Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0091845	10/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Castleton Family Health Center	275 Route 30 North, Bomoseen, VT	

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
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 observation, record review, and staff interview, the laboratory's urinary sediment microscopic analysis procedure manual failed to include instruction for centrifugation speed. Findings include: Observation of the centrifuge dedicated to urine specimens on 10/25/2022 at 9:35 a.m. revealed the centrifuge setting of 3,622 revolutions per minute (rpm) and spun for 10 minutes and 5 seconds. There were no timers located at the urine centrifuge. Review on 10/25/2022 of the lab's procedure manual for urine sediment microscopic analysis revealed no instruction for how fast to centrifuge urine specimens and the urine specimens were to be spun for 2 minutes.

	Interview on 10/25/2022 at 11:45 a.m. with testing personnel confirmed the above findings.