Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0318821	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
East Central Ms Health Care Inc	1488 Highway 487, Sebastopol, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the Boule Con-Diff hematology controls, Lot #21802, in use by the laboratory on 4-3-18 at 10:00 a.m. and review of the manufacturer's instructions for the controls, the laboratory failed to follow manufacturer's instructions for storage of the Boule Con-Diff hematology controls in use with patient complete blood count (CBC) testing on the CDS Medonic M-Series hematology analyzer. Findings include: Manufacturer's instructions for Boule Con-Diff hematology controls state that the controls are stable for fourteen days after opening, when stored refrigerated. Observation of the three vials of Boule Con-Diff hematology controls, Lot #21802, (low, normal, and high levels) in use on the day of the survey revealed there was no open date for the vials to ensure the controls were not used past the stability date.
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 CDS Medonic M-Series hematology analyzer Monthly Quality Control Summary Reports from 9-18-17 through 3-29-18, All Sample Summary Reports, and patient electronic medical record test reports, the laboratory failed to include two control materials each day patient complete blood count (CBC) testing was performed on the hematology analyzer for two days during this time frame, when a total of four patient CBC tests were performed and reported. Findings include: Review of CDS Medonic M-Series hematology analyzer Monthly Quality Control Summary Reports from 9-18-17 through 3-29-18, All Sample Summary Reports, and patient electronic medical record test reports revealed the laboratory failed to include two control materials for CBC testing on the following days when patient testing was performed and reported: 12-6-17--Patient #1381120, #1017100, #1412070 CBC results reported. 1-18-18--Patient #1371640 CBC results reported.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of CDS Medonic M-Series hematology analyzer Monthly Quality Control Summary Reports from 9-18-17 through 3-29-18, All Sample Summary Reports, patient test reports, and the laboratory's Technical Procedure Manual, the testing personnel, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, failed to follow the laboratory's quality control policy for two days during this time frame when a total of four patient CBC tests were performed and reported. Findings include: The laboratory's Technical Procedure Manual policy for Medonic M-Series Quality Control states, "ECMHCI laboratory employees will run three levels of assayed controls at the beginning of the day. A minimum of two levels must be within range of manufacturer's specified ranges before patient samples will be run." Review of CDS Medonic M-Series hematology analyzer Monthly Quality Control Summary Reports from 9-18-17 through 3-29-18, All Sample Summary Reports, and patient test reports revealed the testing personnel failed to include a minimum of two levels of control for CBC testing on two days when a total of four patient CBC tests were performed and reported. Refer to D5447 (Failure to include two levels of control each day of patient testing).