Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0689114	01/21/2020
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with testing personnel (TP) #1; the laboratory failed to retain quality control print-outs for urinalysis testing on the Clinitek Advantus analyzer in 2019. Findings Include: 1. During tour of the laboratory facility on 01-21-2020, the surveyor observed patients' specimens being tested on the Clinitek Advantus analyzer. 2. Interview with TP#1, at 9:50 AM, confirmed the Clinitek Advantus analyzer, used for dipstick urinalysis testing, was not interfaced with the laboratory information system (LIS). 3. Review of patient test results for dipstick urinalysis testing on the Clinitek Advantus analyzer found instrument print-outs for quality control testing failed to be retained by the laboratory for 1 of 3 patient test dates reviewed. Patient Identification - P10, Test Date: 07-08-2019 4. Review of quality control records for the Clinitek Advantus for 06-21-2019 through 7-10-2019 revealed the laboratory failed to retain quality control print-outs for 8 of 12 days when quality controls were performed. 5. Interview with TP#1 on 01-21-2020, at 4:07 pm, confirmed the laboratory failed to retain instrument print-outs for quality control testing on the Clinitek Advantus analyzer for 8 of 12 dates reviewed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with testing personnel (TP) #1; the laboratory failed to perform and document preventative maintenance for urinalysis testing on the Clinitek Advantus analyzer in January of 2020. Findings Include: 1. During tour of the laboratory facility on 01-21-2020, the surveyor observed patients' specimens being tested on the Clinitek Advantus analyzer. 2. Review of the Clinitek Advantus operator's manual, on page 37, revealed the laboratory should clean the push bar, fixed platform, moving table, reagent strip holddown plate, and display screen each day of use. 3. Review of preventative maintenance documentation found no daily preventative maintenance was documented in January for 2020 for the Clinitek Advantus. 4. Review of the quality control log identified 14 days of testing in January of 2020 when daily preventative maintenance was not documented. 5. On survey date 01-21-2020, at 4:07 pm, the surveyor's findings were confirmed by TP#1.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with testing personnel (TP) #1; the laboratory failed to perform maintenance activities as outlined by the laboratory to ensure accurate and reliable test performance for chemistry and hematology testing. Findings Include: 1. Direct observation on 01-21-2020, at 9:50 AM, identified a PSS Select microscope (Serial #200017475) used for semen analysis testing and a Horizon mini-E (Serial # 520804-z61) centrifuge used to centrifuge patients specimens for hematology and chemistry testing. 2. Review of the laboratory's policy and procedure manual identified the policy "Annual Equipment Maintenance Verification" which stated the microscope will be cleaned and checked annually by a service tech and the centrifuge will be routinely cleaned and tached annually by the technical consultant. 3. Review of preventative maintenance records revealed the laboratory microscope failed to have annual maintenance documented by a service tech in 2018 and 2019 and the centrifuge failed to have a documented tachometer check in 2019 by the technical consultant. 4. On survey date 01-21-2020, at 4:07 PM, TP#1 confirmed the laboratory failed to perform annual microscope maintenance in 2018 and 2019 and centrifuge maintenance in 2019 as outlined in the laboratory policy.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to include their name and address on the patients' test reports for 3 of 3 post vasectomy semen analysis patient test reports reviewed. Findings Include: 1. Review of 3 of 3 patient test reports for post vasectomy semen analysis revealed the laboratory failed to indicate the name and address of the laboratory. Patient Identification Test Date P1 10-10-2018 P2 07-08-2019 P3 11-27-2019 2. On survey date 01-21-2020, at 4:07 pm, TP#1 confirmed the above findings. B. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to include their address on the patients' test reports for 3 of 3 urinalysis patient test reports reviewed. Findings Include: 1. Review of 3 of 3 patient test reports for urinalysis testing revealed the laboratory failed to indicate the address of the laboratory on the patients' test reports. Patient Identification Test Date P9 02-13-2019 P10 07-08-2019 P11 01-06-2020 2. On survey date 01-21-2020, at 4:07 pm, TP#1 confirmed the above findings.
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 direct observation, review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory technical consultant (TC) failed to address the training needs for 5 of 5 testing personnel performing urinalysis testing on the Clinitek Advantus. Findings Include: 1. Review of laboratory's designation of testing personnel document identified 5 testing personnel who were authorized to perform urinalysis testing. 2. During tour of the laboratory facility on 01-21-2020, the surveyor observed patients' specimens being tested on a Clinitek Advantus analyzer. 3. Review of patient testing on the Clinitek Advantus found for 1 of 3 patient testing dates reviewed the quality control materials in use were expired, 07-08-2019. Quantmetrix Dropper Control Level 1 Lot #44471 - Expired 6-30-2019 Quantmetrix Dropper Control Level 2 Lot #44472 - Expired 6-30-2019 4. Further review of quality control logs for urinalysis testing identified 5 additional testing dates when quality control reagents were expired, 07-01, 07-02, 07-03, 07-09, and 07-10 of 2019. 3. Review of the daily quality control logs and the Quantimetrix Dropper manufacturer's product insert for urinalysis testing found the laboratory failed to identify the correct expected range for the Quantimetrix Dropper level 2 quality control material in use since July of 2019 on the Clinitek Advantus analyzer for glucose, specific gravity, pH, urobilinogen, and nitrite. The laboratory had identified on the manufacturer's product

	insert the ranges for the Siemens Clinitek 50 and 500 rather than analyzer in use, the Clinitek Advantus. Quantimetrix Dropper Control Level 2 - Lot# 44652 Analyte Manufacturer's Insert Values QC Log Values Glucose Trace - >1000 mg/dL TR - 500 Bilirubin Small to Large Sm - Lg Ketones 15 - 80 mg/dL 15 - 80 Specific Gravity 1.005 - 1.020 1.005 - 1.025 Blood Small to Large Sm - Lg pH 7.5 - 9 7.5 - 8.5 Protein 30-300 mg/dL 30-300 Urobilinogen 1.0 - 8.0 E.U./dL 1.4 - 4.0 Nitrite Positive Tr - pos Leukocytes Negative Tr - Lg 4. The laboratory failed to retain daily quality control print-outs for urinalysis testing reviewed on the Clinitek Advantus for 8 of 12 testing dates reviewed in 2019. See D3031. 5. The laboratory failed to document daily maintenance activities in January of 2020. See D5429. 6. On survey date 01-21-2020, at 4:07 pm, TP#1 confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the technical consultant (TC) failed to ensure annual competency assessments were completed by a qualified TC for 5 of 6 testing personnel in 2018 and 2019. Findings Include: 1. Review of competency assessment records for 5 of 6 testing personnel (TP#2, #3, #4, #5, and # 6) found all competency assessments in 2018 and 2019 were performed by TP#1, who failed to meet the qualifications as a technical consultant. 2. On survey date 01-21-2020, at 4:07 pm, TP#1 confirmed the TC failed to perform competency assessments for TP#2, #3, #4, #5, and # 6 in 2018 and 2019.