Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0994171	04/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baycare Medical Group, Inc	620 10th St N Ste 3a, Saint Petersburg, 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 recertification survey was conducted at Baycare Medical Group, Inc on 04/03/19. The facility 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 with the Laboratory Personnel, the laboratory failed to record the room temperature and room humidity every day that testing was performed from September 2018 to the day of survey, 04/03/19. Findings Included: Review of the cryostat instrument manual revealed that the operating temperature range should be 18 degrees Celsius to 35 degrees Celsius and the maximum humidity should be 60%. Review of the Daily Quality Assurance/Quality Control Checklist showed the laboratory was not documenting the room temperature from September 8, 2018 to April 3, 2019. In addition, the laboratory was not documenting the humidity from December 3, 2018 to April 3, 2019. The laboratory was documenting if the temperatures and humidity were within range during this time period as "yes," but no temperature or humidity value was recorded. Interview on 04/03/19 at 3:10 PM with the Laboratory Personnel confirmed that the laboratory switched from documenting temperatures and humidity percentages to documenting if the temperatures and humidity were within range.

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 with the Office Manager, the laboratory failed to include the address of where Histopathology testing was performed since 12/2017. Findings Included: A review of 4 patient final reports from 12/27/2017, 6/2018, 12 /2018 and 3/2019 revealed that 3 of the reports (12/27/2017, 6/2018, and 3/2019) did not contain the address of where the testing was performed. Interview on 04/03/2019 at 3:15 PM with the Office Manager confirmed the 3 patient reports did not contain the address of where testing was performed.