Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0681006	06/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Urology Specialists	509 North Elam Avenue, 2nd Floor, Greensboro, NC	

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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of 2023, 2024, and 2025 i-STAT records and interview with the TC (technical consultant) 6/25/25, the laboratory failed to retain quality control assay sheets for the lot numbers used from 3/1/23 to 12/31/24. Findings: Review of 2023, 2024, and 2025 i-STAT records revealed the laboratory failed to retain quality control assay sheets for the lot numbers used from 3/1/23 to 12/31/24. During interview at approximately 1:45 p.m., the TC confirmed there were no assay sheets available for the i-STAT quality control material used from 3/1/23 to 12/31/24.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of manufacturer's instructions and review of 2023, 2024, and 2025 i-STAT records 6/25/25, the laboratory failed to perform and document thermal probe checks for the i-STAT analyzer every six months during 2023. Findings: Review of i-STAT manufacturer's instructions revealed "... A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this

	check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, APOC recommends that the thermal probe check be verified every six months. ... 4. Interpretation of the thermal probe check value: Acceptable: a value from -0.1 to +0.1, inclusive. ..." Review of 2023, 2024, and 2025 i-STAT records revealed the laboratory had documented thermal probe checks on 6/18/24, 12/4/24, and 6/18/25. There was no documentation of thermal probe checks in 2023.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records, review of job descriptions, and interview with the TC 6/25/25, the laboratory director failed to ensure competency evaluations were performed by personnel who met the qualifications of a TC. Findings: Review of personnel records revealed TP (testing personnel) #1 had performed the 2024 competency evaluations for TP #2, TP #3, TP #4, and TP #5. Review of personnel records revealed TP #1 did not meet the qualification requirements to serve as TC in a moderate complexity laboratory. Review of the job description for TP #1 revealed the following duties "... Assures the qualifications and validation of all lab personnel in areas of responsibility, specific tests, and/or work stations. Assigns personnel duties as necessary. ... manages personnel ...". During interview at approximately 12:35 p.m., the TC stated that TP #1 serves as the "on-site supervisor/designee", but is not the TC.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of validation records, the absence of records, review of policies and procedures, and interview with the TC 6/25/25, the laboratory director failed to ensure validation procedures used by the laboratory were adequate to verify the accuracy, precision, and reportable range for the new Dirui and i-STAT analyzers installed in 2024. Findings: 1. Review of validation records revealed the laboratory installed a new Dirui 500 urine analyzer in February 2024. The laboratory had performed a correlation with an outside laboratory, but there was no documentation that the laboratory performed any studies to verify accuracy, precision, and reportable range on the new analyzer. Review of the laboratory's policies and procedures revealed a "Dirui H-500 Urine Chemistry Validation Protocol", but there were no records

	available to indicate that the laboratory followed the instructions to validate the new analyzer. 2. Review of validation records revealed the laboratory installed a new i-STAT analyzer in March 2024. The laboratory had performed a correlation with an outside laboratory, but there was no documentation that the laboratory performed any studies to verify accuracy, precision, and reportable range on the new analyzer. During interview at approximately 11:35 a.m., the TC confirmed that the laboratory had not verified accuracy, precision, and reportable range for the Dirui and i-STAT analyzers prior to use for patient testing.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) 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: Based on review of personnel records and interview with TP #1 on 6/25/25, the laboratory director failed to ensure that prior to testing patient specimens, 1 of 5 testing personnel (TP #4) had received appropriate training and had demonstrated the ability to perform all testing operations reliably to provide accurate test results. Findings: Review of personnel records for TP #4 revealed no documentation of training for urine sediment identifications. During interview at approximately 10:15 a.m., TP #1 stated that TP #4 was trained to perform urine microscopics, but the training was not documented.