Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0700883	04/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cooper Voorhees Campus	900 Centennial Blvd, Voorhees, 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) 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 surveyor observation of the Quality Control (QC) reagents and interview with the Technical Supervisor (TS), the laboratory failed to put a new expiration date on the Bioresource Technology Chemistry Control Liquid Assayed (BRT) reagents in use on the Abaxis Piccolo Xpress analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "Thawed and unpinned: The Chemistry Control can be used for up to 14 days when stored unopened at 2-8C" 2. The laboratory did not put expiration date on the BRT QC after thawing. 3. The TS confirmed on 4/27/2021 at 11:10 am the laboratory failed to put new expiration date on the QC reagents. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	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 that PS procedures performed on the Abaxis Piccolo Xpress were adequate from January 2021 to the date of survey. The findings include: 1. Chloride linearity established was 86.5-131.5 mmol/L but the laboratory used 80-135 mmol/L. 2. Creatine linearity established was .45-15.15 mg/dL but the laboratory used .2-20mg /dL.. 3. Glucose linearity established was 29.5-631.0 mg/dL but the laboratory used 10-700 mg/dL. 4. Lactate linearity established was 5.8-83.70 but the laboratory used 2.7-90 mg/dL. 5. Potassium linearity established was 2.35-7.45 mmol/L but the laboratory used 1.5-8.5 mmol/L. 6. Magnesium linearity established was .50-7.10 mg /dL but the laboratory used .1-8.0 mg/dL. 7. Sodium linearity established was 118-159.5 mmol/L but the laboratory used 110-170 mmol/L. 8. Phosphorus linearity established was 1.50-15.55 mg/dL but the laboratory used .2-20 mg/dL. 9. Total Carbon Dioxidelinearity established was 8.5-35.0 mmol/L but the laboratory used 5-40 mmol/L. 10. Aspartate Aminotransferase linearity established was 20.5-1366.5 U /L but the laboratory used 5-2000 U/L. 11. Alkaline Phosphatase linearity established was 24-1775 U/L but the laboratory used 5-2400 U/L. 12. Albumin linearity established was 1.85-5.90 mg/dL but the laboratory used 1-6.5 mg/dL. 13. Direct Bilirubin linearity established was .2-3.90 mg/dL but the laboratory used .1-5 mg/dL. 14. Total Bilirubin linearity established was was .3-4.40 mg/dL but the laboratory used .1-5 mg/dL. 15. Total Protein linearity established was 3.25-9.15 mg/dL but the laboratory used .2-14 mg/dL. 16. Blood Urea Nitrogen linearity established was 6.0-115.0 mg/dL but the laboratory used 2-180 mg/dL. 17. Calcium linearity established was 5.15-15.35 mg/dL but the laboratory used 4-16 mg/dL. 18. The TS confirmed at 11:00 on 4/27/21 that PS records were not adequate.