

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2137469	(X3) Date Survey Completed 11/15/2024
Name of Provider or Supplier Silbiotech, Inc	Street Address, City, State 5107 Pegasus Ct Ste L, Frederick, MD	
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 interview with the technical supervisor (TS), the laboratory did not have an approved written procedure for how the laboratory received and accessioned patient specimens for the laboratory developed test. Findings: 1. During the exit interview on 11/15/2024 at 12:45 PM, the TS confirmed that the laboratory did not have a written and approved procedure describing how the laboratory received patient specimens, assigned them an accession number, and recorded the patient information in the computer prior to testing.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, review of the consumables log, and interview with the laboratory director (LD) and technical supervisor (TS), the laboratory was using expired staining reagents and failed to ensure the consumables log was updated with the current reagent lot numbers. Findings: 1. The laboratory developed testing included staining patient slides with hematoxylin. 2. On the benchtop were two bottles of hematoxylin stain labeled with lot number 125414 with an expiration date of 05 /2024. 3. The consumables log only listed hematoxylin lot number 591867 with no expiration date listed. 4. During the exit interview on 11/15/2024 at 12:45 PM, the LD and TS confirmed that the hematoxylin stain currently in use was expired and the consumables log had not been updated with the current lot number.