Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465694	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Little River Memorial Hospital	451 West Locke Street, Ashdown, 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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 the prothrombin time (PT), platelet count (Plt) and total Cholesterol (TC) quality control (QC) summary reports for March July and November 2022, corrective action documentation, patient result reports and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in three of three occasions when corrective action to correct QC failures required a change in the testing system. Findings follow: 1) QC failure for PT testing in November 2022 A) Review of QC results for PT testing on November 17, 2022 revealed that the level 1 coagulation control lot # 564830 was out of acceptable range (+ 2 standard deviations (SD)) on five successive attempts at 05:03 a.m., 05:18 a.m., 05:37 a.m., and 05:50 a.m. and 06:19 a.m. until being acceptable at 06:50 a.m.. B) Review of the corrective action documentation revealed the statement "reran, reran with fresh QC not OK, reran with new reagent and new control OK". The change to fresh reagent represented a change in the test system. C) Review of the QC summary for PT testing revealed that the last acceptable QC for PT testing prior to 11/17/22 at 06:50 was performed on 11/16/22. D) Review of patient results for PT testing revealed that 3 patients (1151847, 1171770, 1145348) had PT test results performed since the last successful QC on 11/16/22. 2) QC failure for Plt testing in March 2022 A) Review of QC results for Plt testing on March 2,

	2022 revealed that the normal control lot # 1351402 was out of acceptable range (+ 2 SD) on three succesive attempts at 00:20 a.m, 00:27 a.m. and 00:29 a.m. until acceptable at 00:36 a.m.. B) Review of the corrective action documentation revealed the statement "performed autorinse". The the initiation of autorinse procedure represented a change in the test system. C) Review of the QC summary for Plt testing revealed that the last acceptable QC for Plt testing prior to 3/2/22 at 00:36 a.m. was performed on 3/1/22 at 00:36 a.m D) Review of patient results for Plt testing revealed that 16 patients (#'s 1 through 16 on a separate patient identification list) had Plt test performed between 3/1/22 at 00:36 a.m. and 3/2/22 at 00:36 a.m. 3) QC failure for TC testing in November 2022 A) Review of QC results for TC testing on November 2, 2022 revealed that the Biorad Chemistry Control lot # 56683 was out of acceptable range (+ 2 SD) on two successive occasions at 01:37, a.m and 01:45 a.m. until acceptable at 02:05 a.m.. B) Review of the corrective action documentation revealed the statement "rerun, fresh QC, recal"". The recalibration represented a change in the test system. C) Review of the QC summary for TC testing revealed that the last acceptable QC for TC testing prior to 11/2/22 at 02:05 a.m. was performed on 11/1 /222 at 00:50 a.m D) Review of patient results for TC testing revealed that 6 patients (identified as numbers 1 through 6 on a separate patient identification list) had TC tests performed between 11/1/22 at 00:50 a.m. and 11/2/22 at 02:05 a.m. E) In an interview on 5/16/23 at 2:10 p.m., the laboratory staff member (# 1 on the CMS 209 form) confirmed the results on the occasions identified above had not been evaluated and the laboratory did not have a policy to evaluate patients to the last successful QC when corrective action for QC failures required changes to the analytic systems.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through a review of proficiency testing events of 2022 and interviews with laboratory staff, it was determined the corrective actions performed failed to prevent the recurrence of deficient performance. As evidence by: A) Review of American Proficiency Institute (API) 2022 event one "Chemistry Core" proficiency test results for lipase revealed that two of five challenges were scored as unacceptable with a score of 60%. B) Review of corrective action analysis for lipase in API Chemistry Core 2022 event one revealed that the error was caused by clerical error, "ran wrong sample". C) Review of (API) 2022 event two "Chemistry Core" proficiency test results for lipase revealed that two of five challenges were scored as unacceptable with a score of 60%. D) Review of corrective action analysis for lipase in API Chemistry Core 2022 event two revealed "Issues with samples'. E) Review of the American Proficiency Institute 'Performance Summary" report revealed for lipase 1st event 2022 was scored as 60% and 2nd event 2022 was scored as 60% with an overall assessment of "unsuccessful". F) In an interview on 5/17/23 at 12:10 pm, the laboratory staff member (# 1 in the CMS 209 form) confirmed that the corrective action for deficient performence of lipase analysis was not effective.