

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0886541	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier New England Pediatrics Llp	Street Address, City, State 183 Cherry St, New Canaan, CT	
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
D6020	<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 record review and staff interview the laboratory director failed to follow its established individualized quality control plan (IQCP) for the selective strep agar (SSA) media. Findings include: 1. Record review on 9/26/18 of the laboratory's IQCP procedure for quality control plan revealed "Keep the certificate of analysis from the manufacturer stating they performed the quality control (QC) on that specific lot number and shipment number, as indicated". 2. Record review of the laboratory's QC log on 9/26/18 revealed the laboratory did not have the certificate of analysis for each lot of the SSA media for 2017 and 2018. Record review of the QC log further revealed the laboratory is getting 2-3 shipments of SSA media each month. 3. Staff interview with the laboratory director (LD) on 9/26/18 at 11:05 AM confirmed the laboratory failed to keep the certificate of analysis as indicated in the IQCP procedure. The LD further stated he/she was unaware the testing personnel did not keep the certificate of analysis. 4. The laboratory performs 1000 throat cultures annually in the specialty of microbiology.</p>