

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0188647	(X3) Date Survey Completed 06/27/2019
Name of Provider or Supplier Pshmg - Lime Spring	Street Address, City, State 2221 Noll Drive, Lancaster, 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 upon review of the 2019 media quality control records and personnel interview with the Laboratory Manager, Clinic Manager, and Clinic Site Administrator, the laboratory failed to check each batch or shipment of BBL Selective Strep Agar media, for inhibition of non streptococcus organisms, before or concurrent with initial use, from 01/02/2019 through 06/27/2019. . Findings: 1. The laboratory media quality control records revealed only Streptococcus group A and Streptococcus non group A, were used for BBL Selective Strep Agar media quality control, from 01/02/2019 through 06/27/2019. 2. The laboratory failed to document the ability to inhibit growth of non streptococcus organisms, BBL Strep Selective Agar, from from 01/02/2019 06 /27/2019. 3. 223 patients had throat cultures performed from from 02 January through 27 June 2019. 4. During the time of the survey (13:00 06/27/2017), the Laboratory Manager confirmed, ability to inhibit non streptococcus growth, was not performed for the Strep Selective Agar media.</p>