

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2113635	(X3) Date Survey Completed 02/05/2021
Name of Provider or Supplier Physiology Unit, Niaid	Street Address, City, State 12735 Twinbrook Parkway, Room 3w-35, Rockville, 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 announced CLIA recertification survey was conducted by the CMS CLIA Philadelphia Regional Surveyor at National Institute of Allergy and Infectious Diseases: Physiology Unit on February 5, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. Specific deficiencies cited are as follows:
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on a review of temperature records, quality assessment plan and interview, the laboratory failed to document any corrective actions performed for the specimen fridge and reagent fridge for out of range temperatures. Finding include: 1. Review of the laboratory's reagent fridge Refr#2 Temperature Graph from October 17, 2018 until the date of the survey February 02, 2021 revealed 5 out of 30 days in the month of June 2019 temperature reading out of range a. June 5, 2019 b. June 21, 2019 c. June 22, 2019 d. June 23, 2019 e. June 24, 2019 2. Review of the laboratory's specimen fridge Refr#1 Temperature Graph revealed a temperature out of range on July 3, 2019 for a 4 degree fridge temperature ranging from (5.1 - 15.2). 3. Review of the Quality Assessment Plan section Corrective actions states "When problems arise in controls, equipment, reagents, or any other phase of analysis, the Lab Manager will be notified and will note both the problem and the remedial action taken to solve it in the Problem Log (Appendix B). 4. During an interview with the lab director (LD), at approximately 12:40 pm, on the day of the survey, the CMS surveyor requested the</p>

corrective action documentation. The LD stated " we put a lock on both fridges doors, I guess we didn't write it down" During the exit interview at 1:30 pm the LD confirmed the above finding.