Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0717807	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lakeland Womens Health Center Inc	4444 S Florida Ave, Lakeland, 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
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 maintenance records record review for the last two years(2016-2018) and interview with the administrator, the laboratory failed to document all maintenance records. Findings included: During review of maintenance records for the last two years (2016-2018), the laboratory failed to document the following: room temperature, RH viewbox - December 7, 2016 and December 9,2016, room temperature and RH viewbox temperature - December 22, 2016, RH view box temperature - June 8, 2017 and June 9, 2017, room temperature and RH view box temperature - January 25th, 2018. During an interview on 04/05/18 at 11:15 a.m., the administrator confirmed the lack of documentation for RH quality controls, room temperature, and RH viewbox temperatures
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 RH quality control records record review for the last two years(2016-2018) and interview with the administrator, the laboratory failed to document all quality control records and maintenance records. Findings included: During review of quality records and maintenance records for the last two years (2016-2018), the laboratory failed to document the following: RH quality control - December 7, 2016 and December 9,2016, quality control - June 21, 2017, and Quality control - January 17th, 2018. During an interview on 04/05/18 at 11:15 a.m., the administrator confirmed the lack of documentation for RH quality controls, room temperature, and RH viewbox temperatures