

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0306179	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Whit Family Clinic Fitz-Gerald	Street Address, City, State 203 Highway 80 West, Demopolis, 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 direct observation, a review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and an interview with the Testing Personnel 1 (TP1), the laboratory failed to write the new expiration date on the QC vials after opening. The surveyor noted three of three QC vials currently in use were missing the open date stability information, the date opened with the new expiration date. The findings include: 1. During the laboratory tour on 04-24-2025 at approximately 8:18 AM the surveyor observed the testing personnel had not recorded the open date stability information on the CBC QC vials, Lot number 5006, Expiration 04-25-2025. 2. TP1 informed the surveyor the laboratory policy was to open a new set of QC materials every seven days. 3. A review of the QC package insert revealed an 8 consecutive-day open-tube stability requirement. 4. TP1 confirmed the above findings during the exit conference on 04-24-2025 at 12:38 PM.</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 an interview with the Testing Personnel 1 (TP1), the Technical Consultant failed to ensure competency assessments for Testing Personnel (TP) performing moderate complexity testing in Hematology included the six CLIA minimal regulatory requirements. The surveyor noted one of the six requirements was 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 one of the six CLIA minimal regulatory requirements. The surveyor noted this was the missing requirement. (1) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The TP1 confirmed the above findings during the exit conference on 4-24-2025 at 12:38 PM.