

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1068926	(X3) Date Survey Completed 06/13/2019
Name of Provider or Supplier Park Avenue Pediatrics Pc	Street Address, City, State 421 Route 59, Monsey, 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
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 Taxo A disk, Becton Dickinson/Healthlinks Strep Selective Agar plates (SSA) and an interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for plating patient specimens on the SSA plates and reporting throat culture test results. Finding Includes: It was confirmed with the laboratory director on June 13, 2019, at approximately 11:00 am, that: 1) patient test results for throat cultures as documented as "Positive". 2) The laboratory testing personnel places four patient test specimens on one 100 mm SSA plates. 3) The manufacturer's package inserts for the Bacitracin disk and SSA media states that patient test results for throat culture testing are to be reported as "presumptive positive". 4) The manufacturer's package inserts for the SSA plates states that "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".</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</p>

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.

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 specimen on a SSA 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), and any other performance characteristic required for test performance. The laboratory did not comment on how to prevent cross-contamination and did not 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 13, 2019, at approximately 11:30 AM it was confirmed with the laboratory director that four patient specimens were placed on the SSA plates with bacitracin disk. 2. The laboratory failed to validate placing four patient specimens on one-100 mm SSA plate with bacitracin disk prior to the lab performing patient testing. 3. Approximately 320 patient specimens were tested and reported for throat cultures from February 2019 to the date of this survey. 4. Please also note, a qualified high complexity director is required when off-label use is instituted.

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 a review of laboratory procedures, patient test reports, observation, and an interview with the laboratory director, the laboratory director failed to maintain an effective QA program for bacteriology testing. Refer to D5411 and D5423

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the laboratory director, the laboratory failed to have documentation of training for the throat culture testing.

Findings Include: On June 13, 2019, at approximately 10:45 am, it was confirmed with the laboratory director that the director failed to ensure that appropriate training was documented for two of two testing personnel who perform moderate complexity testing for throat cultures testing.