Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0677943	01/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Central Mississippi Health Services	1134 Winter St, Jackson, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation of patient complete blood count (CBC) results since the last survey on 8/1/19 and interview with the testing personnel, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 1/11/22 at 2:00 p.m., the laboratory failed to retain documentation of patient CBC results from the Horiba Medical ABX Micros 60 hematology analyzer, that is transcribed into electronic medical records, for at least two years. Findings include: Interview with the testing personnel, listed on the CMS 209 personnel form, on 1/11/22 at 2:00 p.m. revealed patient CBC results are manually entered into the patient electronic medical records from the Horiba Medical ABX Micros 60 hematology analyzer results, whether results are printed from the analyzer or written on a manual report form. On the day of the survey, there was no documentation of the patient CBC results that were transcribed into electronic medical records, since 8/1/19. The testing personnel stated on 1/11/22 at 2:00 p.m. that CBC results from the hematology analyzer are not retained after the results are entered in the patient electronic medical records. THIS IS A REPEAT DEFICIENCY.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, calibration records, and confirmation by the testing personnel listed on the CMS 209 personnel form, the laboratory failed to perform calibration of the Horiba Medical ABX Micros 60 hematology analyzer at least every six months, according to laboratory policy. Findings include: Review of the laboratory procedure manual revealed the Quality Control Policy states, "Calibration is performed every six months or as often as the manufacturer recommends." Review of calibration records since the last survey on 8/1/19 revealed no documentation of calibration of the Horiba Medical ABX Micros 60 hematology analyzer since 8/14/20. The testing personnel confirmed calibration has not been performed since 8/14/20.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's acceptable ranges for Horiba Medical Minotrol hematology controls, daily quality control (QC) records for the Horiba Medical ABX Micros 60 hematology analyzer from 12/17/19 through 9/22/21, and patient test results, at least two of three levels of control failed to meet the manufacturer's criteria for acceptability for two days during this time frame, when a total of three patient complete blood count (CBC) tests were performed and reported. Findings include: Review of manufacturer's acceptable ranges for Horiba Medical Minotrol hematology controls, daily QC records for the Horiba Medical ABX Micros 60 hematology analyzer from 12/17/19 through 9/22/21, and patient test results revealed on the following days two levels of control were outside the manufacturer's acceptable ranges when patient CBC tests were performed and reported: 4/13/21 - Normal and High controls outside acceptable ranges for red blood cell count and platelets. CBC reported for Patients #70027 and #6812. 4/15/21 - Normal and High controls outside acceptable ranges for platelets. CBC reported for Patient #39554.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory Quality Assessment (QA) procedure manual and interview with the technical consultant on the day of survey, 1/11/22 at 1: 30 p.m., the laboratory failed to ensure that a comprehensive QA program designed to monitor and evaluate the overall quality of the total testing process was maintained and followed to assure the quality of laboratory services provided. Findings include: 1. Review of the QA procedure manual revealed the QA policy states, "The technical consultant will complete a Quality Assessment Report each month (see form) and complete one random chart review per month (see form)." The laboratory did not ensure the QA process was followed monthly as specified in the policy. On the day of the survey, there were no monthly checklists available for review for 8/1/19 through 1 /11/22. 2. The technical consultant confirmed the laboratory failed to ensure the monthly QA checklists were completed and maintained each month since the last survey on 8/1/19.