Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0265635	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Clinch Memorial Hospital	**Street Address, City, State** 1050 Valdosta Highway, Homerville, 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 20, 2019. 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:
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API), proficiency testing provider, Performance Evaluations the laboratory failed to document corrective action for unacceptable analytes scores for 2017 and 2018 events. Findings: 1. Review of the 2017 Chemistry Core 2nd event Performance Evaluation the Laboratory: scored 40% for the analyte CO2. The plan of correction documented is unacceptable, no follow-up plan documented scored 60% for the analyte Myoglobin. The plan of correction documented is unacceptable, no follow-up plan documented scored 60% for the analyte Alcohol. The plan of correction documented is unacceptable, no follow-up plan documented 2. Review of the 2017 Chemistry Core 3rd event Performance Evaluation the laboratory: scored 40% for the analyte Phosphorus. The plan of correction documented is unacceptable, no follow-up plan documented scored 80% for the analyte Myoglobin. The plan of correction documented is unacceptable, no follow-up plan documented 5. Review of the 2017 Immunology/Immunohematology

	3rd event Performance Evaluation the laboratory: failed to submit the results by the deadline. A self evaluation was performed but no follow-up plan documented to prevent this from reoccurring. 6. Interview with the Laboratory Manager, on February 20, 2019, at approximately 5:35 pm in the laboratory manager's office confirmed that there was not an acceptable plan of correction provided for the aforementioned proficiency testing performance evaluation results.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API), proficiency testing provider, Performance Evaluations the laboratory failed to document corrective action for unacceptable analytes scores for 2017 events. Findings: 1. Review of the 2017 Hematology/Coagulation 1st event Performance Evaluation the laboratory: scored 50% on the Microscopy Urine Sediment with no corrective action documented. 2. Review of the 2017 Hematology /Coagulation 2nd event Performance Evaluation the laboratory: scored 80% on the Blood Cell Identification, with no corrective action documented 3. Interview with the Laboratory Manager, on February 20, 2019, at approximately 5:35 pm in the laboratory manager's office confirmed that there was not an acceptable plan of correction provided for the aforementioned proficiency testing performance evaluation results.
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing performance evaluations, the laboratory failed to submit results for the 3rd event of 2017 in the speciality of Immunohematology. Findings: 1. Review of the performance evaluation report for the 3rd event of 2017 Immunohematology testing revealed the laboratory failed to submit the results to API before the deadline. A self evaluation was performed but no plan of correction to make sure this does not occur again was documented. 2. Interview with the laboratory manager on February 20, 2019, at approximately 5:35 pm in the laboratory manager's office confirmed there was no plan of correction to prevent this from happening again.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems in the speciality of chemistry including routine chemistry, toxicology and endocrinology in 2017, 2018 and 2019 up to the date of the survey on February 20. Refer to: D5413 and D5469
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 review of temperature charts for the freezer used to store controls for the Siemens Dimension EXL 200 chemistry analyzer, review of temperature requirements posted by the manufacturer on boxes of controls used on the analyzer and staff interview, the laboratory failed to store controls at the temperature required by the manufacturer. Findings include: 1. Review of temperature storage requirements for BioRad Liquid Assayed Multiqual controls, Immunoassay Plus controls, and Cardiac Markers Plus controls, used on the Siemens Dimension EXL 200 analyzer revealed Bio-Rad controls must be stored at negative 20 to negative 70 degrees centigrade, 2. Review of temperature charts for the freezer used to store the controls revealed the laboratory set the acceptable temperature range at negative 10 to negative 20 degrees. 3. Review of temperature charts for March 2018, November 2018 and December 2018 revealed the temperature was outside the acceptable range on 91 of 92 days recorded. 4. Interview with the general supervisor (see CMS 209) on February 20, 2019 in the supervisor's office at 5 pm confirmed the acceptable temperature range is set at negative 10 to negative 20 degrees centigrade and the temperature of the freezer routinely measures outside the acceptable range set by the manufacturer.
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 Unicel DXH 800 hematology analyzer (DXH 600) and staff interview the laboratory failed to document the calibration for the hematology analyzer at least every 6 months. Findings: 1. Review of 2017 and 2018 calibration documents for the DXH 600 revealed no documentation of calibration between May 8, 2017 and April 11, 2018. 2 Interview with the general supervisor (see CMS 209), on February 20, 2019 at 5 pm in the supervisor's office, confirmed there was no documentation of calibration for the DXH 600 between May 2017 and April 2018.
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 the Quality Control (QC) procedure and QC documents for the Abbott iStat analyzer (iSTAT) used for testing Arterial Blood Gasses (ABG's) and staff interview, the laboratory failed to document two controls of different concentrations at least once each day patient specimens were assayed. Findings: 1. Review of the QC procedure and QC documents for the iSTAT revealed the laboratory did not document two controls of different concentrations each day of patient testing for ABG's. 2. Interview with the general supervisor (see CMS 209) on February 20, 2019 at approximately 5:30 pm in the supervisor's office confirmed the laboratory was not performing two levels of different concentrations of controls at least once each day patient specimens were assayed. It was also confirmed an Individualized Quality Control Plan (IQCP) had not been performed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Siemens Dimension EXL 200 chemistry analyzer , review of the package inserts for controls, review of instructions for use of controls and staff interview, the laboratory failed to establish criteria for acceptability of the controls. Findings include: 1. Review of electronic Levey Jennings charts, logs used to record QC results, monthly reports of QC data submitted to BioRad for evaluation and comparison with other laboratories, historical QC data printed for the surveyor from the Siemens analyzer during the survey and BioRad control assay sheets, including Liquid Assayed Multiqual, Immunoassay Plus, Cardiac Markers Plus, and Lyphochek Diabetes Control, revealed the laboratory uses the 3 standard deviation (SD) range given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. 2. Review of control values obtained by the laboratory also revealed the standard deviations calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 2. Review of on-line instructions for all controls listed above and obtained from BioRad at www.myeinserts.com revealed each laboratory should establish their own acceptable ranges and use the assayed ranges as a guide. 4. Interview with the general supervisor (see CMS 209) on February 20, 2019 at 5 pm in the supervisor's office confirmed the laboratory uses the standard deviation and 3 SD ranges from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory test reports and staff interview, the laboratory failed to include the address of the laboratory where testing is performed. Findings include: 1.

	Review of laboratory reports revealed the address of the laboratory printed on patient reports is a post office box and the physical address of the laboratory is not listed. 2. Interview with the general supervisor (see CMS 209) on February 20, 2019 at 5 pm in the supervisor's office confirmed the physical address of the laboratory is not listed on patient test reports.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to provide overall management and direction for analytic systems in the speciality of chemistry including routine chemistry, toxicology and endocrinology in 2017, 2018 and 2019 up to the date of the survey on February 20. Refer to D 6093
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Siemens Dimension EXL 200 chemistry analyzer , review of the package inserts for controls, review of instructions for use of controls and staff interview, the laboratory director failed to ensure the laboratory established criteria for acceptability of the controls. Findings include: 1. Review of electronic Levey Jennings charts, logs used to record QC results, monthly reports of QC data submitted to BioRad for evaluation and comparison with other laboratories, historical QC data printed for the surveyor from the Siemens analyzer during the survey and BioRad control assay sheets, including Liquid Assayed Multiqual, Immunoassay Plus, Cardiac Markers Plus, and Lyphochek Diabetes Control, revealed the laboratory uses the 3 standard deviation (SD) range given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. 2. Review of control values obtained by the laboratory also revealed the standard deviations calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 2. Review of on-line instructions for all controls listed above and obtained from BioRad at www.myeinserts.com revealed each laboratory should establish their own acceptable ranges and use the assayed ranges as a guide. 4. Interview with the general supervisor (see CMS 209) on February 20, 2019 at 5 pm in the supervisor's office confirmed the laboratory uses the standard deviation and 3 SD ranges from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to ensure the general supervisor who is also a testing personnel was assessed for competency in 2017, and 2018. Findings include: 1. Review of laboratory personnel competency records for 2017 and 2018 revealed no documentation of competency assessment for the general supervisor (see CMS 209) who is also a testing personnel for duties assigned as the general supervisor or the 6 criteria required for testing personnel. 2. Interview with the general supervisor (see CMS 209) on February 20, 2019 at 5 pm in the supervisor's office confirmed documentation of competency assessment for general supervisor duties and testing personnel competency assessment is not available for the general supervisor in 2017 and 2018.