Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305356	04/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Medical Center	220 Hospital Drive, Jackson, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (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. This STANDARD is not met as evidenced by: Based on observations during the laboratory tour, reviews of the package insert for the Hematology Quality Controls (QC) and Triage test cartridges, and an interview with the General Supervisor (GS), the laboratory staff failed to: (1) write the new expiration dates on the three levels of the Complete Blood Count (CBC) and Retic QC vials currently in use; and (2) record the new expiration for Triage D-Dimer cartridges when transferred from the refrigerator to room temperature for patient testing. The findings include: 1. During the laboratory tour on 04-22-2025 at approximately 8:16 AM the surveyor observed the three levels of the CBC and Retic Controls in use. The testing personnel had failed to record the new expiration date after the vials were opened. 2. As the laboratory tour continued, the surveyor observed room temperature D-Dimer test cartridge pouches with "04/18/25", the date when the packages were removed from the refrigerator. The testing personnel failed to record the new expiration date for test cartridges stored at room temperature. 3. A review of package inserts for the Hematology Controls and the Triage D-Dimer cartridges revealed the following: A) Hematology CBC and Retic QC - stable for 16 open vial days B) Triage Test Cartridges: Storage and Handling Requirements, "Once removed from refrigeration, the pouched Test Device is stable up to 14 days at room temperature..." 4. GS confirmed the above findings during the Day 2 exit conference on 04-23-2025 at 2:48 PM.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observations of the Beckman Coulter Bicarbonate Calibrator (BCBC) bottles, an interview with the General Supervisor (GS) and a review of Instructions for Use (IFU), the surveyor determined the laboratory had utilized expired calibrators prior to patient testing. The surveyor noted two of the two levels of calibrators were utilized for 27 days after expiration. The findings include: 1. During the Chemistry laboratory tour with the GS at approximately 8:21 AM, the surveyor observed the BCBC, Levels 1 and 2, Lot number 2763 with a manufacturer's expiration date of 08-11-2025, and open date 02-25-2025. The new expiration date upon opening was not written on the bottles. 2. During the tour, a discussion about the BCBC open stability requirement prompted the GS to show the surveyor a posted reminder (30-day expiration after opening) attached to the analyzer. However, the testing personnel had failed to follow the requirement and record the new open expiration date. 3. A review of the BCBC IFU verified the 30-day open stability requirement. The laboratory utilized the BCBC, Lot number 2763 for 27 days after the calibrators had expired on 03-27-2025 until the date of the current survey on 04-22-2025. 4. The GS confirmed the above findings during the Day 2 exit conference on 04-23-2025 at 2:48 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on reviews of the Chemistry maintenance records, the Policy and Procedure Manuals (PPM) for Beckman Coulter AU 700 and Access 2 and an interview with the General Supervisor (GS), the laboratory failed to provide documentation of the Annual Preventive Maintenance (APM). The surveyor noted one of the two APM for the two analyzers had no documentation from 2023-2024 The findings include: 1. A review of the 2023-2024 Chemistry maintenance records for the Beckman Coulter AU 700 and Access 2 analyzers revealed no documentation for the 2023 APM. 2. A review of the PPM for the Beckman Coulter AU 700 and Access 2 revealed the laboratory's policy required an annual maintenance performed. 3. During an interview on 04-23-2025 at 2:48 PM, the GS confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by:

	Based on reviews of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Quality Control (QC) logs, the ACL Elite analyzer patient result logs, and an interview with the General Supervisor (GS), the laboratory failed to ensure two levels of QC were performed and documented before patient testing. The surveyor noted no QC was performed on one day of patient testing in July 2023. The findings include: 1. A review of the PT and APTT QC logs revealed the laboratory failed to perform the required QC prior to patient testing on 07-01-2023. One patient testing was performed. 2. During an interview on 04-23-2025 at 2:48 PM, the GS confirmed the above findings.