Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2128376	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Cancer & Blood Center, Llc - Monroe	2151 - B West Spring Street, Suite 200, Monroe, 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	Based on an initial CLIA Survey performed on July 24, 2018, this facility was found to be noncompliant with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on hematology document review and staff interview, the laboratory failed to verify the performance characteristics of the hematology laboratory equipment before reporting patient test results as required. Finding include: 1. Beckman Coulter AcT Diff 2 document review revealed the laboratory failed to verify the accuracy, precision, and reportable range of test results for the test system before reporting patient results in 2017 or 2018 thus far. 2. An interview with Staff #2 (CMS 209) in a medical office on 7/24/18 at approximately 5:00 p.m. confirmed instrument validation for the AcT Diff 2 was not performed in 2017 or 2018 thus far.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competencies and staff interview, the laboratory director (LD) failed to ensure that all laboratory duties were properly performed as required. Findings include: 1. TP competency review revealed the 2017 initial training competencies were performed by unqualified personnel for the following TP listed on CMS 209: Staff #2, Staff #4, Staff #5, Staff #6, and Staff #8. 2. TP competency review revealed the 2018 annual competencies were performed by unqualified personnel for the following TP listed on CMS 209: Staff #2, Staff #5, and Staff #8. 2. An interview with Staff #2 in a medical office on 7/24/18 at approximately 5:00 p.m. comfirmed the aforementioned competencies were performed by unqualified personnel in 2017 and 2018.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) or qualified designee failed to perform competencies at least semiannually during the first year the TP tests patients specimens. Findings include: 1. TP competency review revealed the TC or qualified designee failed to perform six-month competencies on the following TP (CMS) during 2017: Staff #2, Staff #3, Staff #4, Staff #5, Staff #6, and Staff #8. 2. An interview with the TC in a medical office on 7/24/18 at approximately 5:00 p.m. confirmed six-month competencies were not performed in 2017 for the aforementioned TP: