Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 21D1062422	**(X3) Date Survey Completed** 12/16/2024
Name of Provider or Supplier Biesecker-Nhgri/Gdrb	**Street Address, City, State** National Institutes Of Health, Bethesda, 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	A recertification survey was conducted on December 16, 2024 at Biesecker-NHGRI /GDRB. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. Standard level deficiencies were 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, reagent packet inserts, environmental monitoring records, operator's guide(s), and confirmed in an interview with the Laboratory Director (LD), the laboratory failed to ensure proper storage temperature and humidity for 3 of 3 months observed. Findings included: 1. Observed during a tour of Room #42 on December 16, 2024, at 12:45 PM, polymerase chain reaction (PCR) reagents stored revealed an acceptable storage temperature of 15C to 25C: a. 1 bottle of Purgene DNA Hydration Solution 100mL, Lot 17043910, Exp 6/20/2025, Store at room temperature (15-25C). b. 1 bottle of Puregene Protein Precipate Solution 50mL, Lot 175043909, 11/20/2025 Store at room temperature (15-25C). c. 1 bottle of Puregene Cell Lysis Solution 125mL, Lot 175012655, Exp 1/9/20225, Store at room temperature (15-25C). d. 1 bottle of Puregene Cell Lysis Solution 125mL, Lot 175025609, Exp 5/27/2025, Store at room temperature (15-25C). e. 1 bottle Puregene RBC Lysis solution 450mL, Lot 175037056, Exp 9/23/2025. 2. A review of the

	laboratory's environmental monitoring records revealed the laboratory had established an acceptable room temperature range for Room #42 set at 15C-30C. 3. Document review of environmental monitoring records for 3 of 3 months (08/1/2024 through 10 /31/2024) revealed 12 of 33 temperature data points observed were above the acceptable reagent storage temperature of 15-25C. 4.During the laboratory tour on December 16, 2024, at 1:00 PM, 2 of 2 instruments for patient testing were in use, but humidity levels were not monitored. a. 1 SeqStudio Genetic Analyzer, "Operation: 20%-80% (noncondencing)." b. 1 Applied Biosystems Veriti The, "Acceptable range: 20-80% (noncondencing)." 5. Durning an interview on December 16, 2024 at 3:00 PM, the LD confirmed the above findings.