Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2277599	(X3) Date Survey Completed 01/18/2024
Name of Provider or Supplier Uams Health Urology Clinic	**Street Address, City, State** 10915 Rodney Parham Road Suite E, Little Rock, 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 on each day of operation in one of three rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 1/18/24 at 09:15 a.m., three separate rooms (Interventional Radiology area, Imaging area and supply storeroom) containing laboratory items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room. C) During a tour of the laboratory on 1/18/24 at 11:00 a.m. 3 cartons of 100 BD Heparin Vacutainer tubes lot # 3163689 expiration date 2024-10-31with a storage temperature requirement of 4 to 25 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 1/18/24 at 11:05 a.m. , the laboratory staff member (# 2 on form CMS 209) confirmed that temperature records for the storage room were not kept.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of Personnel Records for twelve testing personnel listed on the form CMS-209, lack of documentation and through interviews with laboratory staff, it was determined the laboratory director failed to give written authorization to twelve of twelve testing personnel who perform moderately complex procedures. Survey findings include: A) The surveyor reviewed personnel records for twelve testing personnel (listed as #'s 4 through 15 on the form CMS-209) who perform moderately complex procedures and no authorization to perform testing was present for any of the employees . B) Upon request, the laboratory was unable to provide authorization to perform moderately testing for employees (# 4 through 15 on the CMS 209 form). C) In an interview, at 9:47 am on 1/18/24, staff member (#2 on the CMS 209 form) confirmed that employees (# 4 through 15 on the CMS 209 form) perform moderately complex testing and that there is no authorization to perform testing signed by the laboratory director. .