Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0166138	(X3) Date Survey Completed 09/17/2019
Name of Provider or Supplier Madison Irving Pediatrics, Pc	**Street Address, City, State** 6711 Towpath Road Suite 235, East Syracuse, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of College of American Pathologists (CAP) proficiency testing (PT) reports and an interview with the general supervisor/testing person and testing person, the laboratory failed to evaluate, perform and document remedial action for PT scores of less than 100% for the following analytes: 2018 third event: sub-speciality Bacteriology/throat culture = 80% 2019 first event: sub-speciality Bacteriology/throat culture = 80%
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's Quality Assurance (QA) policy and confirmed in an interview with the general supervisor/testing person and testing person, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the CAP PT records and confirmed in an interview with the general supervisor/testing person and testing person, the laboratory director failed to ensure that corrective action was taken for the sub-speciality bacteriology/throat culture scores of 80%. Refer to D5211.
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 QA policy and confirmed during the interview with the general supervisor/testing person and testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy /procedure was followed. Refer to: D5291