Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0698418	12/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Southeast, Inc Birmingham	1019 1st Avenue N, Birmingham, AL	

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
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 a review of API (American Proficiency Institute) proficiency testing (PT) records, a review of the Laboratory Procedure Manual, and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who routinely performed patient testing. This was noted on seven out of seven Immunology/Immunohematology surveys reviewed for 2019 (2nd and 3rd Event), 2020 (all three events), and 2021 (2nd and 3rd Event). The findings include: 1. A review of API attestation statements revealed Testing Personnel #2 had performed all the testing on eight out of eight Immunology/Immunohematology surveys reviewed. The CMS - 209 Laboratory Personnel Report (CLIA) and personnel records revealed Testing Personnel #3 has been performing patient testing since April 2020 and Testing Personnel #4 has been performing testing since May 2021. 2. A review of Laboratory Procedure Manual revealed on page 18 "All staff that performs testing must be included in proficiency testing on a rotating basis." 3. During an interview on 12/07/2021 at 10:45 AM, Testing Personnel #2 confirmed the proficiency testing had not been rotated among other Testing Personnel for the eight Immunology/Immunohematology surveys reviewed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Rh D (rhesus factor D) type: Eldon Cards quality control, a review of the Laboratory Procedure Manual, and an interview with Testing Personnel #2, the laboratory failed to run quality control at least once a day, each day patient specimens are performed. This was noted for two days, when patient testing starting February 2020 to November 2021. The findings include: 1. A review of the quality control for Rh D type revealed the following: a) 02/19/2020 a positive and negative control were not documented and 1 patient was performed. b) 01/27/2021 a positive and negative control were not documented and 2 patients were performed. 2. A review of the Laboratory Procedure Manual revealed on page 65 "Quality Control: Eldon Cards - Each day of use the Eldon Cards are tested for specificity and sensitivity by performing control testing with known positive and negative red cells..." 3. During an interview on 12/07/2021 at 11:52 AM, Testing Personnel #2 confirmed quality control from the days listed above were not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a patient test report and an interview with Testing Personnel #2, the laboratory failed to include the address of the laboratory location where the test was performed. This was noted on one of one patient test report for Rh D (rhesus factor D) type, reviewed by the surveyor. The findings include: 1. A review of a patient test report revealed the address of the laboratory location where the test was performed was not on the Rh D type patient test report performed on 10/27/2021. 2. During an interview on 12/07/2021 at 12:00 PM, Testing Personnel #2 confirmed that the address was not on the patient test report.