Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307800	01/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Vanderbilt Bedford Hospital Llc	2835 Highway 231 North, Shelbyville, TN	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Intakes: TN00050185 Based on review of available Quality Control (QC) and interview with the general supervisor, the laboratory failed to maintain QC records used to establish QC ranges for 2018 and 2019 for the following analytes: Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Cholesterol (CHOL), Carbon Dioxide (C02), Direct Bilirubin(D-Bil), Total Bilirubin (T-BIL), Creatine Kinase (CK), Creatinine, Ethanol, Glucose, Iron, Gamma Glutamyltransferase (GGT), High Density Lipoprotein (HDL), Potassium (K), Lactic Acid, Lactate Dehydrogenase (LDH), Lipase, Magnesium (Mg), Sodium (Na), Phosphorous (PHOS), Prealbumin,(PALB) Total Protein, Triglyceride (TRIG), Total Iron Binding Capacity (TIBC), Uric Acid. The findings include: 1. Review of the QC records available revealed no QC records used to establish QC ranges were retained for Chemistry Bio-Rad Unassayed Multiqual Level and Level 3 for 2018 and 2019 for the following: Lot numbers: 47931- 47933 47941- 47943 56631- 56633 Analytes: ALB, ALP, ALT, AST, BUN, Ca, Cl, CHOL,C02, DBil, TBIL, CK, Creatinine, Ethanol, Glucose, Iron, GGT, HDL, K, Lactic Acid, LDH, Lipase, Mg, Na, PHOS, PALB, Total Protein, TRIG, TIBC and Uric Acid. 2. Interview with the General Supervisor on January 10, 2020 at 12:30 p.m. confirmed the laboratory failed to retain the QC data used to establish the acceptable QC ranges in 2018 and 2019.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of the chemistry reagents in refrigerator #5 and interview with the general supervisor, the laboratory failed to ensure expired reagents were discarded. The findings include: 1. Observation on 1/9/2020 at 9AM showed the Siemens CKMB calibrator (lot number 8BD294) expired on 2/2019. The Siemens THYR calibrator (lot number 8LD308) expired on 12/2019 and the Siemens Sample Diluent (lot number 8KD689) expired on 10/2019. 2. The general supervisor confirmed on 01/09/2020 at 1:30pm that there were expired Siemens reagents stored in the chemistry refrigerator.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on quality control (QC) records available for review for Bio-Rad Liquid Unassayed Mulitqual QC lot to lot data to support the QC reference ranges and interview with the general supervisor, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance for the following test in 2018 and 2019: Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Cholesterol (CHOL), Carbon Dioxide (C02), Direct Bilirubin(D-Bil), Total Bilirubin (T- BIL), Creatine Kinase (CK), Creatinine, Ethanol, Glucose, Iron, Gamma Glutamyltransferase (GGT), High Density Lipoprotein (HDL), Potassium (K), Lactic Acid, Lactate Dehydrogenase (LDH), Lipase, Magnesium (Mg), Sodium (Na), Phosphorous (PHOS), Prealbumin,(PALB), Total Protein, Triglyceride (TRIG), Total Iron Binding Capacity (TIBC), Uric Acid. The findings include: 1. Review of the July 2019 QC level 1 for Bio-Rad Liquid Unassayed Mulitqual lot to lot correlation for lot 47931 to lot 56631 has a correlation date of January 11, 2019. The following analytes show unacceptable correlation data for the following analytes: ALT, Ethanol, GGT and Lactic Acid. 2. Review of the July 2019 Level 3 for Bio-Rad Liquid Unassayed Mulitqual lot to lot correlation for lot 47933 to lot 56633 has a correlation date of August-2018. The following analytes show unacceptable correlation data for the following analytes: HDL and Magnesium. 3. Review of the QC records available revealed no lot to lot correlation for the Bio-Rad Liquid Unassayed Mulitqual QC level 1 & 3 for lot 47931, 47933 for 2018. 4. Review of the QC records available revealed no lot to lot correlation for the Bio-Rad Liquid Unassayed Mulitqual QC level 1 & 3 lot of 47931, 47933 to lot 47941, 47943

	for 2019. 5. Interview with the General Supervisor on January 10, 2019 at 12:30 p.m. confirmed the laboratory director failed to ensure the establishment of acceptable levels of analytical performance for each test in 2018 and 2019.