Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2004734	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ruffolo Hooper & Associates Md Pa	9712 Sorbonne Loop, Seffner, 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 Ruffolo, Hooper, & Associates MD PA on 08/21/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to document the quality of Histopathology control slides for 2 out of 2 years (2018-2019) Findings Included: Review of the CMS 116 Application for Certification, signed and dated (8/21/2019) by the Laboratory Director revealed the lab read hematoxylin and eosin (H&E) , and a list of immunohistochemical and special stains. Record review of the laboratory logs revealed the logs did not include quality control for 2 out of 2 years (2018-2019). Record review of the H&E Control Validation report for 08/2019 provided by the main laboratory where the Histopathology technical component was performed, showed the Laboratory Director had electronically documented quality control but the location was not specific for this laboratory's location where the Histopathology professional component was performed. Interview on 08/21/19 at 10:30 AM with the Laboratory Director revealed the main laboratory sends a photograph through the main laboratory's information system. Through this system, the pathologist was able to document if the quality control slides were acceptable, but quality control documentation was not kept at the pathologist's read only laboratory.