

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2210653	(X3) Date Survey Completed 06/22/2021
Name of Provider or Supplier Ruffolo Hooper & Associates Md Pa	Street Address, City, State 9330 State Road 54, Trinity, 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 initial certification survey was conducted at Ruffolo, Hooper, and Associates MD PA on 06/22/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review of patient reports and interview with the Laboratory Director, the laboratory's patient test report failed to have the address of the histopathology and cytology testing (professional component) laboratory for three out of three reports for the time period of 01/25/21 to 06/22/21. Findings included: Review of two histopathology patient test reports dated 03/31/21 and 06/02/21 and one cytology patient report dated 06/02/21 revealed the location of the testing (professional component) laboratory was not included in the patient report. Interview on 06/22/21 at 11:30 am with the Laboratory Director confirmed the patient test reports did not have the laboratory's address.</p>