Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1017116	10/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Flores Dermatology Llc	6705 Sw 57th Ave Ste 400, 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 conducted on 10/16/2019 found that Javier Flores MD PA clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document the room humidity for 9 out of 35 testing days in 2019. Findings include: Review of the cryostat manual Leica CM1510S indicated a requirement for room humidity at or below 60 %. Quality control records review revealed that there was no documentation of the room humidity for the following testing dates: 4/29/2019, 5/6/2019, 5/20/2019, 6/3/2019, 6/10/2019, 6/17/2019, 6/24/2019, 7/1/2019, 7/8/2019. During an interview on 10/16/19 at 12:00 p.m., the testing personnel # A confirmed that there was no record of room humidity for the days of reference.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient reports review and interview with testing personnel (TP) #A, the laboratory failed to include the correct address in the final reports for 3 out of 3 patients reports reviewed. Findings include: Review of the following 3 patient reports: FD18-0461 (2018), FD19-488, FD19-483 (2019), revealed that the reports had incorrect laboratory name listed. During an interview on 10/16/19 at 11:00 a.m., the TP#A confirmed that the final report did not include the correct laboratory name.