Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0689114	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Urological Group	7309 N Knoxville Ave, Peoria, IL	

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 laboratory records and interview with testing personnel (TP) #1; the laboratory failed to monitor storage temperatures for urinalysis quality control reagents used for urinalysis testing. 1. Review of the laboratory's preventative maintenance logs found no log documenting the temperature of the refrigerator used to store urinalysis quality control reagents in 2016 through date of survey 06-26-2018. 2. Interview with TP#1 at 2:50 pm on 06-26-2018 confirmed that that temperature of the refrigerator where urinalysis quality control reagents are stored was not currently being monitored.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

	minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory failed to conduct calibration verifications as required for all analytes performed on the Roche cobas e411 in 2018. Findings include: 1. Review of calibration verification records found that the most recent calibration verifications were performed in August of 2017 for all analytes on the Roche cobas e411 analyzer. 2. Interview on 06-26-2018, at 3:30 pm, with laboratory TP#1 confirmed that six month calibration verifications had not been completed since August of 2017 resulting in a gap of calibration verifications in 2018.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory director failed to ensure quality assessment plan was maintained in 2016 through date of survey, 06-26-2018. Findings Include: 1. Review of the laboratory procedure manual identified the policy, "Quality Assurance Program", which stated the following: "A summary of data collected will be reviewed by the Laboratory Director." and "Results of Quality Assurance studies are maintained in the laboratory for a period of not less than two years. Data is stored in such a manner that it is accessible for review and inspection upon request." 2. Review of quality assurance documentations found no summary reviews in 2016 through the date of survey, 06-26-2018. 3. On survey date 06-26-2018, at 3:30 pm, TP#1 confirmed no documented quality assurance documents had been completed and reviewed by the laboratory director.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)

	(b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory technical consultant failed to address the training needs for 3 of 8 testing personnel. Findings Include: 1. Review of laboratory personnel records found TP#2 and #3, as identified on the CMS-209, were authorized to perform post vasectomy semen presence/absence and urine culture testing. 2. Review of training documentation found neither TP#2 nor TP#3 had documented training for post vasectomy semen presence/absence and urine culture testing. 3. Review of laboratory personnel records found TP#5, as identified on the CMS-209, was authorized to perform urinalysis testing. 4. Review of training documentation found TP#5 failed to have documented training for urinalysis testing on the Clinitek Advantus. 5. During survey date 06-26-2018, at 3:30 pm, TP#1 confirmed 3 of 8 testing personnel failed to have documented training for testing in which the personnel were authorized to perform.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. 3 of 8 TP, listed on the CMS-209, failed to meet the qualification requirements for moderate complexity testing. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on review of laboratory records and interview with testing personnel (TP) #1; 3 of 8 TP failed to meet the qualification requirements of 493.1423. Findings Include: 1. Review of laboratory personnel records found 3 of 8 TP, listed on the CMS-209, failed to qualify as moderate complexity TP. a. TP#2 - No degree or high school diploma b. TP#3 - No degree or high school diploma c. TP#5 - Foreign degree and no United States foreign equivalency documentation. 2. On survey date 06-26-2018, at 3: 30 pm, TP#1 confirmed the laboratory failed to have qualifying documentation for TP#2, TP#3, and TP#5.