

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0724153	(X3) Date Survey Completed 08/21/2019
Name of Provider or Supplier Advocare Pediatric Medical Associates	Street Address, City, State 420 West Township Line Road, Havertown, 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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control records and interview of the Laboratory Director and Practice Manager, on the date of the survey (08/21/2019), the laboratory failed to document positive and negative reactivity, for each lot or shipment of bacitracin disks when opened. Findings include: 1. Review of the quality control records revealed a gap in bacitracin quality control documentation from (01/27/2018 through 08/21/2019), 2. Bacitracin lot #7107645 was tested 01/26/2018 and the current lot # 8838541 in the lab had no testing record at the time of survey (09:00 08/21/2019). 3. During the survey (11:30 08/21/2019), the Laboratory Director confirmed the above findings.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:

Based on review of the personnel records and interview of the Laboratory Director and Practice Manager, on the date of the survey (08/21/2019), the Technical Consultant failed to document annual competency of all testing personnel. Findings include: 1. The Laboratory Director is the Technical Consultant. 2. At the time of the survey (09:00 08/21/2019), there was no documentation of competency assessment in 2018 or 2019 for 3 of 4 testing personnel. 3. During the survey (11:30 08/21/2019), the Laboratory Director confirmed the above findings.