

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2063831	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Manhattan Pediatric Associates	Street Address, City, State 859 60th Street, Suite Cm 1 A, Brooklyn, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory policies, the personnel competency evaluation records, and an interview with the practice manager, the laboratory failed to follow the laboratory's written policies and failed to perform annual competency reviews of the testing personnel for the 2018 calendar year.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policies /procedures and an interview with and confirmed by the practice manager, on the date of survey at 3:15 PM, the laboratory failed to follow the laboratory's written QA policy and perform general laboratory systems annual QA reviews for hematology testing for the 2018 calendar year.</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 the surveyor's review of the laboratory's policy/procedure manual and an interview with the practice manager, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5291