

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0974790	(X3) Date Survey Completed 04/18/2024
Name of Provider or Supplier Outer Banks Health Family Medicine- Avon	Street Address, City, State 40894 Nc Highway 12, Avon, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of WSLH (Wisconsin State Laboratory of Hygiene) instructions, and review of 2022 AAFP (American Academy of Family Physicians) proficiency testing records and 2023 and 2024 WSLH proficiency testing records 4/18/24, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested for 6 of 7 events reviewed. Findings: Review of the laboratory's "Critical Values" procedure revealed a critical value for hemoglobin of less than or equal to 7.0 grams per deciliter and critical values for platelets of less than or equal to 10 and greater than or equal to 500 x 10⁹ per liter. On page 2, the procedure states "...B. If specimen testing results in a critical value, the personnel performing the test should first repeat the test. ..." Review of "WSLH Proficiency Testing General Instructions" revealed "... Sample Handling, Storage, and Testing Instructions ... Test samples using routine methods, test procedures, and personnel. ..." Review of 2022 AAFP and 2023 and 2024 WSLH proficiency testing records revealed critical values were not repeated for proficiency samples on the following events: 1. 2022 AAFP Event A - critical hemoglobin for sample HD-5 not repeated. 2. 2022 AAFP Event C - critical hemoglobin for sample HD-14 not repeated. 3. 2023 WSLH Event HemeReg1 -</p>

critical hemoglobin for samples AT-2 and AT-5 not repeated. 4. 2023 WSLH Event HemeReg2 - critical hemoglobin for sample AT-8 not repeated. 5. 2023 WSLH Event HemeReg3 - critical hemoglobin for sample AT-11 not repeated. 6. 2024 WSLH Event HemeReg1 critical hemoglobin for samples AT-2 and AT-5 not repeated, critical platelet for sample AT-1 not repeated.