Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305199	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Washington County Hospital	14600 St Stephens Avenue, Chatom, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the 2024 Room Temperature (RT) and Humidity Charts, and an interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure RT and Humidity were recorded each day of patient testing. The surveyor noted no RT and Humidity were recorded for 3 out of the 30 days in September 2024. The findings include: 1) A review of the RT and Humidity Chart revealed the laboratory failed to monitor and record the RT and Humidity of the laboratory from 09-24-2024 thru 09-26-2024 when patient testing was performed. 2. A further review of the RT and Humidity Chart indicated the following specified ranges: A) RT of 18-30 degrees Celsius B) Humidity of 5-40 Percent 3) During Day 2 exit conference on 04-09-2025 at 3:30 PM, TP1 confirmed the above findings.
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 inserts for the Coulter 6C Plus Cell Hematology Controls, Triage test cartridges, and an interview with the Testing Personnel 1 (TP1), the laboratory staff failed to: (1) write the new expiration dates on the three levels of the Hematology Quality Control (QC) vials currently in use; and (2) record the new expiration for Triage D-Dimer and Cardiac Panel cartridges when transferred from the refrigerator to room temperature for patient testing. The findings include: 1. During the laboratory tour on 04-08-2025 at approximately 8:59 AM the surveyor observed the three levels of Hematology Controls in use had "04/06" on the vials, however there was no indication of when the Controls expired upon opening. 2. As the laboratory tour continued, the surveyor observed room temperature Cardiac/D-Dimer test cartridge pouches with "04/06/25", 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 Coulter 6C Plus Cell Hematology Controls, and the Triage D-Dimer/Cardiac Panel test cartridges revealed the following: A) Hematology Controls - stability 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..." 3. TP1 confirmed the above findings during Day 1 exit conference on 04-08-2025 at 4:30 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 during the laboratory tour, a review of the Blood Bank (BB) Quality Control (QC) records, and an interview with the Testing Personnel 1 (TP1), the surveyor determined the laboratory had utilized reagents/materials after expiration dates for patient testing. The expired dates were noted on the reagent bottles to the current date of the survey on 04-08-2025. The surveyor determined three of the four laboratory specialties had utilized expired reagents/materials from 2023-2025. The findings include: 1. During the Chemistry laboratory tour with TP1 at approximately 8:37 AM, the surveyor observed the Vitros CKMB2 calibrators, Levels 1,2,3, Lot 0120 with an Expiration date of 03-20-2025. No open date was written on the vials. Calibrators were utilized from the expiration date of 03-20-2025 to the date of the survey, 04-08-2025. 2. During the Hematology laboratory tour with TP1 at approximately 8:59 AM, the surveyor observed the Epredia Resolve Immersion Oil, Lot 114622 with an Expiration date of 12/2023. No open date was written on the bottle. 3. A review of the BB QC records revealed the following materials had expired on 04-21-2023 but were utilized to run controls and one patient testing on 04-28-2025. A) Screen Cells I Lot 198690 B) Screen Cells II Lot 298690 C) Screen Cells III Lot 398690 D) Check Cells Lot 07447 4. TP1 confirmed the above findings during Day 2 exit conference on 04-09-2025 at 3:30 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 a review of the Hematology and Coagulation maintenance records, a review of the manufacturers' maintenance logs, and an interview with the Testing Personnel 1 (TP1), the laboratory failed to perform and document weekly, monthly, and quarterly maintenance for two analyzers. The surveyor noted no documentation of the weekly maintenance for the Beckman Coulter DxH 690T, and no documentation of the monthly and quarterly maintenance for the Stago Satellite from 2023-2025. The findings include: 1. A review of the 2023-2025 Hematology Beckman Coulter DxH 690T records revealed no documentation of weekly maintenance. 2. A review of the 2023-2025 Coagulation Stago Satellite logs revealed no documentation of monthly or quarterly maintenance 3. During an interview on 04-09-2025 at 1210 PM, TP1 stated TP had refused to follow Laboratory Policies and Procedures even after disciplinary enforcements.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a lack the Quidel Triage Cardiac Panel installation and validation records, and an interview with the Testing Personnel 1 (TP1), the surveyor determined the Laboratory Director failed to document review and approval of the initial verification procedures for Troponin and CKMB before patient testing began. The surveyor noted no documentation was available for review from the last survey, 1-12-2023, to the current survey, 04-08-2025. The findings include: 1. A review of the Quidel Triage records revealed no documentation of installation and validation studies were performed before starting Troponin and CKMB patient testing on the Triage as an alternate analyzer when the Vitros XT 7600 was not operational. 2. An interview with TP1 revealed Quidel Triage Troponin and CKMB patient testing began May 2021 but were not reported on the CMS 116 form from the last survey of 1-12-2023. 3. TP1 confirmed the above findings during Day 2 exit conference on 04-09-2025 at 3:30 PM.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

	This STANDARD is not met as evidenced by: Based on a review of personnel competency records and an interview with Testing Personnel 1 (TP1), the Technical Consultant/Technical Supervisor (TC/TS), failed to assess and document the annual competency of individuals responsible for moderate and high complexity testing. This was noted on ten out of ten Testing Personnel (TP) from the date of the last survey, 1-12-2023 to the date of the current survey, 04-09-2025. The findings include: 1. A review of personnel records listed on the CMS 209 (Laboratory Personnel Report- CLIA) revealed the TC/TS failed to perform and document the annual competency assessments for all ten Testing Personnel from 2023-2025. Personnel records revealed TP1 had performed and signed the competency assessments. 2. During Day 1 exit conference on 04-08-2025 at 4:30 PM, the TP1 confirmed the above findings.