

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0203503	(X3) Date Survey Completed 07/29/2021
Name of Provider or Supplier Advocare Broomall Pediatrics Associates	Street Address, City, State 1246 West Chester Pike, West Chester, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on competency assessment record review and interview with the Nurse Manager (NM), the Laboratory failed to follow the Laboratory's written policies and procedures to assess the competency of 2 of 10 testing personnel (TP) who performed Throat cultures for streptococcus group A from 07/29/2019 to 07/29/2021. Findings Include: 1. On the day of survey 07/29/2021 at 10:05 a.m., review of the competency assessment records revealed the following: - 1 of 10 TP (CMS 209 personnel #4) the laboratory did not evaluate twice yearly for the first year for streptococcus group A throat cultures. - 1 of 10 TP (CMS 209 personnel #8) the laboratory could not provide competency assessment records or streptococcus group A throat cultures from 2019, 2020, and 2021. 3. The NM confirmed the findings above on 07/29/2021 at 10:15 a.m.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with the Nurse Manager (NM), the laboratory failed to include a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from October 20, 2020 through February 2, 2021. Findings include: 1. On the day of survey 07/29/2021, the laboratory could not provide a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from October 20, 2020 through February 2, 2021. 2. The laboratory tested 135 specimens for SARS-CoV-2 from October 20, 2020 to February 2, 2021 3. The NM confirmed the findings above on 07/29/2021 around 12:15 p.m.