

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1055074	(X3) Date Survey Completed 04/12/2018
Name of Provider or Supplier Allied Physicians Group Pllc	Street Address, City, State 18 Washington Avenue, South Nyack, 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
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 a review of quality control (QC) records and an interview with the laboratory director, the laboratory failed to check each new batch or lot number of Select Strep Agar (SSA) Findings Include: It was confirmed by the laboratory director on April 12, 2018 at approximately 12:00 PM that the laboratory failed to test each new batch or lot number of SSA for its ability to support growth or inhibit specific organisms for the following lot numbers: Lot #535010, 6034911, 6124055, 61618989, 6181749, 6223594, 630095, 6356766, 7075897, 7096713, 7123773, 7138901, 72585511, and 7319575. Approximately 600 patient samples were tested and results reported during that time.</p>
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</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of QC records, and an interview with the laboratory director, the laboratory director failed to ensure that the QC program for SSA was maintained to assure the quality of laboratory services. Refer to: D5477