Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0666475	12/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cape Girardeau Urology Associates, Inc	3 Doctors Park, Cape Girardeau, MO	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel documentation, and interview with the testing personnel (TP) #4, the laboratory failed to perform competency evaluations for 2018 and to date December 3, 2019 for the position of technical supervisor #2. Findings: 1. Review of 2018, 2019 personnel documentation revealed the laboratory failed to perform 1 of 2 competency assessments for the position of technical supervisor. 2. Review of the procedure manual revealed a lack of written policies and procedures to assess employees in the position of technical supervisor. 3. Interview with the TP #4 on December 3, 2019 at 11:00 AM confirmed the laboratory failed to have written policies and perform annual competencies for 2018 and to date December 3, 2019 for the position of technical supervisor.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the specimen collection and rejection policy and interview with testing personnel #4, the laboratory failed to follow written policies and procedures for urine specimen collection and rejection (Refer to D5311).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for "CVMS urine specimen collection", observation, and interview with the testing personnel (TP) #4, the laboratory failed to follow the written procedure for specimen collection and rejection. Findings: 1. Review of the "CVMS urine specimen collection" procedure revealed "specimens collected in non-sterile or inappropriate containers" are considered unacceptable. 2. Observation of the laboratory area showed a non-sterile plastic cup used to collect the urine for urinalysis and urine culture testing. 3. Interview with the TP #4 on December 3, 2019 at 11:00 AM confirmed "patients are given the plastic cup to collect the urine. The urine is then dipped into with the urinalysis chem strip for the urinalysis testing. The urine is then sent to the Microbiology area of the laboratory to setup for culture." The TP #4 confirmed the laboratory failed to follow the procedure for proper specimen collection.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, observation of the laboratory, and interview with the testing personnel (TP) #4, the laboratory failed to follow manufacturer's instructions for obtaining urine specimens for urine culture testing (Refer to D5411).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation of the laboratory, and interview with the testing personnel (TP) #4, the laboratory failed to follow manufacturer's instructions for obtaining urine specimens for urine culture testing. Findings: 1. Review of the Healthlink Bullseye urine plate manufacturer's instructions showed "Proper specimen collection and procedural techniques must be followed to ensure the most accurate culture results possible. Sterile collection containers should be used." "Strict adherence to aseptic techniques and established precautions should be followed throughout the procedure." 2. Observation of the laboratory area showed a non-sterile plastic cup used to collect the urine for urinalysis and urine culture testing. 3. Interview with the TP #4 on December 3, 2019 at 11:00 AM confirmed "patients are given the plastic cup to collect the urine. The urine is then dipped into with the urinalysis chem strip for the urinalysis testing. The urine is then sent to the Microbiology area of the laboratory to setup for culture." The TP #4 confirmed the laboratory failed to follow the manufacturer's instructions for proper specimen collection appropriate for culture testing.
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: Based on review of one of two patient test reports and interview with the testing personnel (TP) #4, the laboratory failed to include the name of the laboratory where the test was performed. Findings: 1. Review of one test report for urine microscopic exam showed the laboratory failed to include the address of the laboratory. 2. Interview with TP #4 on December 3, 2019 at 11:00 AM confirmed the test report did not include the address of the testing laboratory.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Review of personnel training records for 2018, 2019 and interview with testing

	personnel (TP) #4, the director failed to ensure one of six testing personnel had appropriate training for high complexity testing prior to testing and reporting patient results. Findings: 1. Review of training documentation for 2018, 2019 revealed the director failed to have initial training for TP #1. 2. Interview with TP #4 on December 3, 2019 at 11:00 AM confirmed, the director failed to ensure each testing person had appropriate training for high complexity testing before testing patient specimens.