

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1060951	(X3) Date Survey Completed 11/19/2018
Name of Provider or Supplier Harshit M Patel Md Pc	Street Address, City, State 120 Bethpage Road, Suite 310, Hicksville, 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 surveyor's review of the laboratory's procedure manual and an interview and confirmed with the laboratory director, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. A written procedure describing laboratory's batch testing system for Allergy testing which are collected daily but tested once per month; 2. A written procedure describing the laboratory's turnaround time for Allergy testing from sample collection to processing and to when final results are entered into the laboratory computer system; 3. A written procedure describing transportation of specimens from six other locations</p>

in Oceanside, Manhattan, Brentwood, Belle Harbor, Babylon and Floral Park to the Hicksville office for testing.

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 lack of the Quality Assessment (QA) records and confirmed in an interview with the laboratory director, the laboratory director failed to ensure that the general laboratory systems QA review was performed and documented two times a year as required by their QA policy in calendar year 2017 and up to the survey date. Refer to D5403

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of the personnel files and interview with the laboratory director, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for the only testing person in calendar year 2017.