Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2126253	12/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ruffolo Hooper And Assoc Md Pa	10740 Palm River D Ste 210, Tampa, 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 and Associates MD PA on 12/17/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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, the conditions for reliable test system operations failed to be monitored and documented for seven (3/27/24, 4/3/24, 5/1/24, 5/8/24, 7/10/24, 10/3/24, and 10/15/24) of nine (3/27/24, 4/3/24, 4/25/24, 5/1/24, 5/8/24, 7/10/24, 8/6/24, 10/3/24, and 10/15/24) days of patient Hematoxylin and Eosin (H&E) Histopathology testing. Findings include: Review of the patient log documented patient samples were received 3/27/24, 4/3/24, 5/1/24, 5/8/24, 7/10/24, 10/3/24, and 10/15/24. Review of Cryostat and Frozen Room Quality Assurance logs for March, April, May, July, and October 2024 revealed no documentation of the cryostat or room temperature, the room humidity, the cleaning of the cryostat, checking of expiration date of supplies, and restocking of supplies for the H&E testing on the seven days patient samples were received. The Lab Manager, on 12/17/2024 at 11:25 AM, confirmed the conditions for reliable test system operations failed to be monitored and documented for the seven dates when patient testing was performed.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of records and interview, the laboratory failed to ensure documentation of test staining materials for the intended reactivity for nine of nine test days (3/27/24, 4/3/24, 4/25/24, 5/1/24, 5/8/24, 7/10/24, 8/6/24, 10/3/24, and 10/15/24) days of patient Hematoxylin and Eosin (H&E) Histopathology testing. Findings include: The Cryostat and Frozen Room Quality Assurance (QA) records for March, April, May, July, August and October 2024 include a column titled "H&E QA Pathologist with instructions to check and initial. There was no check mark or initial by the testing person (pathologist) for 3/27/24, 4/3/24, 4/25/24, 5/1/24, 5/8/24, 7/10/24, 8/6/24, 10/3/24, and 10/15/24 on days of patient Hematoxylin and Eosin (H&E) Histopathology testing for expected reactivity. The Procedure Manual approved by the Lab Director 6/1/2024 included instruction under Quality Control for the H&E quality to be documented on the day of the frozen section by the reading (testing) pathologist. The Lab Director and Lab Manager both confirmed on 12/17/2024 at 10:50 AM there was no documentation of expected reactivity of H&E staining performed on 3/27/24, 4/3/24, 4/25/24, 5/1/24, 5/8/24, 7/10/24, 8/6/24, 10/3/24, and 10/15/24.
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 record review and interview, the test report failed to indicate the name, address, report date, and specific test performed for patient Hematoxylin and Eosin (H&E) Histopathology testing for one of one patient report (Patient #1). Findings include: Review of Patient #1's test report documented under Specimen 1 and 2 the frozen section diagnosis was performed however it did not state the name of the test performed (an H&E), the correct laboratory name and address, or the date the H&E was performed. The Lab Manager confirmed, on 12/17/24 at 11:25 AM, the listed name was not the correct laboratory name for the testing performed at this laboratory. Electronic correspondence with the Lab Manager on 12/17/24 at 3:07 PM and 4:07 PM verified "the frozen section details within the gross description";however, the laboratory's correct name, address, test performed, and date of testing was not documented in the gross description portion of the report.