Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2102180	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Kota Cancer Clinic ,Pllc	**Street Address, City, State** 180 Medical Park Place, Hot Springs, AR	

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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature of one of two rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 10/12/22 at 09:15 AM two rooms containing items with a temperature storage requirement , the laboratory and storage room all separated by a closable door, were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for only the laboratory was presented. C) During a tour of the laboratory on 10/12/22 at 11:55 am, two 20L carboys of Sysmex CallPack lot number Y2028 expiration date 2023-09-23 with a storage temperature requirement of 1 degree C. to 30 degrees C. were observed in the storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored,. E) In an interview on 10/12/22 at 12:05 pm the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the daily temperature of the storage room in which the supplies, identified above, were stored had not been monitored and recorded..