Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0944521	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kun Zhong M D P C	21000 Middlebelt Road, Farmington Hills, MI	

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 lack of documentation and interview with Testing Personnel #1 (TP1), the laboratory failed to monitor and document the room temperature in the reagent storage room and testing area for 2 (May 2017 to May 2019) of 2 years. Findings include: 1. A review of the installation manual for the Perkin-Elmer spectrophotometer instrument stated the operating temperature range for the "instrument operation is 10 to 40 degrees C (50-100 degrees F)". 2. A review of the package insert for the HDL (High Density Lipoprotein) Cholesterol reagent kit specifies the reagents are to be stored between 15 and 30 degrees C. 3. No documentation was found to show the room temperature was being monitored in the reagent storage room and the testing area. 4. An interview with TP1 on 5/15/19 at 9:28 am, the office manager confirmed room temperature for the reagent storage and testing areas were not monitored and documented.