

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0143418	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Manhasset Pediatrics Pllc	Street Address, City, State 450 Plandome Rd Ste 100, Manhasset, 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 direct observations as well as lack of procedures and records, the laboratory failed to draft, approve, and maintain instructions for lot-to-lot validation of new Beckman Coulter DxH 520 Quality Control (QC) reagents. FINDINGS: 1. There was no documentation of Beckman Coulter DxH 520 reagent lot to lot validation from 2019 through the survey date. 2. Confirmed findings by interview with the Laboratory Director (LD) on October 17, 2023, at approximately 1:00 P.M.</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observations, lack of room and humidity temperature records, lack of approved standard operating procedures, and an interview with the LD, the laboratory failed to monitor and document room temperature and humidity where Beckman Coulter DxH 520 patient specimen processing occurred. FINDINGS: 1. The Beckman Coulter DxH 520 manufacturer's specifications indicated ambient temperature range of 64.4 - 89.6 F and humidity max range of 80%, relative humidity non-condensing. 2. There was no documentation of room temperature and humidity from 2019 through the survey date. 3. Confirmed findings by interview with the LD on October 17, 2023, at approximately 1:00 P.M. 4. The Manhasset Pediatrics, PLLC standard operating procedures did not include written, approved instructions for monitoring and documenting room temperatures and humidity where Beckman Coulter DxH 520 patient specimen processing occurred.