

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0280247	(X3) Date Survey Completed 02/23/2022
Name of Provider or Supplier M Elena Kendall Md Pa	Street Address, City, State 318 Alhambra Cir, Coral Gables, FL	
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 February 23, 2022. M Elena Kendall MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to record the temperature of the cryostat for 2020 and 2021. Findings: Review of "Cryostat Maintenance Record" showed there were no temperatures recorded for the Miles Tissue Tek Cryostat serial number 5288 for 2020 and 2021. On 02/23/2022 at 10:15 AM, Clinical Consultant acknowledged the cryostat temperatures were not recorded in 2020 and 2021.</p>