Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465364	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Delta Memorial Hospital	811 Highway 65 S, Dumas, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon observations made during a tour of the laboratory, a review of the laboratory's policy and procedure for Prothrombin Time (PT) assays, the manufacturer's package insert for Innovin PT reagent, the application sheets for the Siemens CA-600 coagulation analyzer and, interviews with laboratory staff members the laboratory PT policy and procedure quoted an on-board reagent stability time which was twice the value quoted by test system manufacturers. Findings follow: A) During a tour of the laboratory on 3/11/25 at 01:15 p.m., the surveyor observed a

	Siemens CA-600 coagulation analyzer which was identified as the analyzer used to perform coagulation testing by the laboratory personnel (# 4 on form CMS 209). B) Review of the laboratory's policy and procedure for PT assays revealed, under the heading "Reagent Storage and Stability, on board stability of Innovin is 48 hours". C) Review of the manufacturer's package insert for Innovin PT reagent revealed "on board stability is specified in the reference guides (application sheets) for the different coagulation analyzers". D) Review of the application sheet for the Siemens CA-600 coagulation analyzer revealed the on board stability for Innovin is 24 hours. E) In an interview on 3/12/25 at 10:40 a.m. the laboratory staff member (# 3 on form CMS 209) confirmed that the on board stability for Innovin is defined by the manufacturer as 24 hours and the laboratory's policy and procedure states the on board stability of Innovin is 48 hours.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based upon a review of the laboratory's "Microbiology Laboratory Log" , lack of documentation and interview with laboratory staff, the laboratory failed to document satisfactory positive and negative reactivty quality control (QC) for oxidase, catalase and, coagulase microbiologic reagents. Findings follow: A) Review of the "Microbiology Log" for the twelve months of 2024 revealed that only a check mark was recorded under the heading of "Oxidase QC", "Catalase QC" and, "Coagulase QC" and no positive and negative reactivity results were recorded. B) Upon request, the laboratory was unable to provide positive and negative reactivity results for the reagents identified above. C) In an interview on 3/13/25 at 10:05 a.m., the laboratory staff member (# 3 on form CMS 209) confirmed that positive and negative reactivity was not recorded in the QC results recorded for the reagents identified above.