Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651950	11/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Perry County General Hospital Lab	206 Bay Avenue, Richton, MS	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of quality control records and patient test counts for the Beckman Coulter AU480 chemistry system, interview on 11/09/2022 at 10:00 a.m. with Technical Consultant #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and lack of documentation of verification of performance specifications for C-reactive protein (CRP) testing, the laboratory failed to verify the manufacturer's performance specifications for CRP testing before patient testing began in July 2021. Findings include: Review of quality control records for the Beckman Coulter AU480 chemistry system and the laboratory's patient test counts revealed CRP testing was added to the Beckman Coulter AU480 chemistry system. In an interview on 11/09/2022 at 10:00 a.m., Technical Consultant #2, listed on the CMS 209 personnel form, stated CRP testing was added to the Beckman Coulter AU480 chemistry system in July 2021. On the day of the survey, 11/09/2022, there was no documentation of verification of performance specifications for C-reactive protein (CRP) testing available for review, to include accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for the laboratory's patient population. The laboratory's annual patient test count for CRP testing was 92.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedure manual for the Abbott i-STAT analyzer, interview on 11/09/2022 at 3:00 p.m. with Technical Consultant (TC) #1, listed on the CMS 209 personnel form, and lack of documentation of thermal probe checks since the analyzer was put in use in May 2021, the laboratory failed to perform and document thermal probe checks every six months, as defined by the manufacturer. Findings include: The manufacturer's procedure manual for the Abbott i-STAT analyzer states to check the thermal probes on each analyzer every six months. There was no documentation available on the day of the survey, 11/09/2022, of the performance of thermal probe checks on the i-STAT analyzer since it was put in use for patient testing in May 2021. In an interview on 11/09/2022 at 3:00 p.m., TC #1 confirmed there was no documentation of thermal probe checks on the Abbott i-STAT analyzer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for urine microalbumin and creatinine testing on the Siemens DCA System and patient test result logs from 04/30 /2022 through 11/03/2022, interview on 11/09/2022 at 4:50 p.m. with Technical Consultant (TC) #2, listed on the CMS 209 personnel form, and lack of establishment of an Individualized Quality Control Plan (IQCP), the laboratory failed to include two levels of control at least once each day patient testing was performed, on a total of 78 days during this time frame when a total of 127 patient specimens were assayed for urine microalbumin and creatinine. Findings include: Review of QC records for urine microalbumin and creatinine testing on the Siemens DCA System from 04/30/2022 through 11/03/2022 revealed two levels of control were performed on 04/30/2022, 05 /28/2022, 06/28/2022, 07/19/2022, 08/17/2022, 09/13/2022, 10/11/2022, and 11/03 /2022. Review of patient test result logs from 04/30/2022 through 11/03/2022 revealed 127 patient specimens were assayed for urine microalbumin and creatinine on a total of 78 days during this time frame when controls were not performed. In an interview on 11/09/2022 at 4:50 p.m., TC #2 confirmed an IQCP was not established for urine microalbumin and creatinine testing on the Siemens DCA System.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter Access 2 immunoassay system quality control and calibration records, confirmation by Technical Consultant (TC) #1, listed on the CMS 209 personnel form, and lack of documentation of comparison of results for creatine kinase-MB (CK-MB) and troponin I testing between the Beckman Coulter Access 2 and the Quidel Triage Meter Pro, the laboratory failed to evaluate the relationship between the results of CK-MB and troponin I tests performed using different methods, at least twice a year, since the last survey on 04/08/2021. Findings include: Review of Beckman Coulter Access 2 immunoassay system quality control and calibration records revealed no documentation of comparison of results for creatine kinase-MB (CK-MB) and troponin I testing between the Beckman Coulter Access 2 and the Quidel Triage Meter Pro since the last survey on 04/08/2021. TC #1, listed on the CMS 209 personnel form, confirmed the Quidel Triage Meter Pro is used for back-up testing for CK-MB and troponin I.