Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0430238	01/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rockford Urological Associates	351 Executive Pkwy, Rockford, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory's procedure manual failed to include the required elements for high complexity ThermoFisher Scientific Urinary Tract Infection (UTI) polymerase chain reaction (PCR) testing for 54 of 54 analytes, affecting over 98,781 tests. Findings include: 1. Review of the laboratory's SOP revealed the following list of 54 ThermoFisher Scientific Urinary Tract Infection (UTI) analytes tested: "PCR List of Organisms & Cut-Offs - Citobacter koseri,

	Proteus vulgaris, Mycobacterium tuberculosis, Streptococcus pyogenes, BK virus, Candida tropicalis, Aerococcus urinae, Candida albicans, Citrobacter freundii, Klebsiella aerogenes, Enterobacter cloacae, Enterococcus faecalis, Ribonuclease P, Serratia marcescens, Escherichia coli, Gardnerella vaginalis, Candida parapsilosis, Enterococcus faecium, Klebsiella oxytoca, AmpC beta-lactamases, Beta-lactamase (D), Klebsiella pneumoniae, Morganella morganii, Carbapenemase Class A Group, Carbapenemase Class B Group, Proteus mirabilis, Providencia stuartii, Extended-spectrum B-lactamase Class A Group, Gryase A Group, Pseudomonas aeruginosa, Salmonella enterica, Extended-spectrum B-lactamase, Staphylococcus aureus, Ureaplasma urealyticum, Carbapenemase Class D, Macrolide resistance, Mycoplasma genitalium, Ureaplasma parvum, Acinetobacter baumannii, Streptococcus agalactiae, Staphylococcus Species, Citrobacter amalonaticus, Candida glabrata, Mycoplasma hominis, Xeno, Quinolone Resistance, Trimethoprim - Resistant Dihydrofolate Reductase Group, sulfonamide resistant 1, sulfonamide resistant 2, mecA gene (methicillin resistance), mecC gene (methicillin resistance), Vancomycin A, Vancomycin B" 2. Review of the "Rockford Urological Associates" procedure manual revealed the laboratory failed to include the following elements for ThermoFisher Scientific UTI PCR testing: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; b) Step-by-step performance of the procedure, including test calculations and interpretation of results. 3. Review of patient test records documented 98,781 UTI PCR based bacteriology, virology, mycology and parasitology tests were performed from December 2023 to January 2025. 4. On 01/22/2025, at 5:05 p.m., the TS confirmed the lab did not have all the required procedures for PCR testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor, the laboratory failed to ensure the verification of performance specifications for high complexity ThermoFisher Scientific Urinary Tract Infection (UTI) polymerase chain reaction (PCR) testing for 54 of 54 analytes utilizing the QIAamp DNA Mini Kit on the appliedbiosystems QuantStudio5 (Serial number: 272533502) instrument, affecting over 98,781 tests. Findings include: 1. Review of the laboratory's SOP revealed the following list of organisms tested: "PCR List of Organisms & Cut-Offs - Citobacter koseri, Proteus vulgaris, Mycobacterium tuberculosis, Streptococcus pyogenes, BK virus, Candida tropicalis, Aerococcus urinae, Candida albicans, Citrobacter freundii, Klebsiella aerogenes, Enterobacter cloacae, Enterococcus faecalis, Ribonuclease P, Serratia marcescens, Escherichia coli, Gardnerella vaginalis, Candida parapsilosis, Enterococcus faecium, Klebsiella

	oxytoca, AmpC beta-lactamases, Beta-lactamase (D), Klebsiella pneumoniae, Morganella morganii, Carbapenemase Class A Group, Carbapenemase Class B Group, Proteus mirabilis, Providencia stuartii, Extended-spectrum B-lactamase Class A Group, Gryase A Group, Pseudomonas aeruginosa, Salmonella enterica, Extended-spectrum B-lactamase, Staphylococcus aureus, Ureaplasma urealyticum, Carbapenemase Class D, Macrolide resistance, Mycoplasma genitalium, Ureaplasma parvum, Acinetobacter baumannii, Streptococcus agalactiae, Staphylococcus Species, Citrobacter amalonaticus, Candida glabrata, Mycoplasma hominis, Xeno, Quinolone Resistance, Trimethoprim - Resistant Dihydrofolate Reductase Group, sulfonamide resistant 1, sulfonamide resistant 2, mecA gene (methicillin resistance), mecC gene (methicillin resistance), Vancomycin A, Vancomycin B" 2. Review of laboratory records and lack of documentation revealed the laboratory failed to ensure the accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, normal values and any other performance characteristic required for test performance for the 54 of 54 UTI PCR analytes listed in Finding 2 utilizing the QIAamp DNA Mini Kit on the appliedbiosystems QuantStudio5 (Serial number: 272533502) instrument. 3. Review of patient test records documented 98,781 UTI PCR based bacteriology, virology, mycology and parasitology tests were performed from December 2023 to January 2025. 4. On 01/22/2025, at 5:05 p.m., the TS confirmed the lab did not have the verification study for the new UTI PCR system available at the time of survey.