

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2252486	(X3) Date Survey Completed 05/15/2025
Name of Provider or Supplier Urgent Care Of Fairhope, Llc	Street Address, City, State 8096 Twin Beech Road, Suite 150, Fairhope, AL	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory tour, review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and interviews with Testing Personnel 2 (TP2) and Testing Personnel 3 (TP3), the laboratory failed to ensure the new expiration date was recorded upon opening on on three of three QC vials currently in use. The findings include: 1. During the laboratory tour on 5-15-2025 at approximately 9:11 AM the surveyor observed testing personnel had failed to record the new expiration date upon opening on the three levels of CBC QC currently in use. 2. A review of the Sysmex EightCheck 3WP X-TRA QC package insert revealed the QC is stable for 14 days when stored at 2-8 degrees Celsius and re-capped after use. 3. During the exit conference at 1:37 PM on 05-15-2025, the TP2 and TP3 confirmed the above findings.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and interviews with Testing Personnel 2 (TP2) and Testing Personnel 3 (TP3), the Technical Consultant failed to ensure competency assessments for Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report), performing moderate complexity testing included all six CLIA minimal regulatory requirements. The surveyor noted two of the six requirements were missing on the semi-annual and annual competencies. The findings include: 1. A review of the 2023-2025 personnel records revealed TP competency assessments for the Hematology specialty had no documentation on two of the six CLIA minimal regulatory requirements. The missing two requirements were as follows: (1) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (2) Assessment of problem-solving skills. 2. The TP2 and TP3 confirmed the above findings during the exit conference on 5-15-2025 at 1:37 PM.