

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0286727	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Lewis H Kaminester Md Pa	Street Address, City, State 840 Us Hwy 1 Ste 300, North Palm Beach, 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	An announced recertification survey was conducted on 5/6/21 at Lewis H Kaminester Md Pa, a clinical laboratory in North Palm Beach, Florida. Lewis H Kaminester Md Pa is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance. .
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 with the office manager, the laboratory failed to document room temperature in the cabinet where patient Dermatophyte Test Medium (DTM) specimens were incubated for two out of two years (2019 - 2021). The findings included: Review of the "Dermatophyte Test Medium - DTM" procedure revealed "Incubation at room temperature, 20 to 30 degrees C (68 to 86 degrees F) is satisfactory for growth of most dermatophytes". Review of laboratory logs revealed that the laboratory had not documented room temperature for two out two years (2019 - 2021). Interview on 5/6/21 at 8:55 a.m., the Office Manager stated she was never told to keep record of room temperature for the DTM testing.</p>