Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2106017	11/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Brigs Center For Cancer Care	1400 Dowell Springs Blvd Ste 220, Knoxville, 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 the Laboratory's Procedure for Calibration Verification for the Hematology analyzer, Calibration Verification records for 2018 and 2019 and upon interview with the Lead Testing Person, determined the laboratory failed to ensure that calibration verification was performed every six months for the two year period. The findings include: 1. A review of the Laboratory's Procedure for Calibration Verification stated that

	Calibration Verification is to be done every 6 months. 2. A review of Calibration Verification records for the hematology analyzer disclosed a 9 month period between calibration verifications in 2018 (3/23/18 to 12/06/18) and an 11 month period between 2018 and 2019 (12/06/18 to 11/22/19). 3. An interview with the Primary Testing Person at 12:45 p.m. on November 26, 2019 confirmed the calibration verifications for the Hematology Analyzer were not performed every 6 months for the two year period. ==========
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 procedure manual, lack of new lot number verification for Complete Blood Count (CBC) control materials and interview with the Lead Testing Person, it was determined the laboratory failed to follow procedure for verifying the acceptable ranges of each new lot of CBC control materials prior to use for 2018 and 2019. The finding include: 1. A procedure review states to verify acceptable ranges for new lot numbers of CBC control materials prior to use. 2. There was no documentation for verification of new lot numbers of CBC control materials prior to use for 2018 and 2019. 2. An interview at 12:45 p.m. on November 26, 2019 with the Lead Testing Person confirmed that new lot number verification of CBC control materials had not been performed for the two year period. ==========
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: ========== Based on review of the laboratory's Quality Assurance (QA) Plan, lack of monthly patient audits and upon interview with the Lead Testing Person, it was determined the laboratory failed to follow their QA Plan for monitoring patient audits monthly for 2018 and 2019. The findings include: 1. A review of the QA Plan states that 5 random patient audits are to be performed

	monthly for completeness and accuracy of testing. 2. There was no documentation of monthly patient audits for 2018 or 2019. 3. An interview at 12:45 p.m. on November 26, 2019 with the Lead Testing Person confirmed that monthly patient audits had not been performed for the two year period. ==========