Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0693675	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Drew County Laboratory	778 Scogin Drive, Monticello, 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
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 observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) In an interview on 5 /22/25 at 10:05 a.m., the laboratory staff member (# 3 on CMS form 209) stated the laboratory staff does not collect inpatient blood samples for testing, that all samples for inpatient testing are collected by nursing personnel. B) During a tour of the Medical/Surgical nursing unit supply closet on 5/22/25 at 10:15 a.m. the surveyor observed one bin containing 100 BD 6.0 ml. K2 EDTA blood collection tubes, lot # 3318891, with an expiration date of 2025-04-30. C) In an interview on 5/22/25 at 10: 05 a.m., the laboratory staff member (# 3 on CMS form 209) confirmed that the blood collection tubes identified above were expired and available for use.
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:
Through review of Biorad Levey-Jennings graphs for quality control (QC) of total bilirubin (TBil) assays, instrument prinit outs of QC results of TBil assays performed on the Abbott Alinity chemistry analyzer, QC Statistic reports for prothrombin time (PT) testing performed on the ACL TOP CTS coagulation anayzer, final verification result reports, and interview with laboratory staff the laboratory failed to: 1) Take corrective action when QC for PT testing failed to meet the laboratory's criteria for acceptability on 6 of 6 occasions reviewed. 2) Evaluate patient results back to the last successful QC performance on 2 of 2 occasions when corrective action taken to achieve acceptable QC results for TBil assays required changes affecting the testing system on the Abbott Alinity chemistry analyzer. Findings follow: 1. The laboratory failed to take corrective action when QC for PT testing failed to meet the laboratory's criteria for acceptability on 6 of 6 occasions reviewed. A) Review of the QC Statistic Report for abnormal control level 3 performed on the ACL TOP 350 CTS coagulation analyzer revealed that the abnormal control was unacceptable on two successive runs on 11/8/24 at 00:04, 00:14, before being acceptable at 00:27; the abnormal control was unacceptable on two successive runs on 11/24/24 at 08:04, 08:18, 08:23, 08:30 before being acceptable at 08:33; the abnormal control was unacceptable on four successive runs on 11/25/24 at 08:04, 08:15, before being acceptable at 08:21; the abnormal control was unacceptable on three successive runs on 11/29/24 at 08:09, 08: 18, 08:28 , before being acceptable at 09:14; the abnormal control was unacceptable on three successive runs on 3/5/25 at 04:49, 05:32, 05:51, before being acceptable at 05:57. B) Review of statements of corrective action revealed that the corrective action was listed as "rerun" for all the instances identified above. Retesting QC does not represent corrective action. C) In an interview on 5/21/25 at 09:00 a.m., the laboratory staff member (# 3 on the form CMS 209) confirmed the only action taken in the instances identified above was to rerun the QC. 2. The laboratory failed to evaluate patient results back to the last successful QC performance when corrective action taken to achieve acceptable QC results for TBil assays required changes affecting the test system. A) Review of instrument print-outs for Biorad Multiqual lot # 460103 revealed that 0n 1/18/25 QC results were unacceptable on four successive runs at 09: 59, 10:36, 10:51, 11:44 before being acceptable at 12:00. The previous acceptable QC for TBil assays was on 1/17/25 at 10:37. B) Review of corrective action taken for TBil assays on 1/18/25 revealed that the test system was recalibrated. C) Review of instrument print-outs for Biorad Multiqual lot # 460103 revealed that 0n 1/19/25 QC results were unacceptable on four successive runs at 11:05, 11:33, 11:47, 11::55, before being acceptable at 12:19. The previous acceptable QC for TBil assays was on 1/18/25 at 12:00. D) Review of corrective action taken for TBil assays on 1/19/25 revealed that the test system was recalibrated. E) Review of patient results revealed that TBil assays were reported on 20 patients (identified as numbers one through twenty on a separate patient identification list) on 1/17/25 and TBil assays were reported on 7 patients (identified as numbers 21 through 27 on a separate patient identification list) on 1/18/25. F) In an interview on 5/21/25 at 01:17p.m., when asked if the patient results identified above had been evaluated, the laboratory staff member (# 3 on form CMS 209) replied "no".