Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2130477	05/10/2023
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 05/10/23 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, and interview, the lab failed to define a step-by-step procedure for reviewing and

	recording the intended reactivity of the Hematoxylin and Eosin (H&E) stain each day of use for testing patient histological samples at the date of survey on 05/10/23. Findings include: 1. Review of the P&P revealed a policy, "Rapid H&E Stain for Fresh Frozen Tissue" (signed as reviewed by the lab director December 2022). The policy lacked documentation of a step-by-step procedure for reviewing and recording the intended reactivity of the H&E stain for each day of use. 2. An exit interview with the Chief Nursing Office on 05/10/23 at approximately noon confirmed the findings.
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 the review of daily patient log sheet for histological samples, lack of documentation, and interview, the lab failed to document the intended reactivity of Hematoxylin and Eosin (H&E) stain for 83 of 83 days of patient testing during the review timeframe of 11/16/21 up to the date of survey on 05/10/23 while reporting 175 patients. Findings include: 1. Review of the daily patient log sheet for histological samples revealed lack of documentation of the H&E stain quality for 83 of 83 days from 11/16/21 up to the date of survey on 05/10/23 and 175 patients resulted during the timeframe. The review also revealed that prior to 11/16/21, a different log sheet was used to record daily patient testing that included a column to document stain quality. The log sheet used after 11/16/21 lacked the column to document stain quality. 2. In an exit interview with the Chief Nursing Office on 05/10/23 at approximately noon, they stated that they did not realize the log sheets had been changed and the findings were confirmed.