

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1099923	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Northeast Pediatrics And Adolescent Medicine Pllc	Street Address, City, State 1290 Trumansburg Road, Ithaca, 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 a review of competency policies, staff competency records and an interview with the laboratory testing person, the laboratory failed to follow their establish written policies and procedures to assess the competency of the laboratory testing personnel that perform both Bacteriology/throat cultures and Hematology/CBC testing. FINDINGS: The laboratory manager/testing person confirmed on August 27, 2019 at approximately 2:00 PM, that the laboratory did not follow the established competency evaluation policy. The laboratory did not perform annual competency for nine of nineteen staff members in 2018.</p>
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 the surveyor's review of College of American Pathologists (CAP) proficiency testing (PT) reports and an interview with the laboratory manager/testing person, the laboratory failed to evaluate, perform and document remedial action for PT scores of less than 100% for the following analytes: 2018 first event: Urine colony counts = 80% 2018 third event: Urine colony counts = 80%</p>

<p>D5291</p>	<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 surveyor's review of the laboratory's Quality Assurance (QA) policy and confirmed in an interview with the laboratory manager/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.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of CAP PT reports and an interview with the laboratory manager/testing person, the laboratory director failed to sign & date attestation forms and review the scored proficiency testing reports received from CAP to evaluate the laboratory's performance. Refer to D5211.</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 the surveyor's review of the laboratory's QA policy and confirmed during the interview with the laboratory manager/testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5291</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of the personnel files and confirmed in an interview with the laboratory manager/testing person, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for nine of nineteen testing persons in calendar year 2018. Refer to D5209.