Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0869645	06/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Allergy Immunology Diagnostic Lab Center	8701 Watertown Plank Rd, Milwaukee, WI	

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) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 surveyor review of procedures and interview with testing personnel (Staff A), one of one laboratory procedure reviewed did not include instructions for the distribution of test reports to the ordering laboratory or authorized person. Findings include: 1. Review of the procedure, "Allergic Bronchopulmonary Aspergillosis (ABPASP)", showed the procedures provided instructions to produce a report for interpretation and signature by the laboratory director. No instructions were evident describing how the laboratory distributes test reports to the ordering laboratory or

	other authorized persons after personnel "Submit the report to the physician consultant / director for interpretation of report." 2. Interview with Staff A on June 1, 2026, at 12: 15 PM confirmed the procedures did not include instructions for distributing test reports to the laboratory that ordered the test or to any authorized persons.