

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2287503	(X3) Date Survey Completed 07/23/2026
Name of Provider or Supplier Gigantest Inc	Street Address, City, State 31 Light Street 3rd Floor, Baltimore, MD	
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	An on-site validation survey was performed on July 23, 2026 with the following standard level deficiency cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, review of manufacturer's instructions, review of temperature records, laboratory written policies and interview with the Technical Supervisor (TS), the laboratory failed to define ambient room temperature consistent with manufacturer's instructions for 45 of 45 Becton Dickinson (BD) Vacutainer blood collection tubes. Findings Included: 1) During a laboratory tour on 7/23/2026 at 10:52 AM, the following laboratory's own commercial specimen collection kits called 'HealthieOne Health Kit' were observed with no storage temperature requirements upon the packaging, each with BD vacutainer tubes packaged within, with 4 to 25 degrees Celsius manufacturer storage requirements: a. 19 HealthieOne Complete Collection by Phlebotomist Single kits, with the following two tubes in each - BD Serum Separator Tube (SST) Gold Top Lot Number 5241635, BD K2E EDTA Purple Top Lot Number 5197548. b. 7 HealthieOne Follow-up Self-Collection SST kits, with the following tube in each - BD Serum Separator Tube (SST) Gold Top, Lot Number 5241635. 2) Review of the laboratory's temperature records revealed an acceptable

temperature range of 72 to 78 degrees Fahrenheit (22.2 to 25.6 degrees Celsius). No temperatures from 2024 to 2025 (Random review) were above 77 degrees Fahrenheit. 3) Review of the laboratory's written policy titled 'GEN.61300 Climate Control Gigantest Temperature Policy' stated the following: "Ambient temperature has to be between 72 to 78 degree Fahrenheit". 4) In an interview in the conference room at 11:00 AM, the TS confirmed the acceptable ambient room temperature range was not defined in accordance with manufacturer instructions.