

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0687812	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier U Of L Campus Health Services	Street Address, City, State 215 Central Avenue, Suite 110, Louisville, 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 conducted on 06/25/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and confirmed in staff interview; the laboratory failed to monitor and document room temperature for 1 of 1 storage areas. Findings included: 1. Observed on 06/25/2023 at 11:15 a.m. was the area in the laboratory where Becton Dickinson (BD) blood collection tubes and "breiner bio-one vacuette tube" tubes were stored: Shot room located next to laboratory; 4 packs of 100 BD Vacutainer Serum Blood Collection Tubes, Lot Number 4059153; 23 individual "breiner bio-one vacuette tube" tubes, Lot Number B23093A7 No temperature monitoring devices were observed in the storage area. 2. The manufacturer's instructions on the label of each package of the BD blood collection tubes stated a storage requirement of 4 degrees Celsius (39.2 degrees Fahrenheit) to 25 degrees Celsius (77 degrees Fahrenheit) and the manufacturer's instructions on the label of the package of "breiner bio-one vacuette tube" tubes stated a storage requirement of 4 degrees Celsius (40 degrees Fahrenheit) to 25 degrees Celsius (77 degrees Fahrenheit) 3. In an interview on 06/25/2023 at 11:15 am in the</p>

conference room, testing personnel (TP) #1 stated that the temperature was not monitored. This confirmed the findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of patient test reports and confirmed in staff interview, the laboratory failed to verify 4 of 4 reference intervals for Complete Blood Cell counts (CBC) for their patient population. Findings include: Review of 4 patient test reports of individuals with different ages titled "Laboratory Report-UL Campus Health Services" for years 2023 and 2024 revealed reference intervals for CBC results: "19 yrs ... F... WHITE BLOOD CELL COUNT 3.8-10.8 Thousand/uL RED BLOOD CELL COUNT 3.8-5.10 Million/uL HEMOGLOBIN 11.7-15.5 g/dL HEMATOCRIT 35.0-45.0 % MCV 80.0-100.0 fL ... 18 yrs ... F White Blood Cells 4.1-10.4 10*3 /uL Red Blood Cells 3.43-5.21 10*6/uL Hemoglobin 10.3-14.8 g/dL Hematocrit 32.5-46.2 % MCV 82.5-98 fL ... 18 yrs ... F White Blood Cells 4.1-10.4 10*3/uL Red Blood Cells 3.43-5.21 10*6/uL Hemoglobin 10.3-14.8 g/dL Hematocrit 32.5-46.2 % Mean Corpuscular Value 82.5-98 fL ... 19 yrs ... F White Blood Cells 4.1-10.4 10*3 /uL Red Blood Cells 3.43-5.21 10*6/uL Hemoglobin 10.3-14.8 g/dL Hematocrit 32.5-46.2 % Mean Corpuscular Value 82.5-98 fL ..." 2. In an interview on 06/25/2024 at 12:15 p.m. in the conference room, the testing personnel (TP) #1 was asked to provide documentation of verification of the reference intervals in use for their patient population. No documentation was provided. This confirmed the findings. Word Key: % = percentage 10*3/uL = thousands per cubic millimeter 10*6/uL = millions per cubic millimeter dL = deciliter F = Female fL = femtoliters g = gram MCV= mean corpuscular volume yrs = Years