtaining copies of all testing personnel proof of education, as of this date of submission, 4 of the 4 testing personnel have submitted their proof of education (attached). These documents will be tracked and placed in their personnel files. All new hire testing personnel will provide proof of education upon hire. Patients were not affected as all staff have now presented proof of education. The Laboratory Director and the Director of Quality/designee will audit quarterly for compliance. This will be monitored during the CQRM quarterly meeting. Meeting minutes will reflect plan of correction compliance. Pt not affected because the staff were competent.	11/8/15

Agency for Health Care Administration

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L 000	Initial Comments A biennial relicensure survey was conducted on . Planned Parenthood of Southwest & Central Florida clinical laboratory had deficiencies at the time of the survey.	L 000	Plan of correction acceptable MRC 12/23/15	
L2513	59A-7.025(2) PARTICIPATION IN PROFICIENCY TESTING (2) Testing of proficiency testing samples. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This Statute or Rule is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing attestation sheets and interview with the Office Manager, laboratory failed to perform proficiency testing in the same manner as patient specimens for 4 of 5 testing events reviewed. Included: Review of API proficiency testing attestation sheets revealed that the same person (#E) was the only one performing proficiency testing for the 1st and 2nd testing events of 2014 and 2015. Review of the Personnel list (signed and dated by the Laboratory Director on) revealed that there are 4 (#C-#F) testing personnel who perform the Type testing. During an interview on at 12:18 PM the Office Manager confirmed the proficiency testing was not being rotated among the Testing personnel who performed patient testing.	L2513	There was no patient harm because the remaining 3 personnel had alternative competancy testing by the Laboratory Director which found them to be proficient in testing. Effective testing personnel have been informed of a rotation schedule for performing the proficiency testing. This will be monitored during Quarterly CQRM meetings. This will be monitored by the Lab Director/ Director of Quality designee & reported quarterly at the CQRM meeting to ensure ongoing compliance 11/19/15	

AHCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Laboratory Director 12/15/15

STATE FORM 6899 WWB911 If continuation sheet 1 of 8

Agency for Health Care Administration

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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 interview with the Office Manager, the laboratory failed to use positive and negative controls that had not exceeded their expiration date on 7 of 79 days of Eldon Card quality control reviewed. This is a repeat deficiency from the relicensure survey. Findings Included: Review of quality control (QC) records from to (79 days) revealed expired positive and negative controls used on , (controls expired on on these 3 days in), , , (controls expired on on these 3 days in), and (controls expired on this day). The controls were used to assure that the Eldon Card gave accurate results each day of use. Review of the relicensure survey from revealed that this is a repeat deficiency. The plan of correction (signed by the Laboratory Director	L2915	We do not believe the patients were affected because results were consistent both before and after results were expired. Effective / all testing personnel were -educated (documentation of inservice attached) regarding performing Eldon control testing, and verifying expiration dates on controls each day and documenting appropriately. In addition, implementation of RN check list now includes verfication of controls run as well as expiration dates. The Director of Quality/designee will monitor this quarterly through review of the control log and reported during the quarterly CQRM meeting to ensure compliance. This will be monitored by the Lab Director/Director of Quality designee and reported quarterly at the CQRM Meeting to ensure ongoing compliance. 11/17/15	

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L2915	Continued From page 2 on) stated that "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 . The Health Center Manager will be responsible for checking the control expiration monthly and documenting the result on the monthly Quality Assurance Checkliist. The QMRM (Quality Manager Risk Manager) Director will require all Health Center Managers to scan the completed QA Checklist to her for review. This will allow the QMRM Director to confirm that the being used for running controls has not expired." During an interview on at 12:34 PM, the Office Manager confirmed that expired controls had been used.	[redacted]	Patients were not affected because both Clinicians successfully completed wet mount proficiencies in 2015 (attached). Clinician A became a clinician in 2015, and completed wet mount proficiency on / . Clinician B completed one wet mount proficiency in 2014, and 2 proficiencies in 2015. Proficiencies for both clinicians have been reviewed and verfied by the Lab Director. Clinician B has been employed by affiliate for over 5 years, and has always been found to be competant in wet mount performance, so unlikely that missing single proficiency in 2014 affected patients. Effective / . Wet mount and KOH proficiency testing will be completed 3x/year to ensure an every six month testing. Additionally the Laboratory Director will review and sign verifying the accuracy of testing. This will be tracked by the director of quality/designee. The results of this will be reported during the quarterly CQRM meeting to ensure ongoing compliance.	11/9/15
L3111	59A-7.031(5)(b) QUALITY ASSURANCE (5) Comparison of test results. (b) If a laboratory performs tests for which 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 interview with the Office Manager, the laboratory failed to verify the accuracy of wet mounts and KOH ( ) testing at least every six months for 2 of 2 (2013-2015) years reviewed. This is a repeat deficiency from the relicensure survey. Findings Included: Review of wet mount (subspecialty of) and KOH (subspecialty of	L3111		

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 _____	

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) testing revealed no peer reviews that verified the accuracy of testing for 2 of 2 (2013-2015) years reviewed. Review of the relicensure survey conducted on 1 revealed that this is a repeat deficiency. According to the plan of correction (signed by the Laboratory Director on) the laboratory "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 , 2013." During an interview on at 12:18 PM the Office Manager confirmed that peer reviews were not being performed for wet mount and KOH testing.	L3111	We do not believe patients were negatively affected because on __/__/__ (C,D, E, and F) performed competency evaluations successfully with the Lab Director, and (A & B) have completed their competencies respectively. Effective immediately, prior to performing lab testing independently and twice per year, all testing personnel will perform Lab competencies, to ensure compliance. The Laboratory Director and Director of Quality/designee will audit this quarterly. This will be monitored during the CQRM quarterly meeting to ensure compliance. Meeting minutes will reflect plan of correction compliance.	12/9/15
L3125	59A-7.031(7) QUALITY ASSURANCE (7) Personnel assessment. The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence. This Statute or Rule is not met as evidenced by: Based on record review and interview with the Office Manager the Laboratory Technical Consultant failed to perform competency evaluations on 6 of 6 (#A-#F) Testing Personnel for 2 of 2 (2013-2015) years reviewed. Findings Included: Review of the Personnel list signed and dated on by the Laboratory Director (who is also the Technical Consultant) revealed that there	L3125		

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 _____	

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
L3125	Continued From page 4 were 6 (#A-#F) Testing Personnel. Review of employee competencies revealed that Testing Personnel #A, B, E, and F did not have any competency evaluations performed by the Technical Consultant for 2014 or 2015. Testing Personnel #C and D (who were both new) did not have any competency evaluations performed by the Technical Consultant for 2015. During an interview on / / at 1:00 PM the Office Manager confirmed that the Technical Consultant did not perform the competency evaluations.	L3125	Effective / / the Quality Department initiated an Education Qualification Project which includes obtaining copies of all testing personnel proof of education, as of this date of submission, 4 of the 4 testing personnel have submitted their proof of education (attached). These documents will be tracked and placed in their personnel files. All new hire testing personnel will provide proof of education upon hire. Patients were not affected as all staff have now presented proof of education. The Laboratory Director and the Director of Quality/designee will audit quarterly for compliance. This will be monitored during the CQRM quarterly meeting. Meeting minutes will reflect plan of correction compliance. Pt not affected because the staff were competent.	11/19/15
L3513	59A-7.035(1)(a)6. STAFFING REQUIREMENTS (a) Laboratory director responsibilities. 6. The director must ensure that the laboratory employs personnel qualified under Chapter 483, Part III, F.S., and Chapter 64B3, F.A.C., to provide consultation, supervise and accurately perform tests and report test results according to this rule and within the limitations described in Section 483.111, F.S. This Statute or Rule is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to verify the proof of education in 4 (#C-F) out of 6 (#A-F) Testing Personnel. Findings Included: Review of the Personnel List (signed and dated on by the Laboratory Director) revealed	L3513		

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 _____	

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
L3513	Continued From page 5 that there were 6 (#A-F) Testing Personnel. Review of Testing Personnel files revealed no proof of education for Testing Personnel (#C-#F). Without proof of education, minimum education requirements could not be verified. During an interview on at 1:00 PM with the Office Manager confirmed that Testing Personnel #C-F did not have proof of education.	L3513		

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

IMPORTANT NOTICE – ACTION NECESSARY

, 2015

Sujatha Prabhakaran, M.D., Director
Planned Parenthood Of Southwest & Central Florida
8950 Martin Luther King Jr St N Ste 102
Saint Petersburg, FL 33702

CLIA # 10D0970415 State I.D. # 800015659

RE: CONDITION-LEVEL DEFICIENCIES

Dear Director/Owner(s):

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 state Relicensure survey of your laboratory that was completed on , 2015.

As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met:

D5200 - 42 C.F.R. § 493.1230 Condition:	General laboratory systems;
D5400 - 42 C.F.R. § 493.1250 Condition:	Analytic systems;
D6063 - 42 C.F.R. § 493.1421 Condition:	Laboratories performing moderate testing; testing personnel;

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

St. Petersburg Field Office
525 Mirror Lake Drive North, Suite 410 A
St. Petersburg, FL 33701
Phone:(727) 552-2000; Fax:(727) 552-1162
AHCA.MyFlorida.com

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office **WITHIN 10 CALENDAR DAYS FROM RECEIPT** of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the
inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
2) 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;
3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, Agency For Health Care Administration will recommend to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

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 State agency at any time to address complaints or other noncompliance 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 regarding this letter, please contact John Urquhart, OMC Manager at 727-552-2000.

Sincerely,

Patricia Reid Caufman
Field Office Director

PRC/aew
Enclosure

10SA