Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2146513	06/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Leavitt Medical Associates Of Florida Inc	27612 Cashford Cir Ste 102, Wesley Chapel, 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
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, manufacturer's instructions, review of the temperature records, and confirmed in interview with staff, the laboratory failed to define a temperature range consistent with the manufacturer's instructions for the storage of 8 of 8 temperature dependent reagents and supplies. Findings Included: 1. During a tour of the laboratory on 6/16/25 at 11:07 AM, the following equipment and reagents were observed in use with manufacturer operator and storage temperature requirements: a. 1 Leica CM1850 Cryostat, S/N# 0972/02.1999, Manufacturer operator temperature requirements 18-40 degrees C. b. 2 Cardinal Health Mounting Media bottles, Lot #140453, Manufacturer storage temperature requirements 15-30 degrees C. c. 2 Reagent Alcohol bottles, Manufacturer storage temperature requirements 15-30 degrees C. d. 1 Cardinal Health Aliphatic Clearing Reagent, Lot #138473, Manufacturer storage temperature requirements 15-30 degrees C. e. 1 Epredia Eosin-Y with Phloxine bottle, Ref#71311, Manufacturer storage temperature requirements 15-30 degrees C. f. 2 Epredia Hematoxylin 7211 bottle, Ref#7211, Manufacturer storage temperature requirements 15-30 degrees C. 2. Review of the laboratory's temperature log titled "Advanced Dermatology Laboratory Temp/Humidity Log" showed an acceptable room temperature range of 5 to 35 degrees Celsius. 3. In an

	interview on 6/18/25 at 1:55PM, the location manager and the director of laboratory accreditation confirmed the temperature range findings.