Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0268310	06/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of South East And North Florida	5978 Powers Ave, Jacksonville, 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 recertification survey was conducted on 6/1/2020 at Planned Parenthood of South East and North Florida, a clinical laboratory in Jacksonville, Florida. Planned Parenthood of South East and North Florida was NOT in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of employee competency records and interview with the Office Manager, the laboratory failed to perform competency evaluations on 1 of 8 Testing Personnel (#F) for two of two years reviewed (2018-2019). Findings Included: Review of employee competency records found no competency evaluations performed on Testing Person #F who performs ABO/RH testing. Interview with the Office Manager on 6/1/2020 confirmed that there was no documented competency evaluations for Testing Person #F. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document acceptable quality control for one day in May 2020. Findings include: The review of the quality control spreadsheet showed on 5/28/20, the positive RH control was documented as negative. The interview with testing person A on 6/1/20 at 9:54am confirmed that although two people verify the quality control entry, it was documented incorrectly.