Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1077790	09/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kenneth A Giraldo Md Pa	1219 Se Ave Ste 101, Sarasota, 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 CLIA recertification survey was conducted at Kenneth A Giraldo MD PA on 09/23/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: D5200 493.1230 Condition: General Laboratory Systems
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing and interview with the General Supervisor the laboratory failed to verify the accuracy of opiates and Tetrahydrocannabinol (THC) testing using the methodology used in patient testing for 2 out of 2 years reviewed (2017-2019). See D5217 This is a repeat deficiency.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on review of API (American Proficiency Institute) proficiency testing and interview with the General Supervisor, the laboratory failed to verify the accuracy of testing using the methodology used in patient testing for opiates and Tetrahydrocannabinol (THC) for 2 out of 2 years reviewed (2017-2019). This is a repeat deficiency from the 09/23/17 survey. Findings Included: Review of API proficiency testing revealed that the laboratory was using a qualitative method (positive/negative) to verify accuracy for opiates and THC. Review of the Patient test results from 12/15/17 thru 07/23/19 revealed that the laboratory was reporting out semi-quantitative results (Numerical). Interview on 09/23/19 at 11:00 AM with the General Supervisor confirmed that the laboratory was using a semi-quantitative (quantitative numbers and positive/negative) method for patient testing and the laboratory was not using this method for proficiency testing. Also the General Supervisor stated that API would be offering a semi-quantitative panel for 2020 enrollment. Review of the Allegation of Compliance (AOC), signed 10/12/17 by the Laboratory Director, revealed that this was a repeat deficiency from the 09/23/17 recertification survey. The AOC stated: In addition to participation in PT testing, the laboratory will complete split sample 2 times per year to verify the accuracy of testing. We will complete our first split sample in Oct 2017. The completion date was 10/31/17.