Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2263531	05/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Partners In Abortion Care Llc	7305 Baltimore Ave Suite 107, College Park, MD	

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 review of the proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that the PT samples were routinely performed with the laboratory's regular patient workload. Findings: 1. The immunohematology PT records for the first event of 2023 were reviewed. 2. Review of the patient worksheets from October 2022 through May 2023 showed that the PT samples were not documented on the patient worksheets in the same manner as the patients. The original test results were not documented and maintained in the same manner as the patients. 3. During the survey on 05/17/2023 at 11:00 AM, the LD confirmed that the PT samples were not being routinely performed and recorded along with the laboratory's regular patient workload.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that the attestation worksheet was printed and signed by the appropriate laboratory personnel. Findings: 1. Review of the immunohematology PT records for the first event of 2023 showed that the attestation worksheet was not available. 2. During the survey on 05/17/2023 at 11:00 AM, the LD confirmed that the attestation worksheet had not been printed and signed by the appropriate laboratory personnel.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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 review of laboratory temperature logs, manufacturer's instructions for use (IFU), and interview with the testing personnel (TP), the laboratory did not monitor and document conditions essential for accurate and reliable test system operation. Findings: 1. Laboratory temperature logs reviewed for October 2022 through May 2023 did not include humidity readings. 2. The quality control section of the "Doctor's Kit DKS RhD" IFU states: "The function of the cards may be destroyed by humidity." Since the manufacturer does not define the humidity requirements, the laboratory must define acceptable criteria for humidity. 3. During the survey on 05/17/2023 at 11: 00 AM, the TP confirmed that the laboratory was not monitoring humidity in the laboratory where the testing was being performed.
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 review of the patient worksheets for the the "Doctor's Kit DKS RhD" testing and interview with the testing person (TP), the laboratory failed to ensure that reagent cards used for patient testing were not used after their expiration date. Findings: 1. The patient worksheets from October 2022 through May 2023 were reviewed and did not include the expiration dates and lot numbers of the "Doctor's Kit DKS RhD" reagent cards used for patient testing. 2. During the survey on 05/17/23 at 11:00 AM, the TP confirmed that the patient worksheets and the other record systems available

	did not include the expiration dates and lot numbers of the "Doctor's Kit DKS RhD" reagent cards used for performing patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the information for use (IFU) procedures for "Doctor's Kit DKS RhD" test and interview with the testing person (TP), the laboratory failed to perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section and establish an Individualized Quality Control Plan (IQCP) for rhesus factor D (RhD) antigen testing. Findings: 1. The QC section on the IFU states: "Upon receipt of a shipment of EldonCards, check for possible damage during transportation and ensure the quality of the cards by testing with red cells with and without the RhD antigen." 2. The laboratory's records failed to include documentation of testing two levels of QC materials each day of testing. 3. The laboratory is required to test two levels of QC materials each day of testing unless they have written an IQCP. An IQCP plan requires the laboratory to perform a risk assessment that included an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to the RhD antigen testing. 4. During the survey on 05/17/23 at 11:00 AM, the TP confirmed that the laboratory did not have an establish IQCP for reducing the performance of the RhD QC from daily to each week of patient testing.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the policy and procedures manual and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established quality control (QC) procedures included an Individualized Quality Control Plan (IQCP) and that the quality assurance (QA) procedures to monitor the overall operation of the laboratory were maintained. Findings: 1. The procedure manuals that were reviewed

	did not include a defined IQCP to reduce the frequency of testing QC materials to a weekly basis. Cross refer to Tag D5445 for details. 2. The QA policy requires the completion of a monthly worksheet that includes review of daily QC results; prompt patient reports; completion of pertinent information in patient records; highlighted results outside parameters in standing orders and marked in read; errors are properly marked through with a single line and technicians initials; and lab results are transferred to the electronic medical record and 10 reports are reviewed monthly. 3. During the survey on 05/17/23 at 11:00 AM, the TP confirmed that the laboratory did not have an establish IQCP for performing RhD QC on a weekly basis and the monthly QA worksheets were not currently in use.