Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326986	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cumberland County Hospital	299 Glasgow Road, Burkesville, 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
D0000	A recertification survey was initiated on 05/28/2025 and concluded on 05/29/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
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 direct observation, review of procedure manual, review of manufacturer's package inserts, and confirmed in an interview with the General Supervisor 3 (GS3), the laboratory failed to label 21 of 21 in-use reagents with revised expiration dates. Findings Included: Observed on 05/28/2025 at 1:45 PM, in the testing area, a sampling of 8 open reagents stored in the refrigerator included: a. One open bottle of Liquichek Diabetes control Level 3, Lot number 89243 b. One open bottle of Ethanol /Ammonia control Level 3, Lot number 54463 c. One open bottle of DOA Total control Level 5, Lot number DAT26085A d. One open bottle of Liquichek Urine Chemistry Control Level 2, Lot number 97452 e. One open bottle of Liquid Assayed Multiqual Level 1, Lot number 45981 f. One open bottle of Liquichek Immunoassay Plus control Level 1, Lot number 85371 g. One open bottle of Lyphochek Specialty Immunoassay control Level 1, Lot number 88751 h. One open bottle of Liquichek Cardiac Markers Plus control LT Level 1, Lot number 67711 The laboratory failed to label the bottles with revised expiration dates specified by the manufacturer. Review of the procedure manual titled, "Cumberland County Hospital Laboratory Policy and Procedure Manual", approved by director on 7/22/2024, stated, "All reagents must be

	labeled with name, date received, and expiration date according to manufacturer's specifications." Review of Manufacturer's instructions titled "Storage and Stability" stated: a. Liquichek Diabetes Control Levels 1,2, and 3: "Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable for 45 days." b. Ethanol /Ammonia Control: "20 day open-vial stability at 2-8C." c. MAS DOA Total: "Once opened, vials of control are stable for 30 days when stored tightly capped at 2-8C." d. Liquichek Urine Chemistry Control Levels 1 and 2: "Once opened and stored tightly capped at 2 to 8 C, this product will be stable as follows: All analytes: 30 days." e. Liquid Assayed Multiqual Levels 1,2, and 3: "Thawed Opened: Once thawed, opened, and stored tightly capped at 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, Creating Kinase (CK), Phosphorus and Triglycerides: 7 days - LAP Arylamidase: 3 days f. Liquichek Immunoassay Plus Control Levels, 1, 2, and 3: "Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: All analytes: 30 days, Except: Androstenedione, 25 days - Prolactin, PSA (Free) and PSA (Total): 14 days - Estradiol: 8 days - Folate: 4 days g. Lyphochek Specialty Immunoassay Specialty Immunoassay Control Levels 1,2, and 3: "After reconstituting and storing tightly capped at 2 to 8C, this product will be stable as follows: All analytes: 30 days, Except: PTH (Intact): 4 days -Procalcitonin: 3 days." h. Liquichek Cardiac Markers Plus Control LT Levels 1,2,3,1A,1B, and 1C: "Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: All analytes: 20 days, Except: Myoglobin: 10 days - N-terminal pro-Brain Natriuretic Peptide (NT-proBNP), B-type Natriuretic Peptide (BNP) and Troponin I: 5 days - Troponin T: 4 days." In an interview on 5/29/2025, at 10:25 AM, the General Supervisor 3 (GS3) in the office area, was asked if expiration dates were placed on the open controls. GS3 stated the dates were not placed on the vials. This confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor accuracy of patient test reference ranges within the procedure when compared to reference ranges in patient test reports for years 2024 and 2025 for 1 of 2 patient test reports. Findings included: Record review on 05/29/2025 at 11:15 p.m. revealed reference ranges in a patient test report did not match reference ranges in the laboratory's procedure for Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), and Mean Corpuscular Volume (MCV). a.) Patient test report 72115,dated 09/09/2024, revealed the following ranges for an adult female: RBC: 4.20-5.40 microliters per milliliter (M/uL) HGB: 12.0-16.0 grams per deciliter (g/dL) HCT: 37.0-47.0 percentage (%) MCV: 81-99 femtoliters (fL) b.) Review of the Cumberland County Hospital Laboratory Infection Control Policy and Procedure Manual titled "Table of Normal Ranges" had the following ranges not based on gender: RBC: 4.7-5.6.1 M/uL HGB: 14.0-18.0 g/dL HCT: 42.0-52.0 % MCV: 80-94 fL During an interview on 05/29/2025 at 11:25 p.m. in an office adjacent to the main laboratory, the General Supervisor 3 (GS3) confirmed that the reference ranges on the patient test reports did not match reference

	ranges in the laboratory's procedure for RBC, HGB, HCT, and MCV. This confirmed the findings.