

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0714540	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Pediatric Practices Of Northeastern Pa - Milford	Street Address, City, State 510 Routes 6 & 209, Suite 103, Milford, PA	
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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Selective Strep Agar (SSA) quality control records and personnel interview with the Medical Staff Manager, the laboratory failed to check and document each batch or shipment of SSA media each batch of media for sterility is required for testing, check each batch of media for its ability to support growth, select or inhibit specific organisms or produce a biochemical response, from 2016 to the date of survey. Findings Include: 1. On the day of survey, 03/20/2018, it was discovered that the lab did not perform end user quality control to check if the Health Link SSA media inhibits specific organisms used for throat cultures in 2016 and 2017. 2. In 2016 roughly 1000 throat cultures specimen were read by providers. 3. In 2017 about 987 throat cultures specimen were read by providers. 4. The Medical Staff manager confirmed the findings above on 03/20/2018 around 02:15 pm</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on, the review of personnel competency assessment records, proficiency testing (PT) records and interview with the Medical Staff manager, the Technical Consultant failed to assess the competency of all TP through internal blind testing samples or external PT samples in 2016 and 2017. Findings Include: 1. At the day of survey, 03/20/2018, review of the competency assessment records revealed the laboratory did not assess test performance of TP through internal blind testing samples or external PT samples: A. 1 of 3 providers reading throat cultures in 2016. B. 2 of 3 providers reading throat cultures in 2017. 2. Provider competencies were marked off for performing PT, but documents were not available to show that they performed in PT testing in 2016 and 2017 (providers did not sign attestation forms). 3. In 2016 roughly 1000 throat culture specimens were read by providers. 4. In 2017 about 987 throat culture specimens were read by providers. 5. The Nursing Manager confirmed the findings above on 03/20/2018 around 01:30 pm.