Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0998002	07/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Stony Point Surgery Center	8700 Stony Point Parkway Suite 100, Richmond, VA	

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 the Stony Point Surgery Center on July 8, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F. R. 493-1250 Condition: Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour of the testing area, review of manufacturer's operations manual, policy and procedures (P&P), maintenance logs, lack of documentation, patient test logs, and an interview, the laboratory failed to: 1. ensure the monitoring and documentation of room temperatures and relative humidity (Refer to D5413) 2. ensure cyrostat instrument maintenance was performed (Refer to D5429 part A) **REPEAT DEFICIENCY** and 3. ensure the microscope preventative maintenance was performed according to the established policy (Refer to D5429 part B).
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 a review of the manufacturer's operations manual, maintenance logs, lack of documentation, patient test logs, and an interview, the laboratory failed to monitor and document the room temperature and relative humidity according to the manufacturer's instructions for the twenty-four (24) months reviewed, performing forty-eight (48) patient tissue samples. Dates of record review 06/01/19 to 6/30/21. Findings include: 1. Review of the Leica CM 1850 Cryostat Operations Manual revealed the following: "4.1 Site Requirements- room temperature max. 35 degrees Celsius, air humidity must not exceed 60%. "Note- high room temperatures and excessive air humidity affect the cooling capacity of the cryostat."" 2. Review of the available maintenance logs revealed lack of documentation of the monitoring of the room temperature and relative humidity for the 24 months reviewed. The inspector requested the aforementioned documentation and it was not available for review. 3. Review of patient test logs revealed 48 patient tissue samples conducted during the timeframe of review. 4. An exit interview with the chief nursing officer on 07/08/21 at 13:30 PM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** A. Based on a review of the manufacturer's operations manual, policy & procedures (P&P), maintenance and patient test logs, and an interview, the laboratory failed to document performance of daily cryostat instrument maintenance according to the manufacturer's instructions on nine (9) days while processing 16 patient tissue samples during the twenty-four (24) months reviewed. Dates of record review 06/01/19 to 6/30/21. Findings include: 1. Review of the Leica CM 1850 Cryostat Operations Manual revealed Cleaning, Disinfection, Maintenance Instructions in Section 9 that stated: "Perform the cleaning procedures every day: removing frozen section waste from the cryostat with the cold brush every day, remove the section waste, drain the cleaning liquid after cleaning daily, spray disinfection (recommend LEICA Cryofect-note the cryostat has to be disinfected after each daily use)". 2. Review of the P&P (signed by the lab director 05/14/19) revealed the following policy- "Preventative Maintenance and Decontamination of the Crytostat" which stated "Routine disinfection cleaning will be performed as needed/ either on a daily, weekly or monthly schedule based on volume of frozen section cases performed. Once the cryostat is used, the site staff will perform cleaning and maintenance procedures before the next scheduled day of frozen sections". 3. Review of the laboratory's Surgery Center Cryostat Temperature and Maintenance logs and patient test logs revealed no documentation of the required daily maintenance on the

	following days while processing patient tissue samples: 12/11/19- 4 patients, 12/31 /19- 1 patient, 1/15//20- 2 patients, 4/21/20- 2 patients, 8/5/20- 1 patient, 8/12/20- 1 patient, 12/02/20- 1 patient, 12/22/20- 2 patients and 12/29/20- 2 patients. Total 9 days and 16 patients. The inspector requested to review the daily maintenance for the dates of patient testing outlined above. No records were available. 4. An exit interview with the chief nursing officer on 07/08/21 at 13:30 PM confirmed the findings. B. Based on the review of the tour of the testing area, policy & procedures (P&P), and interview, the laboratory failed to follow the established policy for performing the yearly preventative maintenance (PM) for the microscope in the calendar year 2020. Findings include: 1. Tour of the testing area on 07/08/21 at approximately 12:30 PM revealed the lab utilizes the microscope to perform the technical component of histological tissue reviews. 2. Review of the P&P (signed by the lab director 05/14 /19) revealed the following statement: "Preventative Maintenance- The pathology microscope will have yearly PM's performed." The inspector requested to review the microscope PM performed for the calendar year 2020. The documentation was not available for review. 3. An exit interview with the chief nursing officer on 07/08/21 at 13:30 PM confirmed the findings.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a tour of the testing area, review of manufacturer's operations manual, policy and procedures (P&P), maintenance logs, lack of documentation, patient test logs, and an interview, the laboratory director failed to ensure: 1) the monitoring and documentation of room temperatures and relative humidity (Refer to D5413); 2) the cyrostat instrument maintenance was performed (Refer to D5429 part A); and 3) the microscope preventative maintenance was performed according to the established policy (Refer to D5429 part B).