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 _____	10/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST &	33 6TH STREET SOUTH SAINT PETERSBURG, FL 33701

(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 The Planned Parenthood of SW and Central FL clinical laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories. Biennial certification survey was conducted The following Condition was not met: D6033 Technical Consultant-Moderate , , 493.1409	D 000		
D5413 510M	493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to record the , for 2 out of 2 years (2015-2017) reviewed. Findings Included: Review of temperature charts revealed that the	D5413		

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

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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D5413	Continued From page 1 laboratory was not documenting the . . . . . , . . . The cards used for testing require them to be stored 41-99 degrees Fahrenheit. During an interview on at 1:54 PM the office manager confirmed that the . . . . . was not being documented.	D5413		
D6033	493.1409 TECHNICAL CONSULTANT-MODERATE COMPEXITY The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the Lab Manager the Technical Consultant failed to perform competency evaluations on 2 out of 4 (#C and #D) Testing Personnel since 2013 (See D6046).	D6033		. . . .
D6046	493.1413(b)(8) TECHNICAL CONSULTANT RESPONSIBILITIES (b) The technical consultant is responsible for-- (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 Lab Manager the Technical Consultant failed to perform competency evaluations on 2 out of 4 (#C and #D) Testing Personnel since 2013. This is a repeat deficiency from the	D6046		

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D6046	Continued From page 2 recertification survey. Findings Included: Review of competency evaluations revealed no competency evaluations for Testing Personnel #C and #D. During an interview on at 2:25 PM the Lab Manager confirmed that competency evaluations had not been completed by the Technical Consultant on Testing Personnel #C and #D. Review of the CMS 2567 signed and dated by the Laboratory Director (who is also the Technical Consultant) on from the recertification survey conducted on found that the laboratory was cited for no competency evaluations on the same two Testing Personnel that did not have any competency evaluations during the current survey. The Plan of Correction stated that "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."	D6046		

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 _____	10/11/2017

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PLANNED PARENTHOOD OF SOUTHWEST &	33 6TH STREET SOUTH SAINT PETERSBURG, FL 33701

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L 000	Initial Comments A biennial relicensure survey was conducted on . Planned Parenthood of SW and Central FL (license# 800015659) clinical laboratory had deficiencies at the time of the survey.	L 000		
L2909	59A-7.029(2)(c) GENERAL QUALITY CONTROL REQUIREMENT All equipment and supplies shall be in good working order, checked and calibrated for the proper performance of tests and services offered in accordance with this rule and CLIA requirements. The laboratory must, at a minimum, follow the manufacturers' recommendations and instructions for equipment operation and document all such activities required for maintenance and operation of such equipment. This Statute or Rule is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to record the , for 2 out of 2 years (2015-2017) reviewed. Findings Included: Review of temperature charts revealed that the laboratory was not documenting the , . The cards used for testing require them to be stored 41-99 degrees Fahrenheit. During an interview on at 1:54 PM the office manager confirmed that the , was not being documented.	L2909		

Agency for Health Care Administration

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L3125	Continued From page 1	L3125		
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 Lab Manager, the Technical Consultant failed to perform competency evaluations on 2 out of 4 (#C and #D) Testing Personnel since 2013. This is a repeat deficiency from the relicensure survey. Findings Included: Review of competency evaluations revealed no competency evaluations for Testing Personnel #C and #D. During an interview on . . . at 2:25 PM the Lab Manager confirmed that competency evaluations had not been completed by the Technical Consultant on Testing Personnel #C and #D. Review of the AHCA Form 3020 signed and dated by the Laboratory Director (who is also the Technical Consultant) on . . . . from the relicensure survey conducted on found that the laboratory was cited for no competency evaluations on the same two Testing Personnel that did not have any competency evaluations during the current survey. The Plan of Correction stated that "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	L3125		

Agency for Health Care Administration

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L3125	Continued From page 2 Quality/designee will audit this quarterly. This will be monitored during the CQRM quarterly meeting to ensure compliance."	L3125		