Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2130477	04/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
West Creek Surgery Center	1630 Wilkes Ridge Parkway - Suite 101, 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 West Creek Surgery Center on April 16, 2019 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:
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 the review of maintenance records, daily patient test log, lack of documentation, policy and procedures (P&P) and an interview with the laboratory director, the laboratory failed to document the Leica CM-1850 Cryostat instrument temperature according to the P&P each day of patient testing for twenty-two (22) of sixty-two (62) days reviewed and reporting a total of sixty-eight (68) patients. Dates of record review included January 1, 2018 and up to March 31, 2019. Findings include: 1. Review of the Leica CM-1850 Cryostat instrument maintenance records and daily patient test log revealed lack of documentation of the instrument temperatures for the following dates: 1/16/2018- 1 patient, 2/26/2018- 1 patient, 2/27 /2018- 4 patients, 6/19/2018- 4 patients, 7/10/2018- 1 patient, 8/21/2018- 4 patients, 9 /18/2018- 4 patients, 10/16/2018- 5 patients, 10/23/2018- 1 patient, 11/6/2018- 6 patients, 11/13/2018- 4 patients, 11/20/2018- 2 patients, 12/4/2018- 3 patients, 12/11

	/2018- 2 patients, 1/15/2019- 8 patients, 1/29/2019- 2 patients, 2/5/2019- 6 patients, 2 /12/2019- 2 patients, 2/21/2019- 1 patient, 2/26/2019- 3 patients, 3/19/2019- 2 patients, 3/26/2019- 2 patients. Total of 22 days and 68 patients. 2. Review of P&P revealed the following statements: "Preventative Maintenance and Decontamination of Cryostat (MP-06)" signed by the lab director on 11/1/2017 "Procedure- f. Record the temperature on the log and initial. The temperature should be -20 Degrees centigrade +/- 3 degrees centigrade. h. Temperature monitoring daily." 3. An interview with the laboratory director at approximately 11:35 AM confirmed the findings.