Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1077328	10/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Robert Klein Md Inc	18350 Roscoe Blvd, Ste 701, Northridge, CA	

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 review of the laboratory's refrigerator temperature logs, random patient sampling test results, and interview with the office staff it was determined that the laboratory failed to follow manufacturer's instructions for an acceptable ranges of storage temperatures and perform corrective action whenever the temperature of the refrigerator are out of required ranges, where quality control (QC) materials and other reagents for testing are stored. The findings included: a. The laboratory uses: Fastpack instrument, an analyzer for Prostatic-Specific Antigen (PSA) and Testosterone analyses. b. Based on the laboratories "Daily Environmental Log" which required reagents and quality control (QC) materials are stored at 2-8 degrees Celsius for their stability. c. Based on observation and review of the refrigerator temperature logs, which stores reagents and QC materials, the following temperatures were recorded by the laboratory personnel. Date: Ref. Range (2-8 degrees Celsius, recommended by the manufacturer.) Recorded Temp.: 2/14, /23/17 9 3/3/17 9 4/11, 26, 27/17 9 5/17, 18, 19 /17 10 5/24, 26/17 10 6/2, 20, 27, 29/17 9 6/30/17 10 7/5/17 11 8/25, 30/17 11 8/31/17 10 9/1/17 11 10/26/17 10 11/8/17 10 11/13/17 1 12/8/17 0 1/23/18 9 2/8, 23/18 9 3/20 /18 9 6/22/18 9 d. For seven (7) out seven (7) random patient sampling test results reviewed covering period from 11/15/2016 to 8/20/2018, the laboratory's refrigerator temperature logs were not monitored and corrected when the refrigerator temperatures

	were out of range. e. The office staff confirmed (10/26/2018, 1630) that the laboratory has no documentation to show of any corrective action for the temperatures recorded that were out of ranges.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's refrigerator temperature logs, and interview with the office staff it was determined that the laboratory failed to document corrective action whenever the temperature of the refrigerator are out of required ranges, where quality control (QC) materials and other reagents for testing are stored. The findings included. a. The laboratory uses: FastPack instrument, an analyzer for PSA and Testosterone analytes. b. Based on the laboratories "Daily Environmental Log" which required reagents and quality control (QC) materials are stored at 2-8 degrees Celsius for their stability. c. Based on observation and review of the refrigerator temperature logs, which stores reagents and QC materials, the following temperatures were recorded by the laboratory personnel. Date: Ref. Range (2-8 degrees Celsius, recommended by the manufacturer.) Recorded Temp.: 2/14, /23/17 9 3/3/17 9 4/11, 26, 27/17 9 5/17, 18, 19/17 10 5/24, 26/17 10 6/2, 20, 27, 29/17 9 6/30/17 10 7/5/17 11 8/25, 30/17 11 8/31/17 10 9/1/17 11 10/26/17 10 11/8/17 10 11/13/17 1 12/8/17 0 1 /23/18 9 2/8, 23/18 9 3/20/18 9 6/22/18 9 d. For seven (7) out seven (7) random patient sampling test results reviewed covering period from 11/15/2016 to 8/20/2018, the laboratory's refrigerator temperature logs were not monitored and corrected when the refrigerator temperatures were out of range. e. The office staff confirmed (10/26 /2018, 1630) that the laboratory has no documentation to show of any corrective action for the temperatures recorded that were out of ranges.