

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0698885	(X3) Date Survey Completed 01/11/2024
Name of Provider or Supplier Unified Government Public Health Department	Street Address, City, State 619 Ann Avenue, Kansas City, KS	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during a tour of the specimen processing area, review of procedure manuals and interview with the general supervisor (GS), the laboratory failed to ensure positive identification and optimum integrity of a patient's specimen from time of collection through reporting of results. Findings: 1. During a tour of the specimen processing area, the surveyor observed four urine samples on the counter with the following: a. One sample had no identifiers (unlabeled). b. One sample had a handwritten number on the specimen lid only and not on the specimen container. Upon opening the specimen, that specimen would then be unlabeled. c. Three of the four samples had only a handwritten number on the specimen. 2. Review of the urinalysis procedure revealed the following: a. Specimen Collection and Preparation- item 7 "Specimens without a patient number or with an incorrect patient number will be rejected." b. The surveyor asked if specimen numbers were consecutive. The lab assistant stated yes. c. The surveyor asked if a number was incorrectly recorded for this sample but could match another sample received that day, the GS stated it was possible. 3. Review of the Pregnancy Test with hCG Strips - Waived revealed under "Sample Requirements, #2 "A cup with a patient label." 4. Transcription error in the handwriting of the specimen number on urine cups can occur. With no other identifier present on patient samples, positive identification of patient samples would be at risk. 5. The laboratory did have patient labels with more than one identifier on them. The surveyor asked why the labels were not being used. The GS stated that once testing was completed, the urine specimen was poured out and the sample cup was discarded</p>

into regular trash. If the specimen label was on the specimen cup, that could not be done due to PHI concerns. 6. Approximately 1,682 urine specimens are processed by this laboratory annually. 6. Interview with the GS on 1/11/24 at 10:25 a.m. confirmed, the laboratory failed to ensure positive identification and optimum integrity of a patient's specimen from time of collection through reporting of results.

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 upon direct observation of expired specimen collection tubes in the specimen collection area, and interview with the general supervisor (GS), the laboratory failed to ensure that specimen collection supplies in use were not expired. Findings: 1. During a tour of the specimen collection area, the surveyor found the following expired specimen collection tubes: a. Ten Vacuette K3EDTA specimen collection tubes with an expiration date of 12/1/23. b. Ten Vacuette Lithium heparin specimen collection tubes with an expiration date of 12/31/23. 2. Interview with the GS on 1/11/24 at 10:25 a.m. confirmed the laboratory failed to ensure that specimen collection supplies in use were not expired.