

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1006972	(X3) Date Survey Completed 06/11/2019
Name of Provider or Supplier Advanced Pediatrics Of Rockland	Street Address, City, State 358 Route 202, Suite 2, Pomona, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Proficiency (CAP) proficiency test (PT) reports and an interview with the office manager/processor, the laboratory did not evaluate, perform and document remedial action for the PT scores less than 100%. Findings Include: It was confirmed by the office manager/processor on June 11, 2019, at approximately 11:45 am, that the laboratory failed to evaluate the following PT results: 2018 3rd event Bacteriology = 80%</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 a lack of Quality Assessment (QA) review records and an interview with the office manager/processor, the laboratory failed to follow their written QA policy and perform monthly QA review for bacteriology testing from May 2, 2017, through the date of this survey. This is a recited deficiency from the last survey of May 2, 2017. The director stated, "Office will perform monthly QA review for all phases of Bacteriology will be done immediately and maintained by the lab director".</p>

D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient test reports, package inserts for the A Taxo disk, Becton Dickinson Strep Selective Agar plates and an interview with the office manager /testing person, the laboratory failed to follow the manufacturer's instructions for reporting patient test results and plating patient specimens on the SSA plates. Finding Includes: It was confirmed with the laboratory director on June 13, 2019, at approximately 11:00 am, that: 1) The laboratory has accepted the manufacturer's instructions for plating patient specimens on SSA plates. 2) The package insert states "To culture, a specimen from a swab, inoculate the medium by rolling the swab over a third of the agar surface and streak the remainder of the plate to obtain isolated colonies. 3) It was observed during the survey that two patient specimens were plated on each of the two SSA plates in the incubator.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observation of the bacitracin reagent, and an interview with the office manager/processor, the laboratory failed to discontinue the use of the expired SSA. Findings Include: It was confirmed with the office manager/processor on June 11, 2019, at approximately 10:30 AM, the laboratory failed to discard the expired bacitracin disk, Lot # 7304772, which expired 5/31/2019. Approximately 11 patient specimens tested were tested and results released from June 3, 2019, through June 11, 2019.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p>

This STANDARD is not met as evidenced by:
 Based on a lack of validation records and an interview with the laboratory director, the laboratory failed to establish and verify the performance specifications for plating more than one patient specimen on a Strep Select Agar plate with Bacitracin disk to show accuracy, precision, analytical sensitivity analytical specificity to include interfering substances, "reportable range of test results for the test system, reference intervals (normal values), any other performance required for test performance. How does the laboratory prevent cross-contamination? How does the laboratory show that the zone size will be the same for all addition specimens plated on the media that is 100 mm in diameter Findings Include: 1. On June 11, 2019, at approximately 11:30 AM, it was confirmed by the laboratory director that two SSA plates observed in the incubator each had two patient specimens streaked on the plate. 2. The laboratory has accepted the plating procedure in the manufacturer's package insert which instructs one specimen per plate. 3. The laboratory failed to validate the SSA plate for testing multiple patient specimens on a 100 mm plate. 4. Approximately 770 patient specimens were tested and reported for throat cultures from May 3, 2017, through June 11, 2019. 5. Please also note, a qualified high complexity director is required when off-labeled use is instituted.

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 lack of quality control (QC) records and an interview with the office manager/processor, the laboratory failed to check QC for each new batch or lot number of Select Strep Agar (SSA). Findings Include: It was confirmed by the laboratory office manager/processor on June 11, 2019 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 which began in January 2018: 1732604, 1735201, 173605,1801808, 8025957, 1804504, 853648, 8109605, 8158656, 8173598, 1818400, 1825300, 1826905, 1828905, 7831800, 1833707, 1831904, 1834603, 1800711, 1903000, and 9121807 .
 Approximately 426 patient samples were tested and results reported during that time. This is a recited deficiency from the last survey of May 2, 2017. The director stated, "Office/lab will document all control procedures performed will be started immediately".

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	<p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and interview with the office manager/testing person, the laboratory director failed to provide overall management and direction for the laboratory and ensure that: 1. Plan of correction (POC) from the May 2, 2017 survey was implemented and maintained; 2. The QC procedures are maintained for bacteriology testing; Refer D6020 3. The QA policies are maintained; Refer to D6021</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of QC records and an interview with the office manager/testing person, the laboratory director failed to ensure that QC testing for bacteriology SSA plates and the bacitracin disk was performed and maintained to assure the quality of laboratory services. Refer to: D5477. This is a recited deficiency from the last survey of May 2, 2017. The director stated, "Office/lab will test for bacteriology QC. To make sure QC is established and maintained to assure the quality of lab services".</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, a lack of records and an interview with the office manager/testing person, the laboratory director failed to maintain an effective QA program for throat culture testing. Refer to D5211, D5291, D5411, and D5417 D5211 and D5291 are being recited deficiency from the last survey of May 2, 2017. The director stated, "Office/lab will ensure the QA program is established & maintained to ensure the quality of the lab. Will maintain an effective QA program".</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p>

This CONDITION is not met as evidenced by:
Based on a review of personnel records and an interview with the office manager /testing person, the laboratory director failed to ensure that the three of three new testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of personnel records and confirmed in an interview with the laboratory managers on June 11, 2019, at approximately 11:00 am, the laboratory director failed to ensure that the three of three new testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.