Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2263531	08/16/2024
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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on quality assurance (QA) record review and interview with the laboratory director (LD), the laboratory failed to retain all laboratory quality system assessment records for at least two years. Findings: 1. A review of monthly QA review records from May 2023 through July 2024 showed that two of 15 monthly review documents were missing (November and December of 2023). 2. During an interview on 08/16 /2024 at 3:00 PM, the LD confirmed that the laboratory did not maintain QA records for at least 2 years.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory director (LD), the laboratory did not ensure that the SOPM was approved the LD. Findings: 1. A review of the current SOPM showed that the procedures were not approved (signed and dated) by the LD. 2. During an interview on 08/16/2024 at 3: 00 PM the LD confirmed that the current SOPM was not approved.
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 observation, procedure manual and quality control (QC) record review, and interview with the testing person (TP) and the laboratory director (LD), the laboratory failed to ensure that immunohematology QC materials were not used after they had exceeded their expiration date. Findings: 1. The laboratory tests patients to determine if their red blood cells are positive or negative for the Rhesus (Rh) Factor antigen. 2. The laboratory uses whole blood samples from previously verified Rh-positive and Rh-negative people as their positive and negative QC. 3. The procedure, "Laboratory Procedures and Practices," "Control Testing" states, "Control samples must be discarded within 28 days of opening (commercial samples) or within 28 days of collection." During a tour of the laboratory on 08/16/2024 at 2:20 PM, it was observed that the vials of in-use positive and negative Rh QC were labeled with a sticker that instructed TP to "Discard by (30 days)." 4. During an interview at 2:20 PM, TP #5 stated that the expiration dates documented on the QC vials and on the QC logs adhered to the 30 day expiration date, not 28 days as written in the procedure manual. 5. A review of QC logs from 05/07/2024 to 08/15/2024 showed that on 06/07/2024, the Rh-positive control (#2021842-001) and the Rh-negative control (#202184843-001) were documented as expiring on 06/07/2024 (30 days from the date of collection). The true expiration date of the QC samples (28 days from the date of collection) was 06/05/2024, meaning that the QC was expired. Three patients were tested on 06/07/2024; and 6. On 07/10/2024 the Rh-positive control (#202188058-001) and the Rh-negative control (#202188059-001) were documented as expiring on 07/11/2024 (30 days from the date of collection). The true expiration date of the QC samples (28 days from the date of collection) was 07/09/2024, meaning that the QC was expired. Four patients were tested on 07/10/2024. 7. During an interview on 08/16/2024 at 3:00 PM, the LD confirmed that QC materials were tested after they had exceeded the expiration date set by the laboratory.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on procedure manual and patient and temperature log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when room temperatures were out of acceptable range. Findings: 1. The procedure, "Laboratory Procedures and Practices," "Rh-typing" states that the testing person should "allow reagents to reach room temperature (20-24C) before use." The laboratory's acceptable room temperature range converts to 68 - 75.2 degrees Fahrenheit. 2. Temperature log record review showed that the testing personnel record the laboratory's room temperature on the daily patient log in Fahrenheit, however the patient log does not list the acceptable room temperature

	range in Celsius or Fahrenheit. 3. A review of patient/temperature logs from 01/02 /2024 to 02/06/2024 showed that the laboratory's room temperature was out of range four out of 16 days of patient testing. No corrective action was documented for the out of range temperatures. 4. During an interview on 08/16/2024 at 3:00 PM, the LD confirmed that the laboratory did not document corrective action when room temperatures were out of the established acceptable range.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the LD acting as the technical consultant failed to perform and document the competency reviews on all testing personnel (TP). Findings: 1. The laboratory currently has five TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). 2. A review of training and competency testing records from 2023 and 2024 showed that there was no documentation of initial training for one of five TP. 3. Three of four TP had no documentation that their six month or annual competency assessments had been performed. One TP had been performing testing for less than six months and was not eligible for their six month competency assessment. 4. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observations of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 5. During the survey on 08/16/2024 at 3:00 PM the LD confirmed that there were no documented evaluations of the TP for 2023 and 2024.