

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0990794	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier White Oak Urgent Care Randleman	Street Address, City, State 608 West Academy Street, Randleman, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions and observation 9/18/24, the laboratory failed to follow manufacturers' instructions and failed to discard supplies that had exceeded their expiration dates. Findings: 1. Review of the OSOM Mono Test product insert revealed "... KIT CONTENTS AND STORAGE ... Do not use the Test Sticks or reagents after their expiration dates. ..." During a tour of the laboratory at approximately 2:00 p.m., the surveyor observed 1 open OSOM Mono Test kit (lot #231345) with expiration date 8/31/24 on a shelf in the laboratory, available for use. 2. During a tour of the laboratory at approximately 2:00 p.m., the surveyor observed the following FOB (fecal occult blood) controls in the laboratory refrigerator, available for use: a. 1 bottle FOB Test Control Kit T1-TC01 Negative Control (lot #L0214229737) with expiration date 2/28/24; b. 1 bottle FOB Test Control Kit T1-TC01 Positive Control (lot #L0214229736) with expiration date 2/28/24.</p>