

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2190318	(X3) Date Survey Completed 03/25/2026
Name of Provider or Supplier Xytex Laboratories	Street Address, City, State 709 Canton Road, Ne Suite 110, Marietta, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 25, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Standard Operating Procedures and staff interviews, the laboratory failed to ensure the establishment and availability of a downtime procedure</p>

for testing personnel. Findings: 1. A review of the Standard Operating Procedures revealed that the laboratory failed to establish and make available a downtime procedure for testing personnel. 2. An interview, with the Technical Supervisor, in a conference room , on March 25, 2026, at 12:32 PM confirmed that a downtime procedure was not available on the date of survey.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on a review of the Standard Operating Procedures and staff interview, the laboratory director failed to specify, in writing, the duties and responsibilities for testing personnel engaged in all phases of laboratory testing. Findings include: 1. A review of the Standard Operating Procedures revealed that the laboratory director failed to specify, in writing, the duties and responsibilities for testing personnel across all phases of laboratory testing. 2. An interview, with the Technical Supervisor, in a conference room, on March 25, 2026, at 12:30 PM confirmed that the Standard Operating Procedures did not include documented duties and responsibilities for testing personnel.