Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2171146	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Arkansas And Eastern Oklahom	1501 Aldersgate Rd, Little Rock, AR	

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
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: . Through a review of the CMS 116 form, proficiency test records for 2020, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to verify the accuracy of KOH and WET Prep examinations at least twice annually. Survey Findings follow: A. A review of the CMS-116 application revealed the laboratory performed an annual volume of 340 KOH and WET Prep examinations. B. A review of Proficiency testing records for 2020 revealed the laboratory had no documentation of verifying the accuracy of KOH and WET prep examinations. C. Upon request, the laboratory could not produce documentation that the accuracy of the KOH and WET Prep examinations were verified at least twice annually. D. In an interview at 11:00 on 09/10/2020, the clinic manager confirmed the laboratory failed to verify the accuracy of KOH and WET Prep examinations at least twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	. Through a review of CMS-116, lack of documentation and interview with staff, it was determined the laboratory failed to have written test procedure for Rh Group D test, KOH and Wet Prep examinations. Survey Findings Follow: A. A review of CMS-116 application form revealed the laboratory performs an annual volume of 340 KOH and Wet Prep examinations and 1400 Rh Group D tests. B. The surveyor requested written policy and procedure for KOH and Wet Prep examinations and Rh Group D test. None was provided. C. In an interview on 09/10/2020 at 10:15, the clinic manager confirmed the laboratory did not have written policies or procedures for KOH and Wet Prep examinations or RH Group D test.
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: . Through a review of the laboratory temperature records for room temperature observations, lack of documentation and interviews with staff, it was determined the laboratory failed to define, monitor or document acceptable criteria for room temperatures. Survey Findings Follow: A. A review of temperature records for 2019 (2 of 12 months) and 2020 (9 of 9 months) revealed the laboratory did not establish an acceptable range for room temperatures. B. In an interview on 9/10/2020 at 9:30 am, the clinic manager stated that there is no acceptable range established for room temperatures. C. During a tour of the Laboratory on 9/10/2020 at 10:30, the surveyor observed the following laboratory supplies stored at room temperature: Thirty BD Tiger Red top tubes (lot #367988 expiration 10/31/2021) storage requirements 4-25 degrees Celsius: one package of 10 ml Red top tubes (lot #367820 expiration date 10 /31/2021) storage requirements 4-25 degrees Celsius: two boxes of N-MultiStix 10SG urine dipsticks (lot #904062 expiration date 10/31/2020) storage requirements 15-30 degrees Celsius: one box of BD Purple top vacutainer tubes (lot #9184931 expiration date 11/30/2020) storage requirements 4-25 degrees Celsius: one box of True HCG (Human Chorionic Gonadotropin) urine pregnanacy test kit storage requirements 15-30 degrees Celsius: one box of Chembio Sure-Check HIV 1/2 test kit storage requirements 8-30 degrees Celsius and four boxes of Eldoncard Rh-D cards (lot #20021 expiration date 1/28/2020) storage requirements 5-37 degrees Celsius. D. During a tour of the laboratory store room on 9/10/2020 at 10:45, the surveyor observed the following laboratory supplies stored at room temperature: one package of BD Vacutainer Purple Top tubes (lot #0072510 expiration date 7/31/2020) storage requirements 4-25 degrees Celsius: two packages of BD 10ML Tiger Top tubes (lot #0034525 expiration date 10/31/2021) storage requirements 4-25 degrees Celsius: one package of BD 10ML Red Top tubes (lot #9291629 expiration date 10/31/2021) storage requirements 4-25 degrees Celsius; 10 BBL Cultural Swabs (lot #001B19 expiration date 12/31/2020) storage requirements 5-25 degrees Celsius and 25 Thin Preps (lot #0098AA) storage requirements 15-30 degrees Celsius. E. The surveyor requested temperature documentation for the rooms where laboratory supplies were stored. None was provided. F. In an interview on 09/10/2020 at 10:50, the clinic

	manager stated the laboratory does not monitor temperatures of the laboratory storage and phlebotomy rooms where the supplies are stored.
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: . Through observations made during a tour of the laboratory, it was determined the laboratory had Becton-Dickinson (BD) vacutainer Coagulation Sodium Citrate (blue tubes) 3.2% blood collection tubes and transport cultural swabs available for use when they had exceeded their expiration date. Survey Findings follow: A. During a tour of the laboratory on 9/10/2020 at 10:30, the surveyor observed one package of BD Blue top vacutainer tubes (lot #9315357 expiration date 8/31/2020) and 10 Venturi Transystem transport swabs (lot #101GIt expiration date 4/30/2020) on the shelf in laboratory storage room available for use. B. In an interview at 10:30 on 9/10/2020, the clinic manager confirmed the expiration date and the vacutainer tubes and transport cultural swabs were available for use after they had exceeded their expiration date.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of CMS form 209, personnel records for five of five testing personnel, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual was authorized to perform and whether supervision was required. Survey findings follow: A. A review of CMS form 209 revealed the names of five laboratory testing personnel performing moderate complexity testing. B. A review of personnel records, revealed there were no signed authorizations to perform moderate complexity testing for five of five testing personnel listed on the form CMS-209. C. Upon request, the laboratory could not provide signed authorizations for testing personnel listed on CMS form 209 to perform moderate complexity testing. D. In an interview at 11:00 a. m. on 9/09/2020, the clinic manager confirmed there was no written authorization from the laboratory director stating which tests the testing personnel (number 1 thru number 5) on the CMS form 209 are authorized to perform.

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: . Through review of the CMS form 209, personnel records, lack of documentation, and interview, it was determined that the technical consultant failed to document personnel competency on an annual basis for five of five personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records revealed no competency evaluations for 2019 and 2020 were performed for moderate complexity testing personnel identified as number 1 thru number 5 on the CMS form 209. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 09/010/2020 at 10:30 a.m., the clinical manager confirmed that competency evaluations had not been performed on the personnel identified above.