

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0706555	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Reproductive Diagnostic Center	Street Address, City, State 5555 East 71st Street, Suite 6230, Tulsa, 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 12/19/18. The findings were reviewed with the laboratory director at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D1001	<p>CERTIFICATE OF WAIVER TESTS 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 laboratory director, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, the surveyors observed the laboratory and identified the following expired material which appeared to be available for use: (a) 1 box (lot #212213) of Hydrion Phenaphtazine paper, with a manufacturer's expiration date of 05/01/16; (2) Surveyor #2 asked the laboratory director to explain what the above material was used for. The laboratory director explained the material was used to determine the pH in the semen analysis testing process; (3) Surveyor #2 reviewed the findings with the laboratory director, who stated the Hydrion Phenaphtazine paper had expired and was available for use.</p>