Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0725975	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Women & Teens Healthcare Inc	**Street Address, City, State** 16876 Ne 19 Ave, North Miami Beach, 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
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with office manager, the laboratory failed 1 out of 3 events for ABO /RHO test during the year 2016. Findings include: Review of API proficiency records revealed that the laboratory failed the ABO/RHO second event of 2016 with a 0 % score due to late submit of results. During an interview on 9/11/2018 at 11:30 AM, the office manager confirmed that the laboratory failed to submit on time the event of reference.
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 the office manager, the laboratory failed to

	document the room temperature for 2 out of 2 years Findings include: Review of the Blood Grouping Reagent Anti D (Anti Rh) user manual indicated a requirement for room temperature range 15 to 30 C, there was no documentation of the room temperature for the period of 2017 to 2018. During an interview on 09/12/18 at 11:30 a.m., the office manager confirmed that there was no record of room temperature for the years of reference.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the officer manager, the laboratory failed to run positive and negative control for Anti D testing from 2017 to 2018. Findings include: Review of Blood Grouping Reagent Anti D (Anti Rh) (BioClone) manufacturer instructions revealed that quality control testing is required to confirm reactivity of the product prior to use. Review of quality controls log, revealed that no positive and negative control ran from 2017 to 2018. During an interview on 9/11/2018 at 11:30 am the office manager confirmed that no positive and negative controls were currently being run.