Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1031713	05/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Laboratory	8150 Perry Highway Suite 102, Pittsburgh, PA	

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 personnel interview of the Laboratory Manager and review of the urine microscopic procedure at the time of the survey (13:30 05/08/2018), the written procedure manual did not include all specimen processing requirements applicable to the urine microscopic procedure. Findings: 1. The written procedure in use on the date of the survey (05/08/2018), did not include speed of centrifugation 493.1251(b) 1, in the urine micriscopic procedure. 2. 1 of 1 centrifuges used for urine microscopic

	procedure, was not adjustable for end users and had a tachometer reading of 3300 taken 12/21/2017. 3. During the survey, the Laboratory Supervisor confirmed the above findings.