Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2120030	02/07/2018
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 findings were reviewed with the medical director, regional director of health services and testing person #1 at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, observation and interview with the regional director of health services and testing person #1, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: REFRIGERATOR TEMPERATURES (1) At the beginning of the survey, the regional director of health services and testing person #1 stated to the surveyors the following tests were performed: (a) Urine pregnancy testing using the Stanbio Labs cassettes (b) Hemoglobin testing using the Stanbio Hemocue Hb 201 analyzer (c) Urinalysis testing using the Urispec Plus analyzer (2) The surveyors observed the contents of the laboratory refrigerator. The following control materials were being stored in the refrigerator, with a manufacturer's storage requirement of 36-46 degrees F (Fahrenheit): (a) One box of Stanbio Hemoglobin Bi-Level Controls (lot# 171151) (b) One box of Standio hCG Bi-Level (positive and negative) Urine Controls (lot# 171571) (3) The surveyors requested temperature records from November 2016 through the day of the survey. The surveyors reviewed the records and identified that either daily monitoring of the refrigerator was not performed, or the documented temperatures were not within the manufacturer's required storage of 36-46 degrees F as follows: (a) December 2016 - temperatures not documented on days 14,15,16,19,20,21,22,23,27,28,30 (b) May 2017 - temperatures not documented on days 26,30; 6 of the 17 temperatures were documented as 34 degrees F (c) June 2017 -

	1 of 22 temperatures was documented at 50 degrees F (d) August 2017 - 3 of 22 temperatures were documented as 34 degrees F (e) November 2017 - 2 of 19 temperatures were documented as 34 degrees F; 3 of 19 temperatures were documented as 35 degrees F (f) December 2017 - 6 of 21 temperatures were documented as 35 degrees F (g) January 2018 - 3 of 21 temperatures were documented as 34 degrees F; 1 of 21 temperatures was documented as 35 degrees F; 2 of 21 temperatures was documented at 33 degrees F (4) The surveyors reviewed the findings with the regional director of health services and testing person #1. Both stated the refrigerator temperatures were not being monitored as indicated above and materials were not being stored at temperatures required by the manufacturer. ROOM TEMPERATURE (1) At the beginning of the survey, the regional director of health services and testing person #1 stated to the surveyors the following tests were performed and stored at room temperaturewith a manufacturer's storage requirement of 59 - 86 degrees F (Fahrenheit):: (a) Urine pregnancy testing using the Stanbio Labs cassettes (b) Hemoglobin testing using the Stanbio Hemocue Hb 201 analyzer (2) The surveyors requested temperature records from November 2016 through the day of the survey. The surveyors reviewed the records and identified daily monitoring of the room temperature was not documented as performed: (a) Between 11/18/2016 through 11/01/2017 (b) Between 11/05/17 through 12/01/2017 (3) The surveyors reviewed the findings with the regional director of health services and testing person #1. Both stated the room temperatures were not being monitored as indicated above.
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 regional director of health services and testing person #1, the laboratory failed to maintain copies of proficiency testing records. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified for 4 of 4 testing events: (a) Third 2016 Immunohematology Event (i) A copy of the proficiency testing report forms could not be located. (b) First 2017 Immunohematology Event (i) The attestation statement could not be located; (ii) A copy of the proficiency testing report forms could not be located. (c) Second 2017 Immunohematology Event (i) A copy of the proficiency testing report forms could not be located. (d) Second 2017 Immunohematology Event (i) A copy of the proficiency testing report forms could not be located. (e) Third 2017 Immunohematology Event (i) A copy of the proficiency testing report forms could not be located. (2) The findings were reviewed with the regional director of health services and testing person #1 who stated an attestation and copies of the proficiency testing reports could not be located.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the regional director of health services and testing person #1, the laboratory failed to verify the accuracy of Wet Prep testing at least twice annually. Findings include: (1) At the beginning of the survey, the regional director of health services and testing person #1 stated Wet Prep testing was performed as a PPM (Provider Performed Microscopy)Procedure; (2) Surveyor#2 reviewed 2016 and 2017 records. There were no records to indicate the accuracy of the testing had been verified before or after 07/17/17 (the accuracy of wet prep testing had been verified once during the review period); (3) The records were reviewed with the director of health services and testing person #1 who stated the accuracy of wet prep testing had not been verified twice annually.
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 written policies and procedures and interview with the regional director of health services and testing person #1, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the current laboratory director. Findings include: (1) At the beginning of the survey, the regional director of health services and testing person #1 stated to the surveyors the following testing were performed: (a) Rh typing using the Eldon Cards (b) Wet Prep analysis as a PPM (Provider Performed Microscopy) Procedure (2) Surveyor #2 reviewed the procedure manual for the above testing. It had not been approved, signed, and dated by the current laboratory director; (3) The surveyors reviewed the procedure manual with the regional director of health services and testing person #1, who stated it had not been approved, signed, and dated by the current laboratory director.
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 a review of records, observation and interview with the regional director of

	health services and testing person #1, the laboratory failed to ensure laboratory tests and testing materials were being stored as required. Findings include: REFRIGERATOR TEMPERATURES (1) At the beginning of the survey, the regional director of health services and testing person #1 stated to the surveyors Rh typing was performed using the Eldon Cards; (2) The surveyors observed the contents of the laboratory refrigerator. The following control materials were being stored in the refrigerator, with a manufacturer's storage requirement of 36-46 degrees F (Fahrenheit): (a) Two boxes (3 bottles) of Immunocor Panoscreen I, II, III Red Blood Cells (lot# 01084) (3) The surveyors requested temperature records from November 2016 through the day of the survey. The surveyors reviewed the records and identified that either daily monitoring of the refrigerator was not performed, or the documented temperatures were not within the manufacturer's required storage of 36-46 degrees F as follows: (a) December 2016 - temperatures not documented on days 14,15,16,19,20,21,22,23,27,28,30 (b) May 2017 - temperatures not documented on days 26,30; 6 of the 17 temperatures were documented as 34 degrees F (c) June 2017 - 1 of 22 temperatures was documented at 50 degrees F (d) August 2017 - 3 of 22 temperatures were documented as 34 degrees F (e) November 2017 - 2 of 19 temperatures were documented as 34 degrees F; 3 of 19 temperatures were documented as 35 degrees F (f) December 2017 - 6 of 21 temperatures were documented as 35 degrees F (g) January 2018 - 3 of 21 temperatures were documented as 34 degrees F; 1 of 21 temperatures was documented as 35 degrees F; 2 of 21 temperatures was documented at 33 degrees F (4) The surveyors reviewed the findings with the regional director of health services and testing person #1. Both stated the refrigerator temperatures were not being monitored as indicated above and materials were not being stored at temperatures required by the manufacturer. ROOM TEMPERATURE (1) During the survey, the surveyors observed the following stored at room temperature: (a) Eldon Cards - used for Rh typing (storage requirement 41 - 98.6 degrees F) (b) Blood Collection tubes used for collecting reference (send out) specimens: (i) Vacutte 4 ml K2EDTA tubes (50 tubes of lot# B17053MQ with a storage requirement of 39.2 - 77 degrees F) (ii) Vacutte 9 ml Z Serum Clot Activator tubes (79 tubes of lot# B17013CD with a storage requirement of 39.2 - 77 degrees F) (iii) Vacutte 7 ml Z Serum Clot Activator tubes (100 tubes of lot# B1711374 with a storage requirement of 39.2 - 77 degrees F) (2) The surveyors requested temperature records from November 2016 through the day of the survey. The surveyors reviewed the records and identified daily monitoring of the room temperature was not documented as performed: (a) Between 11/18/2016 through 11/01/2017 (b) Between 11/05/17 through 12/01/2017 (3) The surveyors reviewed the findings with the regional director of health services and testing person #1. Both stated the room temperatures were not being monitored as indicated above.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the regional director of health services and testings person #1, the technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, surveyor #2

	reviewed personnel records. The following was identified: (a) Testing Person #1 - The initial training was completed on 12/02/16. There was no evidence that a semiannual evaluation had been performed (due 06/17); (b) Testing Person #2 - The initial training was completed on 09/04/16. There was no evidence that a semiannual evaluation had been performed (due 3/17). (2) The surveyors reviewed the records with the regional director of health services and testing person#1, who stated there were no records to prove the above persons had been evaluated semiannually.