Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0261672	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Chatuge Regional Hosp & Nursing Home	**Street Address, City, State** 110 Main Street, Hiawassee, 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	Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 23, 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 deficiency was cited:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedure manual (SOP) review, the laboratory failed to establish a written procedure for all tests, assays, and examinations performed by the laboratory. Findings include: 1. The laboratory failed to establish a written procedure for a sterility check of the bacteriology media. 2. The laboratory failed to establish a written procedure for quality control (QC) of the bacteriology media. 3. An interview with the laboratory supervisor on 1/23/18 at approximately 3 p.m. in a hospital room confirmed the laboratory SOP did not contain a procedure for bacteriology media sterility check or QC.
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 calibration document review and staff interview, the lab failed to calibrate the Penta 60 C+ and Pentra 80XL hematology analyzers every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Pentra 60 C+ was calibrated 02/17/16, 04/28/16, 03/31/17, and 07/28/17. A span of 11 months for calibration between 2016 and 2017. 2. Review of calibration data revealed the Pentra 80 XL was calibrated 02/17/16, 05/05/16, 03/31/17, and 07/28/17. A span of 10 months for calibration between 2016 and 2017. 2. Interview with testing personnel #11 (CMS 209 form) on 01/23/18 at approximately 2 PM in a back hospital room, confirmed the time spans.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms, and to check each batch for sterility. Findings include: 1. QC document review revealed the laboratory failed to perform a sterility check for each batch of media for 2016, 2017, and 2018 thus far. 2. QC document review revealed the laboratory failed to check each batch of media for its ability to support growth. or, as appropriate, inhibit growth for each batch of media for 2016. 2017, and 2018 thus far. 2. An interview with the laboratory supervisor in a hospital room on 1/23/18 at approximately 3:00 p.m. confirmed a sterility check for each batch of media had not been performed nor a check for each batch of media to support or, as appropriate, inhibit growth for 2016, 2017, and 2018 thus far.