

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2273215	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Fort Smith Emergency Hospital, Llc	Street Address, City, State 4701 Phoenix Ave, Fort Smith, 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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Medonic M-series User's Manual, Medonic -M series CBC analyzer procedure, quality control summary log from the Medonic M-series, and interviews with laboratory Technical Consultant, it was determined the laboratory failed to document function checks as defined by the manufacturer. Survey findings include: A. A review of the Medonic M-series User's Manual revealed that Instrument Startup is required daily. The following sequence guides the operator through the beginning of the day startup routine for the analyzer. There are 2 simple steps to follow which takes the user through a background and control analysis sequence with detailed guidance at each step. It is recommended that the performance of the Medonic M-Series system is checked daily with certified blood controls authorized by Boule. B. The laboratory procedure Medonic-M series CBC analyzer states "three levels control material performed daily", and "two levels must pass prior to patient testing". C. During a review of quality control summary log for February 2023 it was determined on 2/27/2023 and morning of 2/28/2023, the laboratory had documentation of background counts but no documentation of the quality control for Medonic M-series CBC analyzer. The laboratory failed to document quality control on one of twenty-eight days in February 2023. D. In a review of patient test reports it was determined that eleven patients had complete blood counts reported from the Medonic M-Series CBC analyzer on 2/27/2023 and 2/28/2023. Patients #1398, #1399, #1403, #1406, #1409, #48448, #1414, #48462, and #900424000019 were reported on</p>

2/27/2023. Patients #1420, and #1424 were reported on 2/28/2023. E. In an interview at 2:07 p.m. on 10/17/2023 the technical consultant (TC) (TC listed on the form CMS-209) confirmed the laboratory had no documentation of quality control counts on 2/27/2023 and morning of 2/28/2023.