Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2111115	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Excelsior Diagnostic Lab	12 Snow Hill St, Spotswood, NJ	

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) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) reagents in use, Bio-Rad Liquid Assayed Multiqual controls Manufactuers Package Insert (MPI), and interview with the Technical Supervisor (TS), the laboratory failed to put proper expiration dates on the Bio-Rad Liquid Assayed Multiqual controls control reagents in use for the Beckman Coulter DxC AU-700 analyzer on 3/16/26. The findings include: 1. The MPI stated "Thawed opened: Once thawed, opened and stored tightly capped sat 2 to 8C, This product will be stable as follows: All analytes: 14 days, Except: Alkaline Phosphatase, AST/SGOT, Bilirubin (Neonatal) and Bilirubin Total: 9 days. Bilirubin (Direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK), Phosphorus and Triglycerides: 7 days. LAP Arylamides: 3 days" 2. Bio-Rad Liquid Assayed Multiqual QC Lot 4630 in use had an open date of 3/16/26 and expiration date of 4/13/26. 3. The laboratory did not put proper expiration dates on the Bio-Rad Liquid Assayed Multiqual controls after being thawed and opened. 4. The TS confirmed on 3/18/26 at 12:05 pm the laboratory failed to put proper expiration dates on the QC reagents in use.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy,

	precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure the PS for the Sysmex CA-600 analyzer were adequate before patient testing from 1/8/24 to 3/18/26 . The findings include: 1. Linearity was not performed. 2. The TS confirmed on 3/18/26 at 12:30 pm, the LD not ensure the PS records were not adequate.