Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2089691	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wakemed Urology	210 Ashville Ave, Cary, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on absence of performance specification records for the Abbott I-STAT CHEM8+ cartridges and interview with the Manager of Clinical Quality and Education 7/14/21, the laboratory failed to verify the performance specifications of the Abbott I-STAT CHEM8+ cartridges when it was determined by the FDA to be moderate complexity. Approximately 97 patients were affected. Findings: On January 14, 2020 Abbott Point of Care released a customer letter (APOC2020-001) stating the Abbott I-STAT CHEM8+ cartridge was not Federal Drug Administration (FDA) cleared or approved for use. On 2/19/20 the Abbott I-STAT Chem 8+ cartridge was cleared by the FDA and categorized as moderate complexity. Review of laboratory records revealed no documentation the laboratory had verified the performance specifications of the Abbott I-STAT CHEM8+ cartridge before continuing to perform patient testing. Review of laboratory testing records, sent via email after survey date, revealed approximately 97 patients were tested from 2/19/20 until 8/19/20 when the laboratory ceased testing on the I-STAT and began testing on the Piccolo analyzer. Interview with Manager of Clinical Quality and Education at approximately 9:45 a.m. confirmed the laboratory failed to verify the performance specifications of the Abbott

	I-STAT CHEM8+ cartridge. She stated the facility had been notified by Abbott in regards to the Chem 8+ cartridges, but they continued to use them until they could get a new test system, the Piccolo, validated and in place.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records for the I-STAT CHEM8+ cartridge, review of laboratory testing records and interview with the Manager of Clinical Quality and Education 7/14/21, the laboratory failed to perform QC on the Abbott I-STAT CHEM8+ cartridge each day of patient testing for 6 months, from 2/19 /20 until 8/19/20. Approximately 97 patients were affected. Findings: On January 14, 2020 Abbott Point of Care released a customer letter (APOC2020-001) stating the Abbott I-STAT CHEM8+ cartridge was not FDA cleared or approved for use. On 2/19 /20 the Abbott I-STAT Chem 8+ cartridge was cleared by the FDA and categorized as moderate complexity. Review of laboratory QC records revealed the laboratory was performing QC for the Abbott I-STAT CHEM8+ cartridge with each new lot number or shipment and at least every 30 days. The laboratory failed to perform QC each day of patient testing. The laboratory performed QC on 2/28/20, 3/9/20, 5/5/20, 5/27/20 and 6/24/20. Review of laboratory testing records, sent via email after survey date, revealed approximately 97 patients were tested from 2/19/20 until 8/19/20 when the laboratory ceased testing on the I-STAT and began testing on the Piccolo analyzer. Interview with Manager of Clinical Quality and Education at approximately 9:45 a.m. confirmed the laboratory was not performing QC each day of patient testing. She stated the facility had been notified by Abbott in regards to the Chem 8+ cartridges, but they continued to use them until they could get a new test system, the Piccolo, validated and in place.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on deficiency cited 7/14/21, the laboratory director (LD) failed to ensure performance verifications were performed on the Abbott I-STAT CHEM8+ cartridges. Findings: See D5421.

D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on deficiency cited 7/14/21, the LD failed to ensure QC was performed as required on the Abbott I-STAT CHEM8+ cartridge. Findings: See D5447.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment records, review of corrective action reports and interview with Manager of Clinical Quality and Education 7/14/21, the LD failed to ensure quality assessment (QA) programs were maintained after the previous practice manager and technical consultant were no longer employed by the facility, a period of approximately 16 months in which QA activities were not performed. Findings: Review of laboratory QA records revealed no documentation of QA activities from January 2020 until July of 2021. The records did include a monthly QA for July of 2021 and a patient chart review from 4/20 until 7/20 completed in July of 2021. Review of corrective action reports, dated 7/8/21, and signed by the LD 7/13/21 revealed the following: a. The laboratory had no documentation of the performance of proficiency testing or a biannual verification for 2019. b. The laboratory failed to document weekly cleaning maintenance from 9/20 through 12/20. c. The laboratory had not performed QA activities since the previous consultant performed them in January of 2020, a period of approximately 16 months is which QA activites were not performed. Interview with Manager of Clinical Quality and Education at approximately 11:45 a.m. confirmed the laboratory had not performed any QA activities from 1/20 until 7/21. She stated they became aware of problems when the new practice manager and technical consultant were hired and have been working to ensure all problems discovered are corrected and to ensure that the facility will be performing testing within the regulations in the future.