

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0720005	<b>(X3) Date Survey Completed</b>  12/03/2018
<b>Name of Provider or Supplier</b>  Advocare Broomall Pediatric Associates	<b>Street Address, City, State</b>  1991 Sproul Road, Suite 40a, Broomall, PA	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual (PM), throat culture (TC) log, and interview with the testing personnel (TP) #1, the laboratory failed to follow TC incubation procedures in 2018. Findings include: 1. The laboratory TC PM (also the Presumptive Identification of Group A Beta-Hemolytic Streptococci by Culture, Bureau of Laboratory, Department of Health), the laboratory directory signed off on 10/03/2018, states "If negative for growth beta-hemolytic streptococci, re-incubate for an additional 24 hours." 2. The laboratory TC log shows the laboratory streaked 5 plates (11/30/2018-12/01/2018), from which a summary reads as follows: Plate Read Result (Hours) Streak Date Number 24 24-48 11/30/2018 3 Negative No Data 12/01/2018 1 Positive ----- 12/01/2018 1 Negative No Data 3. Of the 4 TC tested negative at 24 hours, none (4 of 4) re-incubated and re-tested at 24-48 hours. 4. The laboratory reported all these TC results electronically. 5. The TP #1 confirmed above findings on 12/03/2018 at 10:00 AM.</p> <p>=====</p>