

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0664512	<b>(X3) Date Survey Completed</b> 04/04/2022
<b>Name of Provider or Supplier</b> Planned Parenthood Great Plains	<b>Street Address, City, State</b> 1007 S Peoria Ave, Tulsa, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The initial survey was performed on 04/04/2022. The findings were reviewed with the director of abortion and surgical services and the assistant health center manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation of the laboratory, and interview with the assistant health center manager, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) On 04/04/2022 at 09:45 am an observation of the laboratory revealed the following expired material which appeared to be available for use: (a) One box (lot #207519) of Hydrion pH paper, with a manufacturer's expiration date of 03/15/2022. (2) The assistant health center manager explained the material was used to determine the pH in the vaginal testing process; (3) The findings were reviewed with the assistant health center manager, who stated on 04/04/2022 at 10:00 am the Hydrion pH paper had expired and was available for use.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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</p>

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the assistant health center manager the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of five events. Findings include: (1) On 04/04/2022, a review of 2020 and 2021 proficiency testing events revealed for one of five events, the attestation statements had been signed approximately four months after the samples had been tested, (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2020 Immunohematology Event - The sample testing had been completed on 12/08/2020, and the attestation statement had not been signed by the laboratory director /designee until 04/16/2021. (2) The findings were reviewed with the assistant health center manager who stated on 04/04/2022 at 10:42 am the attestation had been signed approximately four months after the proficiency samples had been tested.