Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2169553	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mohammed Ogaily, Md	19727 Allen Rd, Suite 12, Brownstown, MI	

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 interview with Phlebotomy Staff, the laboratory failed to establish a specimen collection procedure for its specimens collected for Complete Blood Count (CBC) testing for 2 (August 2020 to August 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's procedure manual on 8/9/22 revealed a lack of specimen collection procedure established for its specimens collected for CBC testing. 2. The surveyor requested the laboratory's specimen collection

	procedure on 8/9/22 at 10:03 am and it was not made available. 3. An interview on 8/9 /22 at 10:15 am with Phlebotomy Staff revealed no specimen collection procedure had been established.