Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0123811	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Advocare Pediahealth Medical Associates	**Street Address, City, State** 745 Us 202/206, Bridgewater, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION 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 enroll in an approved PT program for Throat Culture (TC) tests in the calendar year 2020. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 9:40 am the laboratory was not enrolled in PT for TC tests.
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: a. Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain work records for Throat Culture PT in event D1 - A 2021 performed with the College of American Pathologists (CAP). The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 9:45 am that PT work records were not maintained. b. Based on surveyor review of the PT records and interview with the TP, the laboratory failed to maintain the Attestation Statements (AS) signed by the the Laboratory Director for Throat Culture tests performed with the CAP in the D1 - A event. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 9:45 am that the AS was not signed by the LD.
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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP) the laboratory failed to follow its policies and procedures for assessing the competency of TP who perform Throat Culture testing in the calendar years 2019 and 2020. The findings include: 1. The CA was not performed on four out of four TP in 2019 and 2020. 2. The laboratory CA policy stated: for new employees, an evaluation will be done after 6 months and thereafter for the first year of continued employment. A yearly evaluation shall then follow but there was no evidence of CA being performed on any new employee on the day of the survey. 3. The laboratory failed to use all the required elements applicable to Bacteriology testing for assessing the competency of TP in the 2021. The laboratory did not use: a. #4 assessment of test performance through proficiency testing, blind sampling or previously analyzed specimens b. #5 assessment of problem solving skills. 4. CA reviewed were not signed by the TP being reviewed. 5. The TP #1 listed on the CMS form 209 confirmed on 8/17/21 at 10:00 am the laboratory did not use the follow the CA procedure.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. 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 review and evaluate PT results obtained from the College of American Pathologists (CAP) for Throat Culture events D1-A 2021. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 10:30 am that the laboratory did not review PT results stated above.

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 Temperature Logs and interview with the Testing Personnel (TP), the laboratory failed to monitor and document Room/Humidity, Refrigerator and Incubator temperature where Throat Culture supplies were stored on the date of the survey. The findings include: 1. The Room and Refrigerator temperature had not been recorded from 1/1/20 to the date of the survey. 2. The incubator temperature was not recorded from 6/25/21 to the date of the survey. 3. Humidity temperature was not recorded from 6/25/21 to the date of the survey 4. The TP #1 listed on CMS 209 confirmed on 8/17/21 at 10:30 am that temperature was not monitored and documented where TC testing was performed.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 3/16/20 to the date of the survey. The finding includes: 1. There was no documented evidence QC was performed on the Bacitracin discs in use; Lot 0178594 expiration date: 1/31/22 prior to patient use. 2. There was no record of Bacitracin QC on the QC log after 3/16/20 expiration date: 2/28/21. 3. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 9:50 am that the laboratory did not perform QC on Bacitracin disc as stated above.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each batch of Selective Strep Agar (SSA) used for Throat Culture (TC) tests for sterility, its ability to support growth and select or inhibit specific organisms from 3/19/20 to the date of the survey. The findings include: 1. QC documentation revealed Lot #9106825 received 1/2/20 expired 3/19/20 but there was no documented evidence QC was performed on SSA agar received after expiration date until 9/9/20. 2. QC Lot# 9115787 received 9/9/20 expired 11/16/20 but there was no documented evidence QC was performed on SSA to the date of the survey 3. Current lot of SSA in use #485301 did not have documented evidence QC was performed prior to putting into use. 4. The laboratory receives SSA shipments approximately every other month. 5. The laboratory performed approximately 15-20 TC per month. 6. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 9:50 am that the laboratory did not perform QC as stated above.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Records (PR), Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to delegate competency evaluation to a qualified person for the performance of Throat Culture CA to the date of the survey. The finding includes: 1. CA was performed by TP #4 who had a high school diploma which did not meet the qualifications found in 493.1409, 493.1415, and 493.1421 2. The TP #1 listed on the CMS form 209 confirmed on 8/17/21 at 10:20 am that the LD did not delegate the evaluation of competency to a qualified person.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	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 Director (LD) failed to ensure that PT samples were tested for Throat Culture (TC) tests in the calendar year 2020. The TP #2 listed on CMS form 209 confirmed on 8/17/21 at 9:45 am that the LD did not ensure PT TC samples were tested.
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 failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Throat Culture testing performed with the College of American Pathologists (CAP) in the 1st event of 2021. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 10:30 am that the CAP PT results were not reviewed.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QA program was maintained from March 2019 to the date of survey. The finding includes: 1. The QA policy stated "QA will be checked monthly by the General Supervisor" but there was not documented evidence QA was checked after March 2019. 2 The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 10:20 am that the laboratory did not maintain the QA program.
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 Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have appropriate training documented for four out of four TP on the date of the survey. The TP #1 listed on CMS form 209 confirmed on 8/17/21 at 10:10 am that training records were not available.