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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>26D2037986      | <b>(X3) Date Survey Completed</b><br>07/19/2023 |
| <b>Name of Provider or Supplier</b><br>Avertest Llc DbA Averhealth   | <b>Street Address, City, State</b><br>4709 Laguardia Drive, Saint Louis, MO |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5201</b>              | <p><b>CONFIDENTIALITY OF PATIENT INFORMATION</b><br/>CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation of urine specimens and interview with the general supervisor (GS) #1, the laboratory failed to ensure confidentiality of patient information through all phases of the testing process. Findings: 1. Observation of multiple boxes of urine specimens located in the receiving area of the facility showed patient identification information visible on the urine containers. 2. Interview with the general supervisor (GS) #1 on July 19, 2023 at 9:00 AM, the general supervisor (GS) #1 stated that "those urine specimens are discarded in the dumpster outside as is." 3. Interview with the general supervisor (GS) #1 on July 19, 2023 at 9:00 AM confirmed the laboratory failed to maintain patient confidentiality through all phases of the testing process by discarding urine specimens in a public dumpster where patient information would be visible to the public.</p> |
| <b>D5311</b>              | <p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b><br/>CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p>   |

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedures, "Thermometer Logs", and interview with the general supervisor (GS) #1, the laboratory failed to follow the established procedure for specimen storage for 6 of 19 days in July 2023. Findings: 1. Review of the laboratory's procedure "Temperature-Sensitive Equipment", states "Acceptable operating ranges are -2 to 10 C for refrigerators and below 0 C for freezers. If temperature exceed these ranges, corrective actions must be performed." 2. Review of the the laboratory's "Thermometer Logs" states "Acceptable temp range for LEFT refrigerator only: 0 - 10 C" 3. Review of the laboratory's thermometer logs showed an unacceptable temperature recorded on July 1, 2023, July 2, 2023, July 3, 2023, July 6, 2023, July 7, 2023, and July 19, 2023 with no corrective action documented. 4. Interview with the general supervisor (GS) #1 on July 19, 2023 at 12:00 PM confirmed the laboratory failed to follow the established procedure for specimen storage.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on observation of the reagent and quality control refrigerator, review of the "Reagent and Preparation & Storage" procedure, and interview with the general supervisor (GS) #1, the laboratory failed to follow the procedure for labeling reagents. Findings: 1. Observation of the reagent and quality control refrigerator located in the laboratory showed three bottles of DRI Creatinine lot #7400102, four bottles of creatinine calibrator lot #100722, four bottles of pH detect control lot # 74801005, two bottles pH 11.0 calibrator lot #74864569, 3 bottles specific gravity calibrator lot #74674450, and five bottles of urine calibrator for toxicology testing opened and in use with no preparation date (open date), date received, technician initials, and expiration date. 2. Review of the "Reagent and Preparation & Storage" procedure, showed "All reagents, controls, and calibrators will be labeled according to assay, lot number, date received, date opened, OSHA hazard classification, technician initials, and expiration date on the box and/or bottle." 3. Interview with the GS #1 on July 19, 2023 at 12:00 PM confirmed the laboratory failed to follow the procedure for labeling reagents. 4. The laboratory reports approximately 91,548 toxicology patient results annually.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, the laboratory's "Heating Block Log", and interview with the general supervisor (GS) #1, the laboratory failed to define criteria for an acceptable temperature range for 5 of 5 heating blocks. Findings: 1. Review of the laboratory's procedure "Comprehensive LC-MS/MS Screen" states, "Incubate for 60 minutes at 55 C." 2. Review of the laboratory's "Heating Block Logs" showed no defined acceptable temperature range. 3. Interview with the general supervisor (GS) #1 on July 19, 2023 at 12:00 PM confirmed the laboratory failed to define criteria for an acceptable temperature ranges for the laboratory's heating blocks.