Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0116586	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Advocare Aygen Pediatrics	**Street Address, City, State** 530 East Main Street, Suite 4a - 5 A, Chester, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) Records and interview with the Testing Personnel (TP), the laboratory failed to ensure that the attestation statements for Bacteriology PT events in cycle 1 - 2017 and 2 and 3 - 2018 performed with Acutest were signed by the TP and Laboratory Director. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 12:45 pm that the attestation statements listed above were not signed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Instructions (MI), observation of streaked plates and interview with the Testing Personnel (TP), the laboratory failed to follow MI for plating throat culture specimens from 10/20/16 to the date of the survey. The finding includes: 1. The MI stated to inoculate one patient per plate but the laboratory streaked two patients per plate. 2. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 1:40 pm that the laboratory did not follow the MI.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Temperature Log (TL) and interview with Testing Personnel (TP), the laboratory failed to monitor and document Room Temperature (RT) where Throat Culture tests were performed from 10/20/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 1:20 pm that the laboratory did not document RT.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Throat Culture testing performed with Accutest in cycle 2 and 3 - 2018. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 12:30 pm that the PT results were not reviewed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of five Testing Personnel (TP) from 10/20/16 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 1:10 pm that all TP did not have education records.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to perform Competency Assessment (CA) from 10/20/16 to the date of survey. The findings include: 1. The CA was not performed by TC. 2. The TP #1 performed CA on four of five TP, TP #3 performed CA on one of five TP but neither TP was qualified to perform CA. 3. The TP #1 listed on CMS form 209 confirmed on 11/29/18 at 1:15 pm that the CA was not performed by TC.