Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2037986	08/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Avertest Llc Dba Averhealth	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on interview with the complainant, review of the state complaints of patient A's residence, and interview with the laboratory director (LD) and the vice president of operations, the laboratory failed to ensure documentation of all complaints. Findings: 1. Phone interview with patient A on May 1, 2024, at 8:15 AM: patient A stated that he/she had contacted the laboratory multiple times trying to get a copy of the results and was told he/she could not have them. Phone interview with patient A's personal representative on August 22, 2024, at 11:00 AM, stated "Patient A called the laboratory and requested access to the test reports four times and the laboratory refused to provide the test reports." Complainant (patient A) was not provided with the process to file a complaint against laboratory. 2. Review of complaints from patient A's resident state from January 2024 to date August 19, 2024 and interview with the vice president of operations showed, "After a search, we did not find any client complaints from the state of patient A in the last year. This search included all customers in patient A, not just the Drug Courts." 3. Interview with the LD on August 19, 2024 at 2:00 PM confirmed the laboratory failed to ensure it documented all complaints.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the laboratory director (LD), the laboratory failed to ensure a step-by-step procedure for complaints was available. Findings: 1. Review of procedures revealed no procedure for taking complaints, processing complaints and documentation of response to complainants. 2. Interview with the LD on August 19, 2024 at 2:00 PM confirmed the laboratory failed to ensure a step-by-step procedure for complaints was available.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, observation of oral fluid specimens and urine specimens for toxicology, lack of temperature logs and interview with the laboratory director (LD), the laboratory failed to ensure toxicology specimens were stored within the laboratory's stated performance specifications. Findings: 1. Review of "Accessioning and Internal Chain of Custody-CLIA" procedure states "After a maximum of 7 days, all urine and oral fluid specimens will be moved to frozen storage." 2. Review of "Temperature-Sensitive Equipment" procedure states "Acceptable operating ranges are -2 to 8 degrees Celsius for reagent storage refrigerators, -2 to 15 degrees Celsius for working refrigerators and below 0 degrees Celsius for freezers. If temperatures exceed these ranges, corrective actions must be performed." 3. Observation of oral fluid specimens older than 7 days revealed specimens kept in 2 refrigerators and one freezer with no documentation of temperature. Approximately 11,000 oral fluid specimens were being stored. 4. Observation of urine specimens being stored at room temperature revealed approximately 1,600 urine specimens older than 7 days old being stored at room temperature. These specimens included positive urine toxicology specimens that were going to be repeated. 5. Interview with the the LD stated "we have no room for more refrigerators or freezers". 6. Interview with the LD on August 19, 2024 at 2:00 PM

	confirmed the laboratory failed to ensure toxicology specimens were stored within the laboratory's stated performance specifications.
D5823	TEST REPORTS CFR(s): 493.1291(l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. This STANDARD is not met as evidenced by: Based on phone interview with patient A, phone interview with patient A's personal representative, review of laboratory procedures, and interview with the laboratory director (LD), the laboratory failed to provide patient A with access to completed test reports. Findings: 1. Phone interview with patient A on May 1, 2024 at 8:15 AM, stated he/she had reached out to the laboratory multiple times trying to get a copy of the results and was told he/she could not have them. 2. Phone interview with patient A's personal representative on August 22, 2024 at 11:00 AM, stated, "Patient A called the laboratory and requested access to patient A's test reports four times and the laboratory refused to provide the test reports." 3. Review of laboratory procedures showed no written policy available to the laboratory staff on how to handle patient requests for access to their completed laboratory reports. 4. Interview with the LD on August 19, 2024 at 2:00 PM confirmed the laboratory failed to provide patients with access to completed test reports.