

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  08D0205676	<b>(X3) Date Survey Completed</b>  07/11/2018
<b>Name of Provider or Supplier</b>  Christiana Care Pediatric Associates	<b>Street Address, City, State</b>  Map-2, Suite 1116, Newark, DE	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5477</b>	<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 the Procedures Manual and interview with testing personnel 1 it is determined that each batch of purchased media received is not checked for ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. Findings include: 1. In reviewing the procedure on Strep Cultures which has a revision date of 06/23/16 it is stated in the Quality Control section that the manufacturer of the plates does the Quality Control. Two sentences down the procedure on Strep Cultures states that "A known positive and a known negative are used to streak the blood agar plate." 2. In interviewing testing personnel #1 they confirmed that they do not perform Quality Control on incoming plates but rely on manufacturer's Quality Control certificate. It was also found in interviewing testing personnel #1 that in performing the Strep Cultures test that positive and negative controls are not streaked on the blood agar plates as the procedure states.</p>