Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465387	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Chicot Memorial Medical Center	2729 S Hwy 65 & 82, Lake Village, AR	

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 upon observation made during a tour of the laboratory, review of reagent package insert, review of the laboratory's "Coagulation QC/Patient Log" review of the laboratory policy and procedure for Prothrombin Time (PT) assay, lack of documentation, and interview with laboratory staff determined that the laboratory failed to document the time that Prothrombin Time (PT) reagents were place on the CA 600 coagulation anayzer as required. Findings follow: A) During a tour of the laboratory on 1/15/25 at 10:55 a.m., the surveyor observed a bottle of reagent labeled only as "INN"placed in the slot used for innovin on the CA 600 coagulation anayzer. B) In an interview on 1/15/25 at 10:55 a.m., the laboratory staff members (#2 and 4 on CMS form 209) confirmed that the bottle contained innovin reagent used in PT testing and stated that the reagent is changed "daily". C) When asked if the date and time the reagent was changed is documented, staff member (# 4 on CMS form 209) produced a copy of the "Coagulation QC/Patient Log" for the CA 600 coagulation analyzer. D) Review of the Coagulation QC/Patient Log revealed that entries are documented as to date, time, "QC01, QC02 and patient names and no entry specifies a change of innovin reagent . E) The manufacturer insert for innovin reagent specified that the reagent was stable for a period of 24 hours on the CA 600 coagulation analyzer. F) Review of the laboratory policy and procedure for PT assays revealed that "after reconstitution the Dade Innovin is stable for 24 hours on board". F) In an interview on 1/15/25 at 10:55 a..m. the laboratory staff members (#2 and #4 on CMS 209 form)

	confirmed that the date and time Dade Innovin was placed on the CA-600 analyzer was not documented.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control Summary Reports for Prothrombin Time assays (PT) for March 2024, July 2024, and November 2024, laboratory policy and procedure CMMC/LAB-GEN-027 titled "General Quality Control Policy, the "Coagulation QC/Patient Log", patient result reports, and interview determined that the laboratory failed to ensure two levels of quality control material are performed every eight hours of patient testing in one of three months reviewed . Findings follow: A) Review of the Quality Control Summary Reports for March 2024 revealed that quality control for PT assays was performed at 05:20 a.m. on 3/24/24 and not performed again until 05:25 a.m on 3/25/24. B) Review of the Coagulation QC/Patient Log for 3/24/24 and 3/25/24 confirmed that PT QC was performed at 05:20 a.m. and not performed again until 05:25 a.m. on 3/25/24 . C) Review of patient result reports revealed that a PT assay was performed for patient, identified as number 1 on a separate patient identification list at 02:42 p.m. on 3/24 /24, (a period of 9 hours since QC was performed), and a PT assay was performed on patient identified as number 2 on a separate patient identification list, on 3/24/24 at 04: 08 p.m., (a period of over 10 hours since QC was performed). D) Review of laboratory policy and procedure CMMC/LAB-GEN-027 titled "General Quality Control Policy" revealed "The coagulation analyzer (CA600) two levels of controls are performed every 8 hours of testing. Daytime schedule: 5-530 AM and 1-130 PM and after 9 PM only if patient testing if performed". E) In an interview on 1/15/24 at 10:56 a.m., the laboratory staff member identified as number 4 on the CMS 209 form confirmed that the PT assays identified above were performed and reported greater than eight hours since the last succesful performance of quality control.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based upon a review of the "Coagulation QC/Patient Log", documentation of corrective action, lack of documentation, and interview of laboratory staff, the laboratory failed to evaluate patient results back to the last successful quality control (QC) performance when corrective taken to achieve acceptable QC results for Activated Partial Thromboplastin Time (APTT) analysis required a change in test system in one of one instances reviewed. Findings follow: A) Review of the

	"Coagulation QC/Patient Log" revealed that on 3/2/24 Dade Citrol Level 3 QC material, lot # 556566, failed to be within acceptable range for APTT analysis at 01: 15 p.m., was repeated and failed to be within acceptable range at 01:29 p.m., was repeated and failed to be in acceptable range at 01:44 p.m., before being acceptable at 02:24 p.m. B) Review of corrective action documentation revealed that in order for QC to be acceptable for APTT analysis fresh reagent was prepared, which represented a change in the testing system for APTT analysis. C) Review of the "Coagulation QC /Patient Log" revealed that the last successful QC for APTT analysis was performed on 3/2/24 at 05:20 a.m. and APTT analysis was performed and reported on one patient, identified as number one on a separate patient identification log, at 06:38 a.m. D) Upon request, the laboratory was unable to provide evidence that the APTT result was evaluated for the patient identified above. E) In an interview on 1/15/25 at 10:30 a.m., the laboratory staff member, number 2 on the form CMS 209, confirmed that the APTT result for the patient identified above had not been evaluated.