Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2171146	09/22/2022
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, laboratory procedure manual, Plan of Correction from 2020 CLIA Survey, proficiency test records for 2021-2022, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to verify the accuracy of 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 547 WET Prep examinations. B. A review of the laboratory procedure manual revealed the policy for Provider Performed Microscopy"Vaginal Wet Mount microscopy accuracy will be assed semi-annually." C. A review of the Plan of Correction from the CLIA survey dated 9/10/20 revealed the action for Citation D5417: "Create a proficiency binder for all proficiency testing for KOH and Wet preps. Lab Director will check and sign off on all proficiency testing regularly. Health center manager will check the binder regularly (monthly) to ensure testing is schedule at proper time." D. A review of Proficiency testing records for 2021-2022 revealed the laboratory had no documentation of verifying the accuracy of WET prep examinations. E. Upon request, the laboratory could not produce documentation that the accuracy of the WET Prep examinations was verified at least twice annually. F. In an interview at 13:00 on September 22, 2022 , the clinic manager and laboratory employee #6 (as listed on CMS form 209) confirmed the laboratory failed to verify the accuracy of WET Prep examinations at least twice annually. This is a repeated deficiency from CLIA Laboratory Survey dated 9/10/2020.
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 laboratory procedure manual, Plan of Correction for CLIA Laboratory survey 2020, lab QA(Quality Assurance) form for 2021-2022, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to document and monitor refrigerator and room temperatures. Survey findings follow: A. A review of laboratory procedure manual revealed the policy for documenting temperatures: "Daily lab QA activities (recording room temperature, refrigerator temperature, etc) are recorded on the monthly lab QA form." B. A review of the Plan of Correction for the CLIA Laboratory survey dated 9/10/2020 revealed the corrective action for Citation D5413:"A temp log will be placed in the storage location to record the temp 2X daily. The health center manager will assume oversight of this and check temperature logs weekly for accuracy." C. A review of the daily lab QA form for January-September 2021 (nine of nine months) revealed the laboratory failed to monitor and document room and refrigerator temperatures. D. The surveyor requested documentation of room and refrigerator temperatures for January-September 2021. None was provided. E. In an interview with clinic manager and employee #6 confirmed the laboratory failed to monitor and document room and refrigerator temperatures for nine of nine months in 2021. This is a repeated deficiency from CLIA Laboratory Survey dated 9/10/2020.
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: . Through a review of the laboratory procedure, temperature records for 2021 and 2022, lack of documentation, and interviews with staff, it was determined the laboratory failed to document corrective actions taken when room temperatures were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of the laboratory procedure manual revealed the policy for remedial actions:" Remedial actions for the monthly QA review are discussed directly with the individuals involved. If there is a quality fall-out (the fridge temp is too high) there must be a written plan to correct it." B. A review of temperature logs for 2021-2022 revealed the laboratory room temperature acceptable range was listed as 60 to 77 degrees Fahrenheit. C. A review of the temperature logs for one of twelve months revealed the room temperature was documented outside the acceptable criteria and no corrective actions were performed on two of twenty-three days in December 2021. D. A review of the temperature logs for six of six months (January-June 2022) revealed the room

	temperature was documented outside the acceptable criteria and no corrective actions were performed on four of eighteen days in February 2022: four of twenty-seven days in March 2022: five of twenty-six days in April 2022 and eight of twenty-four days in May 2022. E. In an interview at 10:30 on 9/22/22, clinic manager confirmed the temperatures listed above were outside of acceptable ranges and the laboratory had no documentation of corrective action
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Through a review of laboratory procedure manual, personnel records, proficiency testing documentation, temperature records, and the Laboratory problem log, it was determined the laboratory failed to correct problems identified in the analytic systems. Survey Findings Follow: A. A review of the laboratory procedure manual revealed the Quality Assurance Policy: "The quality assurance program(QAP) is designed to satisfy CLIA and OSHA regulations, which ensure accurate lab results and the safety of patients and testing personnel. The QAP program provides daily, weekly, monthly, quarterly and annual quality activities to monitor and evaluate the general, preanalytic, analytic, and post-analytic lab systems. The QAP assures the competency of testing personnel and identifies and corrects problems." B. The laboratory QAP failed to identify and correct problems identified in the analytic system as follows: D5217: Laboratory failed to verify the accuracy of WET Prep examinations at least twice annually. D5413: Laboratory failed to monitor and document room and refrigerator temperatures. D5785: Laboratory failed to document corrective actions taken when room temperatures were outside of the laboratory's acceptable criteria. C. A review of the laboratory procedure manual revealed: "Any quality problems will be documented on the Laboratory Problem Log/incident reporting system along with the plan to resolve the problem, prevent recurrence, and an evaluation of efficiency." D. A review of the Laboratory Problem Log revealed there was no documentation of the laboratory identifying problems in the analytic systems.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Through a review of proficiency testing records, personnel records, temperature records, competency assessment, and lack of documentation and the Plan of correction for the CLIA survey conducted 9/10/2020 , it was determined that the laboratory director failed to provide overall management and direction of the laboratory. Survey findings follow: D6021: laboratory director failed to ensure the quality assessment program established to assess the accuracy of Wet Prep testing at

	least twice annually, was maintained. D6030: Laboratory Director failed to ensure competency assessment for six of six testing personnel were maintained as cited at 6046. D6032: Laboratory director failed to ensure testing personnel were authorized to perform moderate complexity testing without direct supervision.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Through a review of the forms titled "Quality Assurance Policy Statement section Provider Performed Microscopy", lack of documentation, review of temperature logs, and interviews with staff, it was determined the laboratory director failed to ensure the quality assessment program established to assess the accuracy of Wet Prep testing at least twice annually was maintained. Survey findings follow: The laboratory director failed to ensure the Quality Assurance used to verify the accuracy of Wet Prep testing was completed for 2021-2022 as cited at D5217. The laboratory Director failed to ensure corrective actions were taken on days the room temperatures were out of laboratory range as cited at D5785.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . Through a review of personnel records for six of six testing personnel, lack of documentation, and interviews with staff, it was determined the laboratory director failes to ensure that testing personnel maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently. Survey Findings follow: D6046: Laboratory director failed to ensure that testing personnel (as listed on form CMS-209) competency assessments were performed by the Technical Consultant as cited at D6046.
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, Plan of Correction for 2020 CLIA Laboratory survey, personnel records for six of six testing personnel, lack of documentation, 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 six laboratory testing personnel performing moderate complexity testing. B. A review of the Plan of Correction from the CLIA Laboratory survey dated 9/10/2020 revealed the corrective action for Citation D6032 with date of completion 12/2020:" Rebuild the CLIA Binder with employee competencies up to date with signed authorizations for each test performed. The Lab director will sign the authorizations and ensure that it is completed for each employee performing tests." C. A review of personnel records revealed there were no signed authorizations to perform moderate complexity testing for six of six testing personnel listed on the form CMS-209. D. Upon request, the laboratory could not provide signed authorizations for testing personnel listed on CMS form 209 to perform moderate complexity testing. F. In an interview at 11:00 a.m. on 9/22/2022, the clinic manager confirmed there was no written authorization from the laboratory director stating which tests the testing personnel (number 3 thru number 8) on the CMS form 209 are authorized to perform. This is a repeated deficiency from the CLIA Laboratory Survey dated 9/10/2020.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Through interviews with staff, review of personnel records, it was determined competency assessments were not documented by the technical consultant listed on the CMS 209. Survey Findings include: D6046 - the technical consultant failed to document personnel competency on an annual basis for six of six personnel identified on the CMS form 209.
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 laboratory policy manual, CMS form 209, Plan of Correction for CLIA Laboratory survey 2020, personnel records, lack of documentation, and interview with staff, 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 laboratory policy manual revealed the policy for competency assessment:" Competency to perform testing is assessed using a six step approach. New employees must document training and competency prior to reporting patient test, at six months and yearly thereafter. All employees of the lab are required to be evaluated for competency annually." B. A review of personnel records revealed no competency evaluations for 2021 and 2022 were performed for moderate complexity testing personnel identified as number 3 thru number 8 on the CMS form 209. C. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. D. In an interview on 09 /22/2022 at 10:30 a.m., the clinical manager confirmed that competency evaluations had not been performed on the personnel identified above. This is a repeated deficiency from CLIA Laboratory Survey dated 9/10/2020.