Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0290593	**(X3) Date Survey Completed** 01/21/2020
Name of Provider or Supplier Tampa Womens Health Center Inc	**Street Address, City, State** 2010 E Fletcher Ave, Tampa, FL	
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	An announced CLIA recertification survey was conducted at Tampa Women's Health Center on 01/21/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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: Based on record review and interview with Testing Personnel #B, the laboratory failed to document the temperature where reagents were stored for 2 of 2 (2018-2020) years reviewed. Findings Included: Review of the Quality Assurance procedure revealed that temperature check of refrigerators would be recorded. Review of the package insert for the "Directions for Use Blood Grouping Reagent Anti-D by Slide or Modified Tube Test" showed that the Anti-D reagent should be stored at 2 - 8 degrees Celsius. Review of maintenance and quality control logs revealed that the refrigerator temperature where the Anti - D reagent was stored had not been recorded for 2 out of 2 years (2018-2020). Interview on 01/21/20 at 12:40 PM with Testing Personnel # B revealed testing personnel were trained to check the refrigerator temperature, but confirmed that the refrigerator temperature was not being recorded.