

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1007514	(X3) Date Survey Completed 07/02/2018
Name of Provider or Supplier Farmington Pediatrics Llc	Street Address, City, State 7 Melrose Drive, Farmington, 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
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 record review and laboratory director interview, the laboratory failed to check each lot number and shipment of media for its ability to select or inhibit specific organisms in the specialty of microbiology. Findings include: 1. Record review of the Strep test patient log on 7/2/18 revealed the laboratory was using Healthlink Strep Select Agar (SSA) media for throat culture (TC) testing. 2. Record review of the quality control records for new lots and shipments of the SSA media on 7/2/18 revealed the following: a) A positive control from a previous positive proficiency sample was used and documented for its ability to support growth. b) No evidence or documentation of a negative control to confirm selective or inhibitory characteristics of the SSA media was available, specifically, 5 of 5 shipments between 7/27/17 and 6/30/18. 3. Staff interview with the laboratory director on 7/2/18 at 11:30 AM confirmed the above findings. 4. The laboratory performs 68 TC annually in the specialty of microbiology. * Repeat Deficiency</p>