Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0265983	07/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital And Manor	1500 E Shotwell St, Bainbridge, 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 July 18, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition and deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings: For details refer to D2015.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) and/or the testing personnel (TP) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute(API) PT document review revealed the LD and TP performing the testing of the PT samples did not sign the attestation statement for the following PT events: 2018 -- Immunohematology (Event 1). 2. API PT document review revealed the LD not sign the attestation statement for 2018 Miscellaneous Chemistry (Event 1). 2. An interview with Staff #2 (CMS 209) in a conference room on 7/18/2019 at approximately 7:45 p.m. confirmed the LD and TP did not attest to the aforementioned PT events.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Proficiency Institute (API) document review revealed the laboratory was unable to provide the following PT attestation statements at the time of survey: 2018 Immunohematology (First Event), 2018 Chemistry (Second Event), and 2019 Hematology/Coagulation (First Event). 2. American Proficiency Institute (API) document review revealed the laboratory was unable to provide the following PT reports at the time of survey: 2017 Third Event -- Bacteriology and Hematology /Coagulation; 2018 Second Event -- Chemistry; 2019 First Event -- Hematology /Coagulation. 3. An interview with Staff #2 (CMS 209) in a conference room on 7/18 /2019 at approximately 7:45 p.m. confirmed the aforementioned documents were unavailable at the time of survey. This is a REPEAT deficiency.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to evaluate and verity all PT activities as required. Findings include: 1. API (American Proficiency Institute) PT document review revealed the laboratory failed to perform corrective action for the following PT scores less than 100 percent -- 2018: Chemistry (99 percent - First Event); Chemistry (99 percent - Second Event). 2. An

	interview with Staff #2 (CMS 209) in a conference room on 7/18/2019 at approximately 7:45 p.m. confirmed the aforementioned lack of corrective action for PT scores less than 100 percent.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), quality assurance (QA) documents, and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor and assess all phases of laboratory testing as required. Findings include: 1. Laboratory SOP review revealed the SOP did not include a required quality assurance (QA) policy and procedure to monitor and assess all phases of testing. 2. Laboratory QA document review revealed there were no Levey-Jennings charts available at the time of survey for the three chemistry analyzers (UniCel Dxl 800, DXC 600 i, and the DXC 800 pro) for 2017 (June through December), 2018 (January through December), and 2019 thus far. 3. An interview with Staff #2 (CMS 209)on 7/18/2019 in a conference room at approximately 7:45 p.m. confirmed there was not a QA policy and procedure in the laboratory SOP. 4. During the same interview, Staff #2 (CMS 209) confirmed there were no Levey-Jennings charts available at the time of survey for the aforementioned instruments for the aforementioned dates.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to monitor and document temperature and humidity as required. Findings include: 1. Review of laboratory temperature and humidity logs revealed there were no Hematology temperature and humidity logs for 2017 (June through December) 2018 (January through December), and 2019 thus far. 2. Review of laboratory temperature logs revealed there were no temperature logs for the Immunohematology area for 2017 (June through December), 2018 (January through December), and 2019 thus far. 3. An interview with Staff #2 (CMS 209) in a conference room on 7/18/2019 at approximately 7:45 p.m. confirmed the aforementioned lack of temperature and humidity logs.

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 both DxH 600, (DxH600) Hematology Analyzers and staff interview, the laboratory failed to provide documentation for performing calibrations every six months. Findings: 1. Review of the calibration documents for both DxH600 Hematology analyzers revealed the the analyzers were not calibrated every 6 months. Calibration documents showed that the DxH600 analyzers were calibrated on the following dates: 10-23-2017 on installation 12-08-2018 14 months 06-04-19 6 months 2. Interview with staff# 2 (CMS 209 form), on July 7, 2019 at approximately 7:30 p.m. in the hospital education room confirmed that the calibrations for the two DxH600 Hematology analyzers were calibrated as stated above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control documents for the Hematology Analyzers, the

	Chemistry Analyzers, the Coagulation Analyzer, and staff interview, the laboratory was not printing Levey Jennings charts to monitor over time the accuracy and preciesion of test performed. Findings: 1. Review of the Quality Control documents for the following instruments: Two Beckman Coulter DxH600 (DxH), Hematology Analyzers Beckman Coulter Unicell DxC 600-Pro, (DxC 600P), Chemistry Analyzer Beckman Coulter Unicell DxC 600i (DxC 600i), Chemistry Analyzer Beckman Coulter DxI 800 (DxI 800), Chemistry Analyzer Sysmex CA-600 (6A600), Coagulation Analyzer The review showed that the laboratory had not printed Levey Jenning charts, to monitor over time the accuracy and precision of test performance, in Hematology, Chemistry, and Coagulation. 2. Interview with Staff #2 (CMS 209 form), on July 18, 2019, at approximately 7:40 pm, in the Hospital Conference, confirmed that the laboratory did not print Levey Jennings charts for the above mentioned instruments.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the Competency Documents, and staff interview, the laboratory failed to have complete competency documents for 4 out of 10 Testing Personnel. Findings: 1. Review of the Competency Documents, the laboratory failed to have a competency assessment for Staff # 3, 5, 6, and 9.(CMS 209 form) for the year 2018. 2. Interview with staff #2(CMS 209 form) on July 18, 2019, at approximately 7:14 pm in the Educational Class Room, confirmed the aforementioned staff did not have competency assessments for 2018.