Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2237654	04/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
University Cancer & Blood Center, Llc-Commerce	110 Mercer Place, Commerce, 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 April 23, 2025. 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: A review of 2023 - 2025 Proficiency Testing Records, confirmed that the laboratory failed to enroll in a proficiency testing program for the high complexity testing. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Proficiency Testing Records confirmed that the laboratory was not enrolled in a proficiency testing program for sodium citrate platelet count or the bone marrow biopsy procedures. 2. An exit interview, conducted with TC1 (see form CMS-209), on April 23, 2025, at 1:30pm, confirmed that the laboratory failed to enroll in a proficiency testing program for all non-waived test procedures performed in the laboratory.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	(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: A review of the laboratory's i-STAT 1 Daily Operating Procedure confirmed that testing personnel failed to follow the manufacturer's procedure. THE FINDINGS INCLUDE: 1. An interview with the Technical Consultant 1 (see CMS Form 209) confirmed that blood samples were drawn into a light green top (Lithium Heparin) and plasma used for testing on the Chemistry i-STAT analyzer. 2. Review of the The i-STAT 1 Daily Operating Procedure confirmed the instrument requires the collection of venous whole blood samples. 3. An exit interview conducted with Technical Consultant 1 (see CMS Form 209), on April 23, 2025, at 1:30pm confirmed testing personnel failed to follow the manufacturer's procedure.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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: A review of 2023 - 2025 Quality Assurance (QA) Records and 2023 - 2025 Personnel Training and Competencies Records (PTC), and Letters of Delegation confirmed that Laboratory Director (LD) failed to fulfill his duties of the overall responsibilities and administration of the laboratory operations. THE FINDINGS INCLUDE: 1. A review of the Letter of Delegation, approved and signed by the LD, dated January 1, 2025 confirmed that the LD delegated QA oversight duties to unqualified TP1(see 2025 CLIA Form 209). 2. A review of 2023 - 2025 QA Records confirmed that 23 out of 23 of the QA reviews were incomplete and performed by unqualified staff. 3. A review of the aforementioned QA Records confirmed that the LD did not review QA Records. The QA review was performed by the Laboratory Manager. 4. A review of the PTC Records revealed that the 2025 Competency Form for TC1 was signed by the LD, but the competency form was not complete. 5. An exit interview with TC1, on April 23, 2025, at 1:30pm, confirmed that the LD failed to fulfill the QA and overall responsibilities and administration of the laboratory operations.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.

	1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: A review of the Laboratory Procedure Manual (SOP) and CMS Form 209 CLIA Laboratory Personnel Report, confirmed that high complexity testing was performed in the laboratory. The laboratory failed to ensure qualified staffing for high complexity lab testing. THE FINDINGS INCLUDE: 1. A review of the Sodium Citrate Platelet Count Procedure, confirmed that the procedure was put in use June 01, 2023 and a Bone Marrow Biopsy Procedure was inititiated around of Jan 07, 2025 (as evidenced by the LD approval signature.) The Sodium Citrate Platelet Count Procedure is deemed High Complexity Testing given the FDA cleared Hematology Analyzers for the testing of blood samples collected in EDTA tubes. 2. A review of the current laboratory test procedures confirmed that Bone Marrow Biopsies (high complexity procedure) are performed at the testing location. 3. An interview with TC1 (identified on CMS-209 Form) confirmed that the high complexity testing was performed by unqualified testing personnel TP1, TP2, and TP3 (see Form 209 Form). 4. An exit interview, with TC1, on April 23, 2025, at 1:30pm, confirmed that the LD failed to ensure qualified staffing for High Complexity lab testing.