Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	11D0257390	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Sylvan Grove Hospital	1050 Mcdonough Road, Attn Laboratory, Jackson, 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 October 23, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the Beckman/Coulter LH500 (LH500) hematology procedure manual, and LH500 Quality Control (QC) documents, and staff interview, the laboratory failed to establish the frequency of performing Quality Control (QC) as required by the State Licensure Requirements for Hematology analyzers. Findings: 1. Review of the LH500 procedure manual showed that the Laboratory did not have a frequency listed for performing QC for the Hematology Analyzer. QC must be performed each shift of patient testing per State of Georgia Laboratory Regulatory Requirements. 111-8-10-.14 Quality Control for Hematology. Instruments used in hematological examination of specimens shall be recalibrated, retested or reinspected, as appropriate, each day of use. Each procedure shall be recalibrated or rechecked each shift of use with standards or controls covering the entire range of expected values, unless required more frequently by the manufacturer or federal laboratory regulations. Tests such as the hematocrit and one-stage prothrombin time test shall be run in duplicate except as specified in published guidelines. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by the laboratory. All control materials used to satisfy the control requirement must have documented established limits. Authority: O.C.G.A. 31-22-1 et seq.. 2. Review

	of a universal example of LH500 QC showed the following: a. March 2017 - 58 QC runs for 31 days - showed 33 QC runs were performed greater than 8 hours apart b. July 2017 - 80 QC runs for 30 days - showed 54 QC runs were performed greater than 8 hours apart c. April 2018 - 78 QC runs for 31 days - showed 34 QC runs were performed greater than 8 hours apart d. July 2018 - 82 QC runs for 31 days - showed 42 QC runs were performed greater than 8 hours apart 3. Interview with the Laboratory Manager, and Laboratory Administrator, on October 23, 2018 at approximately 3:30 pm in the Conference Room, confirmed the above forementioned statement.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Laboratory Policy and Procedure manuals, and staff interview, the current Laboratory Director failed to approve, date and sign the Laboratory Policy and Procedure manuals. Findings: 1. Review of the Policy and Procedure manuals for Hematology, Chemistry, Urinalysis, Coagulation, Blood Bank, and Miscellaneous Testing, showed that the current Laboratory Director had not reviewed, approved, and signed the procedure manuals. 2. Interview with Lab Manager on October 23, 2018, at approximately 11:19 am in the conference room, confirmed that the current Laboratory Director had not approved and signed any of the Laboratory Department Policy and Procedure Manuals.
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 the calibration documents for the Beckman Coulter LH500 Hematology Analyzer (LH500), and staff interview the laboratory failed to calibrate the LH500 at least once every 6 months. Findings: 1. Review of the calibration documents for the LH500, the laboratory calibrated the LH500 in January 2017, and September 2018. There was no documentation of calibrations performed between January 2017, and September 2018. (July 2017, January 2018, July 2018). 2. Staff interview with Lab Manager, on October 23, 2018 at approximately 3 pm in the conference room confirmed that there was not documentation for calibrations on the LH500 between January 2017 and September 2018.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the review of the Blood Bank Refrigerator, Laboratory Refrigerator, and Laboratory Freezer temperature monitor graphs, and staff interview, the laboratory failed to change the temperature monitor graph papers from 3-29-18 to 7-2-18. Findings: 1. Review of the Blood Bank Refrigerator, Laboratory Refrigerator, and the Laboratory Freezer termperature monitor graphs, graph paper was placed on the temperature monitor recorder device on May 29, 2018 and was not removed until 7-2-2018. There were no other graphs available between May 29, 2018 and July 2, 2018. Review of the graphs show that the recorder went around on the same graph numerous times. 2. Interview with the laboratory Manager, and the Laboratory Administrator, on October 23, 2018 at approximately 4pm in the blood bank area, confirmed the above forementioned statement.