

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451969	(X3) Date Survey Completed 01/21/2021
Name of Provider or Supplier Wichita Urology Group	Street Address, City, State 2626 N Webb Rd, Wichita, KS	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, temperature monitoring records and interview, the laboratory failed to ensure that chemistry controls were stored at the required temperature. Findings: 1. A review of the manufacturer's instructions for Bio-Rad Immunoassay Plus Control revealed that the proper unopened storage requirement was -20 degrees Celsius (C). to -70 degrees C. 2. A review of the temperature monitoring system records from 1/01/19 to 1/21/21 for the lab freezer showed temperatures recorded during this period failed to maintain consistent manufacturer's required temperature. The 2 year period of daily temperatures recorded for the freezer showed only 7 days when temperatures were within the acceptable range to meet the manufacturer's requirements. Temperature log sheets listed a range of -10 C to -30 C. 3. Interview with General Supervisor (GS) 1/21/21 at 10:40 a.m. confirmed, the laboratory failed to ensure that chemistry controls were stored at the required temperature.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain</p>

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of competency assessment records and interview, the technical supervisor failed to evaluate the competency for one of three testing personnel (TP). Findings: 1. No competency assessment records on TP #1 for the years 2019 and 2020 were made available at the time of survey. 2. Interview with GS on 1/21.21 at 10:05 a. m. confirmed, the technical supervisor failed to evaluate the competency for one of three testing personnel (TP).