Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0896115	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Planned Parenthood Of Southwest & Central Florida	**Street Address, City, State** 6418 Commerce Park Dr, Fort Myers, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Planned Parenthood of Southwest and Central Florida on 12/17/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Planned Parenthood of Southwest and Central Florida laboratory locations under CLIA certificate 10D0896115 were surveyed: 736 Central Avenue Sarasota, FL 34236 8068 N. 56th Street Tampa, FL 33617 8595 College Pkwy Suite B4 Fort Myers, FL 33919 The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 American Proficiency Institute (API) proficiency testing records and interview with the Health Center Manager, the laboratory failed to have a Testing Personnel that routinely tested patients to participate in 2 (2019 1st and 2nd Testing Events) out of 5 (2018 1st, 2nd, and 3rd, and 2019 1st and 2nd Events) Immunology /Immunohematology Proficiency testing for RH Testing. Findings included: Record review of API proficiency testing record review for 2018 - 1st, 2nd, 3rd Events, and 2019 - 1st, and 2nd Events revealed the Health Center Manager, who did not routinely test patients, had participated in the 2019 1st and 2nd Immunology /Immunohematology proficiency testing events. Interview on 12/17/2019 at 10:45 AM with the Health Center Manager confirmed that she performed the 2019 1st Event and 2nd Event and did not perform testing on patients. Interview on 12/17/2019 at 4:00 PM with the Laboratory Director revealed that the Health Center Manager had been trained for RH testing, but the training documentation could not be found.

D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review and interview with the Health Center Manager, the laboratory failed to ensure proficiency testing samples were run the the same number of times as routine test patient samples for one event (2019 1st event) out of 5 events reviewed (2018 1st, 2nd, and 3rd Events and 2019 1st and 2nd Event) for the specialty of Immunology/Immunohematology which included RH blood cell typing. Findings included: Review of the laboratory's proficiency testing with API for the 2019 1st Event revealed 2 Testing Personnel, the Health Center Manager and Testing Personnel B, had signed the 2019 1st Event attestation statement. Interview on 12/17/19 at 10:45 AM with the Health Center Manager revealed that she had tested the proficiency testing samples and when she went to document the results, she saw Testing Personnel B's name on the paperwork. She then told Testing Personnel B to perform the proficiency testing, and they both signed the attestation form.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review, record review of the CMS 209, and interview with the Quality Assurance Director and Laboratory Director, the Laboratory Director failed to ensure an assigned delegate was performing the duty of attesting proficiency testing samples and performing the review of proficiency testing events for 3 (2018 3rd Event and 2019 1st and 2nd Event) events out of 5 (2018 1st, 2nd, and 3rd and 2019 1st and 2nd) events reviewed for Immunology/Immunohematology proficiency testing for RH blood cell typing. Findings Included: Review of the CMS-209 Form, Laboratory Personnel Report, signed and dated on 12/16/2019 by the Laboratory Director and record review of API Immunology/Immunohematology proficiency testing records for 2018 1st, 2nd, and 3rd Events and 2019 1st and 2nd Events revealed the Laboratory Director signatures did not reconcile on the 2018 3rd Event, and 2019 1st and 2nd Event Proficiency testing Attestation Statements and the Performance Review and Corrective Action forms. Interview on 12/17/19 at 12:00 PM with the Quality Assurance Director revealed the person who signed the 2018 3rd Event, and 2019 1st and 2nd Event API proficiency Attestation Statements, Performance Review, and Corrective Action

	forms was a Laboratory Director at another Clinical Laboratory Improvement Amendment (CLIA) location that belonged to the same company. Interview on 12/17 /19 at 4:00 PM with the Laboratory Director revealed that she was unaware that the other Laboratory Director had been signing these forms and had not delegated this duty to him. She stated she had told staff even though she was out on leave she would still sign for proficiency testing.