

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2160182	(X3) Date Survey Completed 02/28/2025
Name of Provider or Supplier Nshoa	Street Address, City, State 1 Delaware Drive Suite A & Suite B, New Hyde Park, NY	
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>(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 review of the laboratory's standard operating procedures (SOPs), lack of maintenance performance records, as well as interview with the Quality Assurance Associate (QAA), the laboratory failed to establish slide stainer cannula frequency maintenance performance. FINDINGS: 1. The current, approved, "Slide Stainer</p>

Instructions" SOP did not include written instructions for Siemens Hematek 3000 automated slide stainer cannula change frequency. 2. The QAA confirmed the findings on February 28, 2025, at approximately 11:30 A.M.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on direct observation, review of SOPs and maintenance log records, as well as interview with the QAA, the laboratory failed to perform and document slide stainer pump tubing change. FINDINGS: 1. The surveyor's observations confirmed on February 28, 2025, at approximately 11:30 A.M. the Siemens Hematek 3000 slide stainer pump tubing was not changed after third stain pack install. a. There was no documentation of maintenance log slide stainer cannula change between February 2023 through April 2023. 2. This is contrary to instructions included in the current, approved SOPs. 3. The QAA confirmed the findings on February 28, 2025, at approximately 11:30 A.M.