Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2037986	05/04/2021
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
D0000	A complaint investigation (MO00181535) was conducted on May 4, 2021 under 42 CFR part 493, the requirements for the Clinical Laboratory Improvements Amendments (CLIA). The complaint was found to be unsubstantiated with unrelated definciencies.
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: Review of verification procedures revealed and interview with Laboratory Director, the laboratory failed to verify precision for one of ten analytes on the AU5400. Findings: 1. The laboratory provided the acceptable criteria in the validation report labeled Valid ation Report AU 5400 Wonder Woman as" %CV less than or equal to 25% or 1 ng/mL" for precision. Review of OPI low revealed that the %CV was greater than 25%, the laboratory obtained a %CV of 31.77%. Review of the OPI revealed a greater than 1 ng/mL value difference between target value of 5 ng/mL and laboratory result of 6.63.ng/mL. The laboratory failed to meet established acceptable criteria for precision. 2. Interview with Laboratory Director on May 4, 2021 at 1:45 P. M. confirmed, the laboratory failed to address the unacceptable criteria for precision for OPI low.
D5807	TEST REPORT

	CFR(s): 493.1291(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 review of the Immunoassay Testing procedure, review of patient test report for oral fluids and interview with the general supervisor (GS) #2, the laboratory failed to ensure the procedure cut off value for Benzodiazepines- SI 20 matched the cut off value on the patient test report. Findings: 1. Review of the Immunoassay Testing procedure showed the cut-off value for Benzodiazepines- SI 20 as 5 ng/mL. 2. Review of the patient test report for oral fluids showed the cut-off value for Benzodiazepines- SI 20 as 20 ng/mL. 3. Interview with GS #2 on May 4, 2021 at 11:30 AM confirmed that the Immunoassay Testing procedure cut off value for Benzodiazepines- SI 20 did not match the cut off value on the patient test report for oral fluids.