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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D0474417 | (X3) Date Survey Completed 01/11/2018 |
| Name of Provider or Supplier Reproductive Services | Street Address, City, State 6136 E 32nd Place, 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 findings were reviewed with the clinic administrator at the conclusion of the survey. |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the clinic administrator, the laboratory failed to ensure materials were being stored as required. Findings include: (1) At the beginning of the survey, the clinic administrator stated the following to the surveyors: (a) Rh slide typing was performed using the Baxter Rh Viewbox; (b) Patient blood specimens were collected in Becton Dickinson Vacutainer K2 EDTA 10.8 mg tubes. (2) Later during the survey, surveyor #1 observed the laboratory and reviewed the manufacturer's instructions for the room temperature requirements, which were as follows: (a) The Baxter Rh Viewbox required an ambient operating temperature of 18-26 degrees Centigrade (C); (b) The Becton Dickinson EDTA Vacutainer tubes required storage at 4-25 degrees C (26 tubes, lot #6342985, were observed in the laboratory). (3) Surveyor #1 then reviewed temperature records for 7 months (January, October, November, and December 2017; and January, February, and March 2016) and identified the following for 1 of 7 months: (a) January 2017 - There was no documentation the room temperature had been monitored 17 of 17 days of patient testing (days</p> |

03,04,05,06,10,11,12,13,17,18,19,20,21,24,25,26,31). (4) The surveyors reviewed the findings with the clinic administrator who stated the room temperature had not been monitored as indicated above.