Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2120030	01/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Great Plains	619 Nw 23rd St, Oklahoma City, OK	

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	The recertification survey was performed on 01/24/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the center manager and director of abortion and surgical services at the conclusion of the survey.
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 a review of records and interview with the center manager, the testing person (s) failed to sign proficiency testing attestation statements for two of seven events. Findings include: (1) The surveyor reviewed 2019 (third event), 2020 (first, second, and third events), and 2021 (first, second, and third events) proficiency testing records and identified the following for two of seven events: (a) Third 2019 Immunohematology Event - The attestation statement had not been signed by the person performing the test; (b) First 2021 Immunohematology Event - The attestation statement had not been signed by the person performing the test. (2) The surveyor

	reviewed the findings with the center manager who stated on 01/24/2022 at 10:10 am, the attestation statements had not been signed by the person(s) performing the test as shown above.
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 a review of records, written policy, and interview with the center manager, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 01/24 /2022, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant, including the frequency for the assessments; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019, 2020, 2021, and to date in 2022. There was no evidence of competencies performed for the technical consultant based on job responsibilities; (3) The surveyor asked the center manager if a written policy to evaluate the technical consultant based on job responsibilities was available and if competencies had been performed. The center manager stated on 01/24/2022 at 11:05 am, a policy had not been written and the above competencies had not been performed. NOTE: D5209 was cited on the previous recertification survey performed on 09/26/2019.
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 a review of the procedure manual and interview with the center manager, the laboratory failed to ensure written policies and procedures had been approved, signed, and dated by the laboratory director. Findings include: (1) On 01/24/2022 at 09:35, the center manager stated to the surveyor the following testing was performed in the laboratory: (a) Wet Prep Analysis as a PPM (Provider Performed Microscopy) procedure (b) Rh testing using Eldon Cards (2) The survey reviewed the manual titled, "Lab Manual", which contained written policies and procedures. There was no indication the manual had been approved, signed, and dated by the laboratory director; (3) The surveyor showed the manual to the center manager who stated on 01/24/2022 at 12:15 pm, the manual contained the policies and procedures and had not been signed and dated by the laboratory director.
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 a review of records and interview with the center manager, the laboratory failed to ensure reagents had not exceeded their expiration date for one of 13 months reviewed. Findings include: (1) On 01/24/2022 at 09:35, the center manager stated the following to the surveyor: (a) The laboratory performed Rh testing using Eldon Cards; (b) QC (Quality Control) testing was performed each day of patient testing using Panoscreen Reagent Red Blood Cells (level I was used as the positive control and level III was used as the negative control). (2) The surveyor reviewed QC and patient testing records from 01/04/2021 through 01/21/2022 and identified expired QC material had been used during one of the 13 months reviewed: (a) Panoscreen Reagent Red Blood Cells level I and level III, lot #31491 had an expiration date of 10/08/2021; (b) The QC had been used to determine acceptability of patient testing on 10/11,12 /2021. (3) The surveyor reviewed the records with the center manager who stated on 01/24/2022 at 12:20 pm the documentation on the logs showed that expired QC had been used as stated above.