

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2161996	(X3) Date Survey Completed 03/02/2022
Name of Provider or Supplier Nicholas Halper Md Pc	Street Address, City, State 145 Pinelawn Rd Suite 100 North Lower Level, Melville, 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>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 a review of procedure manual and Quality Control (QC) lot to lot validation of IgE, the laboratory failed to have written procedure for establishing acceptable QC range other than manufacturer's range. Findings: 1.The review of lot-to-lot validation documentation for year 2020 and 2021 of Ige had different range than manufacturer's package insert. 2.The laboratory director and testing person confirmed on an interview 3/2/2022 about 11:15am, the laboratory does not have procedure for establishing acceptable QC range.</p>

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, lack of a written Quality Control (QC) procedure establishing acceptable QC range and confirmed in an interview with the laboratory testing person, the laboratory director failed to establish a written QA for all phases for the general laboratory system. Refer to D5403.