

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2147777	(X3) Date Survey Completed 07/06/2022
Name of Provider or Supplier Advanced Genetics Lab	Street Address, City, State 810 Main St, Monroe, CT	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow a complete written procedure prior to patient testing in the specialty of hematology and subspecialty of routine chemistry. Findings include: 1. Record review on 06/28/2022 of the 'Technical Procedure' binder revealed lack of documentation of the following procedural steps: a. Corrective action to be taken when control results fail to meet acceptability. b. The laboratory's protocol for interpretation and entry of results including life threatening/panic outcomes. 2. Staff interview on 06/28/2022 at 12:00 PM with the general supervisor confirmed the above findings. 3. The laboratory</p>

performs 300 tests in the specialty of hematology and 1500 tests in the subspecialty of routine chemistry annually.