Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1022385	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Outer Banks Health Urgent Care Nags Head	5002 South Croatan Highway, Suite A, Nags Head, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of 2020 and 2021 API (American Proficiency Institute) proficiency testing records and interview with the TP (testing personnel) and the TC (technical consultant) 4/20/21, the laboratory failed to enroll in proficiency testing for analytes tested on the i-STAT analyzer. Review of 2020 and 2021 API proficiency testing records revealed the laboratory was not enrolled in proficiency testing for sodium, potassium, chloride, blood urea nitrogen, creatinine, and glucose performed on the i-STAT analyzer using the blue Chem 8 cartridges. During interview at approximately 9:50 a.m., TP #1 confirmed that the laboratory uses the blue Chem 8 cartridges for testing performed on the i-STAT. During interview at approximately 3:00 p.m., the TC stated she was unaware the i-STAT blue Chem 8 cartridge was no longer waived and proficiency testing was required.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the laboratory's policies and procedures and interview with TP (testing personnel) 4/20/21, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a procedure for use of the electronic medical records system, including how to order tests, generate patient labels, and enter patient test results. 2. The procedure manual did not include a procedure for reporting positive and negative COVID test results to state and local public health authorities. During interview at approximately 10:50 a. m., TP #1 stated that their instrument is interfaced and positive and negative results are automatically reported to the state. She stated they also call all positive results to their local health department. She confirmed the laboratory did not have a written procedure describing their process for reporting COVID test results.
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 the laboratory's policies and procedures and review of 2020 and 2021 i-STAT quality control records, and interview with the TC (technical consultant) 4/20/21, the laboratory failed to test two levels of external controls each day that patient specimens were tested or failed to establish an IQCP (Individualized Quality Control Plan). Review of the laboratory's i-STAT procedure revealed the following quality control requirements: Test three levels of liquid quality control material with each new lot number/shipment of cartridges and once per week. Test the electronic simulator every 8 hours. Review of 2020 and 2021 i-STAT quality control records revealed the laboratory had followed their procedure for testing quality control material. The laboratory had not tested two levels of external quality control material each day that patient specimens were tested. During interview at approximately 3:00 p.

	m., the TC stated she was unaware the i-STAT Chem 8 cartridges were no longer waived. She confirmed the laboratory had not tested two levels of control material each day that patient specimens were tested, and she verified that the laboratory had not established an IQCP.
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 and interview with the TC (technical consultant) 4/20/21, the laboratory director failed to ensure that testing personnel competency evaluations were performed by a person who met the qualification requirements to serve as a technical consultant in a moderate complexity laboratory. Review of personnel records revealed 2020 and 2021 testing personnel competency evaluations were performed by a person employed by the affiliated hospital who has a Bachelor of Science degree in Health Promotion. Review of her transcript revealed the person does not meet the qualification requirements to serve as technical consultant in a moderate complexity laboratory. During interview at approximately 3: 15 p.m., the TC stated that she was not aware the person who performed the competency evaluations did not meet the qualification requirements to serve as TC in a moderate complexity laboratory.
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 the laboratory's quality assessment plan and review of quality assessment documentation 4/20/21, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems in the preanalytic, analytic, and postanalytic phases of testing. The "Laboratory Quality Assurance Program Overview" states "... Quality Monitors/Indicators (The laboratory) monitors Laboratory process for quality and timliness. Monitors which are currently in place include: Complaint evaluation and resolution API proficiency testing Review of abnormal results Critical value

	communication ..." The laboratory had used a checklist to perform a monthly review. The checklist included items such as: Daily patient reports (urinalysis, i-STAT, Sysmex) Weekly maintenance Monthly maintenance Quality control (i-STAT, urinalysis, Sysmex) Parallel testing Critical values Proficiency testing Competency The reviews had been signed and dated by the technical consultant. The laboratory's quality assessment program failed to identify problems identified during the survey in the following areas: Proficiency testing (see D2000) Procedures (see D5403) Quality control (see D5447) Personnel (see D6004, D6032).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TC (technical consultant) 4/20/21, the laboratory director failed to specify in writing the duties and responsibilities for 7 of 20 testing personnel (TP #2, #9, #15, #16, #17, #18, #20). Review of personnel records revealed there were no job descriptions available for TP #2, #9, #15, #16, #17, and #20. Review of personnel records revealed the job description for TP #18 had not been updated to include the laboratory's current test menu. During interview at approximately 3:20 p.m., the TC stated that she was unaware job descriptions were not included in all personnel records.