Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0664963	02/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Mcg Health	818 St Sebastian Way, Suite 400, Augusta, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 13, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records for the secondary Beckman

	Coulter ACT Diff 2 hematology analyzer,serial number 29261811, and staff interview, the laboratory failed to perform calibration verification every 6 months as required. Findings include: 1. Review of calibration records revealed the analyzer was calibrated upon installation on 8/26/16 and calibration verification was performed on 3 /9/17. No other records of calibration or calibration verification are available. 2. Interview with testing personnel # 1 (see CMS 209) on February 13, 2018 at 11:30 am in the counseling room confirmed calibration verification was not performed every 6 months as required.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel competency assessment policy and yearly checklist as well as interview with testing personnel # 1 (see CMS 209) the technical consultant failed to ensure the competency assessment policy and procedure for testing performed in the speciality of hematology met the 6 required criteria. Findings include: 1. Review of the laboratory's competency assurance policy revealed initial competency is verified and evaluated by a preceptor and yearly competency of testing personnel is evaluated by having the laboratory supervisor observe testing personnel prepare and analyze 5 specimens for external proficiency testing. 2. Review of the yearly competency assessment checklist revealed it does not include the 6 required criteria and does not list the test each personnel is competent to perform. 3. Interview with testing personnel # 1 (see CMS 209) on February 13, 2018 in the counseling office at 11:30 am confirmed competency assessment is not performed by the technical consultant and it does not include the 6 required criteria for assessment.