Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0720005	08/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advocare Broomall Pediatric Associates	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. 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 1 of 9 testing personnel (TP) who performed throat cultures for streptococcus group A from 08/12/2019 to the day of survey. Findings Include: 1. On the day of survey 08/12/2021 at 10:00 a.m., the laboratory could not provide competency assessment records for 1 of 9 TP (CMS 209 personnel #6) who analyzed streptococcus group A throat cultures from 08/12/2019 to the day of survey. 3. The NM confirmed the finding above on 08/12/2021 at 11:00 a.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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) 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 (PA NEDSS) as required from October 06, 2020 through February 04, 2021. Findings include: 1. On the day of survey 08/12/2021, 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 06, 2020 through February 04, 2021. 2. The laboratory tested 260 specimens for SARS-CoV-2 from October 06, 2020 to February 04, 2021. 3. The NM confirmed the findings above on 08/12/2021 around 09:40 a.m.