

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0951395	(X3) Date Survey Completed 12/17/2024
Name of Provider or Supplier Inflammatory Disease Section, Nhgri	Street Address, City, State Building 10 East/Room B34129, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, reagent packet inserts, operator's guide(s), and confirmed in an interview with the Laboratory Director (LD) and Testing Personel #1 (TP-1), the laboratory failed to ensure temperature ranges and humidity were documented and monitored within the manufacturer's specifications for 3 of 3 areas. Findings included: 1. Observed during a tour of the PCR extraction room (B3-4129) on December 17, 2024, at 10:15 AM, it was revealed that the temperature of reagents stored in refrigerator #2 (Sanyo Biomedical) was not being monitored. 2. Review of the reagent manufacturer's storage specifications on the box(s) revealed an acceptable storage temperature of 2C to 8C. a. 1 box of ApliTaq Gold Fast PCR Master Mix, Lot 2894116, expiration 01/31/2025, Store at 2C-8C. b. 1 box of SeqStudio (Trademark) Cartridge v2, SN 2240710-012 expiration 12/29/2024, Store at 2C-8C. c. 1 bottle of 5x Sequencing buffer, Lot 2002304, Exp N/A, Store at 2C-8C. 3. Observed during a laboratory tour in PCR extraction room (B3-4129) on 12/17/2024 at 10:15 AM, revealed that TI00 thermocycler was in use and temperature and humidity were not being monitored. 4. A review of the T100 Thermocycler Instruction manual revealed that the "operating temperature range 15-31C" and "relative humidity up to 80% (noncondensing)." 5. Observed during a laboratory tour in PCR extraction room (B3-4156) on 12/17/2024 at 10:25 AM revealed that SeqStudio applied biosystems were in</p>

use and temperature and humidity were not being monitored. 6. Review of the SeqStudio applied biosystems user guide revealed that the acceptable operation range "15C to 30C (60F to 85F)" and "Operation: 20%-80% (noncondensing)" 7. In an interview with TP#1 on December 17, 2024, at 10:20 AM, stated that they do not monitor the temperature in the refrigerator where the reagents are stored. 8. In an interview with the LD on December 17, 2024, at 11:00 AM, they confirmed the findings listed above.