Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D1092600	08/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Biomedical Dba United Diagnostic Lab	2754 Veach Road, Owensboro, KY	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review and staff interview on 08/05/2019, the laboratory failed to follow manufacturer's requirements for reconstitution of Beckman Coulter Lyophilized calibration material used on the AU 480 chemistry analyzer for the calibration of creatinine. Findings include: 1. The manufacturer's instructions for storage and stability of reconstituted Beckman Coulter Lyophilized Chemistry Calibrators Level 1 and Level 2 state "Reconstituted calibrator materials are stable for seven days from the date of reconstitution when stored at 2-8 degrees C, except for Total and Direct Bilirubin which are stable for four days." 2. The Technical Supervisor acknowledged in an interview at 11:20 AM on 08/05/2019, calibration material used to calibrate creatinine was reconstituted every fourteen days. 3. The Technical Supervisor acknowledged the laboratory failed to have a system in place to ensure the manufacturer's instructions were followed for the reconstitution and storage of calibration materials.