Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1004148	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Verzosa Ungab Internal Medicine	2851 Stage Center Drive, Bartlett, TN	

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
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 a review of 2018 complete blood count (CBC) instrument calibration records, the corrective action logs, the service records and interview with the technical consultant, the laboratory failed to calibrate the hematology analyzer at least once every six months in 2018. The findings include: 1) Review of the 2018 CBC instrument calibration records revealed a calibration was due in August 2018, but not performed. 2) Review of the corrective action logs and the service records revealed

	numerous dates of corrective actions, dates that the instrument was shut down due to failures, and technical onsite service performance, with no calibration verification or performance between February 8, 2018 and February 4, 2019. 3) Interview on August 13, 2019 at 1:30 p.m. with the technical consultant confirmed there was no calibration verification or performance between February 8, 2018 and February 4, 2019 with numerous corrective actions and technical onsite service performance.
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 2019 complete blood count (CBC) quality control (QC) records and interview with the technical consultant, the laboratory failed to maintain the CBC QC manufacturer's package insert with the stated values for the CBC analytes. The findings include: 1) Review of the 2019 CBC QC records revealed lot number 9042 was in use from April 2, 2019 to April 19, 2019 and lot number 9070 was in use from May 7, 2019 to May 31, 2019 with no manufacturer's package insert with the stated mean and limits for the CBC analytes. 2) Interview on August 13, 2019 at 1:45 p.m. with the technical consultant confirmed that lot numbers 9042 and 9070 were in use with no manufacturer's package insert to ensure the mean and limits were correct during use.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan and interview with the technical consultant, the laboratory failed to establish and maintain a QA plan for the post-analytic process for the complete blood count (CBC), in 2018 and 2019. The findings include: 1) Review of the QA plan revealed no procedure to assess or monitor the process for patient laboratory reports that are manually entered and/or scanned into the electronic medical record (EMR) for the complete blood count. There is no procedure for the patient paper charts to include the patient CBC instrument printouts. 2) Interview on August 13, 2019 at 11:00 a.m. with the technical consultant confirmed

	the QA plan for the CBC review post-analytic process was not included in the QA plan.