Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2116157	03/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Florida Medical Clinic Pa-Wiregrass Lab	2100 Via Bella Blvd Ste 206, Land O Lakes, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Technical Consultant, the laboratory failed to enroll in proficiency testing under their CLIA (Clinical Laboratory Improvement Amendment) number since 09/2016 when the laboratory first opened. Findings Included: Review of 2016, 2017, and 2018 API enrollment confirmation confirmed that the wrong CLIA number was used for enrollment. Review of proficiency testing records from 09/2016 to current revealed that the proficiency testing was performed at the correct location using the testing personnel from the correct location. During an interview on 03/28/18 at 3:00 PM the Technical Consultant confirmed that CLIA number that was put on the enrollment was accidentally transcribed as a sister facility and that all testing was performed at the correct location and only the CLIA number was incorrect.
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 interview with the Technical Consultant the laboratory failed to document the room temperature and humidity since opening in 09/2016. Findings Included: Review of the manufacturers instruction for the CBC (Complete Blood Count) analyzer revealed that the operating temperature was 18-32 degrees Celsius and the maximum humidity was 80%. Review of temperature records revealed that the room temperature and humidity was not being documented since the laboratory opened in 09/2016. During an interview on 03/28/18 at 3:30 PM the Technical Consultant confirmed that they were not documenting the room temperature or humidity in the laboratory.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Technical Consultant, the Laboratory Director failed to recognize that the laboratory was not enrolled in proficiency testing under their CLIA (Clinical Laboratory Improvement Amendment) number since 09/2016 when the laboratory first opened (See D6015).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Technical Consultant, the Laboratory Director failed to recognize that the laboratory was not enrolled in proficiency testing under their CLIA (Clinical Laboratory Improvement Amendment) number since 09/2016 when the laboratory first opened. Findings Included: Review of 2016, 2017, and 2018 API enrollment confirmation revealed that the wrong CLIA number was used for enrollment. Review of proficiency testing records from 09/2016 to current revealed that the proficiency testing was performed at the correct location using the testing

	personnel from the correct location. During an interview on 03/28/18 at 3:00 PM the Technical Consultant confirmed that CLIA number that was put on the enrollment was accidentally transcribed as a sister facility and that all testing was performed at the correct location and only the CLIA number was incorrect.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Technical Consultant, the Technical Consultant failed to recognize that the laboratory was not enrolled in proficiency testing under their CLIA (Clinical Laboratory Improvement Amendment) number since 09/2016 when the laboratory first opened (See D6041).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Technical Consultant, the Technical Consultant failed to recognize that the laboratory was not enrolled in proficiency testing under their CLIA (Clinical Laboratory Improvement Amendment) number since 09/2016 when the laboratory first opened. Findings Included: Review of 2016, 2017, and 2018 API enrollment confirmation revealed that the wrong CLIA number was used for enrollment. Review of proficiency testing records from 09/2016 to current revealed that the proficiency testing was performed at the correct location using the testing personnel from the correct location. During an interview on 03/28/18 at 3:00 PM the Technical Consultant confirmed that CLIA number that was put on the enrollment was accidentally transcribed as a sister facility and that all testing was performed at the correct location and only the CLIA number was incorrect.