Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0268310	05/17/2018
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) attestation sheets and interview with the Director of Quality Improvement for Health Services, the Laboratory Director failed to sign the attestation sheets for six out of ten testing events reviewed for 2016-2018. Findings Included: Review of the attestation sheet for the 1st, 2nd, and 3rd Hematology/Coagulation testing event in 2017, the Immunology 3rd testing event in 2017, and the 1st event of 2018 for Hematology/Coagulation and Immunology showed that the Laboratory Director did not sign the attestation sheet that affirms to the fact that proficiency samples were treated in the same manner as patient specimens. During an interview on 5/17/18 at 11:13 AM, the Director of Quality Improvement for Health Services confirmed that the Laboratory Director failed to sign the attestation statements and stated she was never told it needed to be done.
D2154	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the facility failed to achieve a score of 100 percent for one of six American Proficiency Institute (API) proficiency testing events reviewed from 2016-2018. The findings include: The record review of the API proficiency testing scores for the first event in 2018 showed a score of 60% for D (RHo) typing. The interview with the facility administrator on 5/17/18 at 11:13am confirmed the score of 60%.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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 facility failed to ensure the Eldon Cards used for patient testing were not expired for 4 days reviewed in 2017. The record review of the Eldon Card Rh control excel spread sheet for 2017 showed on 10 /6/17 and 10/20/17 for Eldon Card package with lot number 17131 expired on 4/6/17 and 3/8/17. The Eldon Cards documented on 10/27/17 and 11/3/17 with lot number 17131 expired 4/6/17. The 10:58am interview with the clinic manager on 5/17/18 confirmed the Eldon Card information was documented as expired and determined it was due to a typing error.
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 facility failed to ensure quality control was documented and in range before reporting patient results for two days in January 2018, two days in February 2018, one day in March 2018, one day in April 2018, and one day in March 2018. The findings include: The record review of the Eldon Card Rh control excel spreadsheet for 2018 showed on 1/19/18, 1/26/18, 2/2/18, 3/2/18, and 5/4/18 the positive and negative QC was not performed for each pack of Eldon Cards. The interview with testing person #1 on 5/17/18 at 10:44am confirmed that QC is performed for each packed of Eldon Cards which are labeled A and B. She confirmed the duplicate QC was missing on those dates. The record review of the Eldon Card Rh control excel spreadsheet for 2018 showed on 2/2/18 the positive control "AMR" was reported as negative. The 10:32am interview on 5/17/18 with testing person #1 confirmed the control labeled "AMR" was the positive control and had been documented as negative. The record review of the Eldon Card Rh control spreadsheet for 2018 showed on 2/16/18 the negative control "BRH1446850" is reported as positive and the positive control "EP" is reported as negative. The 10:44am interview with testing person #1 confirmed the QC had been documented incorrectly. The record review of the Eldon Card Rh control spreadsheet for 2018 showed on 4/16/18 no QC was documented. The 10:44am interview with testing person #1 confirmed no QC was documented on that date.