Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0673184	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Island Pediatrics Associates	114-12 Beach Channel Drive, Rockaway Park, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's College of American Pathology (CAP) Proficiency Testing (PT) reports and confirmed in an interview with the laboratory medical assistant/processor, the laboratory failed to satisfactorily participate in a CMS-approved PT program for Bacteriology. The following score was assigned: 2016 third event = 60%. This is considered unsatisfactory PT performance.
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 a review of CAP PT reports and an interview with the laboratory medical assistant/processor, the laboratory did not evaluate, perform and document remedial action for the PT scores less than 100% for the 2nd event in 2016 throat culture testing. Findings Include: It was confirmed with the laboratory medical assistant processor at approximately 11:15 am, that the laboratory failed to evaluate the results received for: 2016 second event Bacteriology = 80%
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and an interview with the laboratory medical assistant/processor, the laboratory failed to check each new batch or lot number of Select Strep Agar (SSA). Findings Include: It was confirmed by the laboratory medical assistant/processor on May 2, 2018 at approximately 11:25 AM that the laboratory failed to test each new batch or lot number of SSA for its ability to support growth or inhibit specific organisms for the following lot numbers: Lot # 7208618, 7138901, 1726200, 1731903, 1734607, 7341515, 1800200, 7348738, and 8025957. Approximately 4791 patient samples were tested and results reported from June 2016 through May 1, 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 CAP PT test reports, and an interview with the medical assistant /processor, the laboratory director failed to ensure that an approved corrective action plan is followed when proficiency testing results are found to be unsatisfactory. Refer to D2020 & D5211
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of QC records, and an interview with the laboratory director, the laboratory director failed to ensure that the QC program for SSA was maintained to assure the quality of laboratory services. Refer to: D5477