Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0090617	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier White River Family Practice, Pc	**Street Address, City, State** 331 Olcott Drive Suite U3, White River Junction, 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 record review and staff interview, the laboratory's procedure manual for endocrinology testing failed to include instruction for the time needed to allow the blood specimen to clot prior to centrifugation. Findings include: 1) Review on 10/6 /2022 of the laboratory's procedure titled "TSH NANOENTEK FRENDTM SYSTEM" revealed the specimen used for thyroid stimulating hormone (TSH) testing was serum. Further review revealed no instruction to allow the blood specimen to clot and for how long to allow to clot prior to centrifugation. 2) Interview on 10/6/2022 at

	9:45 a.m. with Testing Personnel revealed blood specimens are given 10 minutes to clot before centrifuging for TSH testing. 3) Review on 10/6/2022 of the manufacturer's instructions revealed blood specimens for serum TSH testing must be allowed to clot for 30 minutes prior to centrifugation. 4) The laboratory's annual test volume for TSH is 1,109.