Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2037986	(X3) Date Survey Completed 12/09/2020
Name of Provider or Supplier Avertest Llc Dba Averhealth	**Street Address, City, State** 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of procedure manual, personnel documentation and interview with the technical supervisors, the laboratory failed to perform semi-annual competency evaluations in years 2019 and 2020 for seven of twenty two testing personnel. Findings: 1. Review of the procedure manual revealed the laboratory requires an initial, semi-annual and yearly evaluation of employee competencies. 2. The laboratory failed to perform seven semi-annual competency evaluations for testing personnel #11, #13, #14, #16, #17, #18 and #22. 3. Interview with the technical supervisors #1 and #2 on December 08, 2020 at 2:30 PM confirmed the laboratory failed to perform seven semi-annual competency evaluations in the years 2019 and 2020.
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 the manufacturer's product insert and interview with technical supervisor (TS) #1, the laboratory failed to monitor and document the humidity of the laboratory for proper operation for eleven of eleven AB Sciex 4000 LC/MS analyzers located in two separate rooms. 1. Review of the manufacturer's product insert for performance specifications revealed the analyzer requires relative humidity of 20-80 percent. 2. The lack of the relative humidity logs showed the laboratory failed to document humidity for the AB Sciex 4000 LC/MS analyzers in the two rooms. 3. Interview with the technical supervisor on December 8, 2020 at 2:00 PM confirmed the laboratory failed to document the relative humidity in two locations of the laboratory where the AB Sciex 4000 analyzers were in operation.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of performance evaluations for years 2019 and 2020 and interview with the technical supervisor (TS) #1, the TS failed to perform the semiannual performance reviews for seven of twenty two testing personnel. Finding: 1. Review of 2019, 2020 performance evaluations showed the TS failed to perform semi-annual competency evaluations for testing personnel #11, #13, #14, #16, #17, #18 and #22. 2. Interview with TS #1 on December 08, 2020 at 2:30 PM confirmed the laboratory failed to perform seven performance evaluations semiannually during the first year the individual tests patient specimens.