

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2043662	(X3) Date Survey Completed 04/17/2024
Name of Provider or Supplier Outer Banks Health Urgent Care Kitty Hawk	Street Address, City, State 5112 N Croatan Highway, Kitty Hawk, 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2022, 2023, and 2024 i-STAT records, and interview with the "offsite manager" 4/17/24, the laboratory failed to perform and document thermal probe checks at least every six months as required by the manufacturer. Findings: Review of "Procedure Manual for the i-STAT 1 System" revealed "... Every 6 Months Procedures ... Update i-STAT 1 Analyzer Software Update the software as provided by Abbott Point of Care. Perform an external Electronic Simulator test after software update. Verify thermal probe reading as described below. Thermal Probe Check Procedure ... Acceptable: a value from -0.1 to +0.1, inclusive ..." Review of the laboratory's 2022, 2023, and 2024 i-STAT records revealed no documentation of thermal probe checks. During the exit interview at approximately 4:30 p.m., the "offsite manager" confirmed that the laboratory had not performed the thermal probe checks during 2022, 2023, and 2024.</p>