

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115763	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Advocare Sussex County Pediatrics	Street Address, City, State 39 Newton-Sparta Rd, Newton, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Package Insert (MPI), Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instruction for bacitracin discs from 12/5/17 to the date of survey. The finding includes: 1. The MPI stated to read the discs between 18 and 24 hours but the laboratory read patient results after 24 hours. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 11:10 am that the laboratory did not follow the MPI.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with</p>

the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Throat Culture media for sterility, ability to support growth and select or inhibit organisms from 12/5/17 to the date of the survey. The findings include: 1. There was no documented evidence ability to support growth and select or inhibit organisms was checked on any lot number of media. 2. Sterility was not checked on media received from 12/5/17 to 10/1/19. 3. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 10:50 am the laboratory did not perform the above QC.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on surveyor review of the Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to maintain an accurate information system for Throat Culture tests from 12/5/17 to the date of the survey. The findings include: 1. Review of ten AL entries revealed: a. Two patients had illegible patient names. b. One patient had the incorrect date of service. c. One patient had a TC result in the AL but patient was not found in the Electronic Medical Record (EMR) for that day. d. Two patients had incorrect spelling of their name. e. Six dates in December of 2019 were written over making the date illegible. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 11:25 am that the laboratory did not maintain an accurate information system.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Throat Culture TR included all the required information from 12/5/17 to the date of survey. The findings include: 1. The TR did not have the name and address of the reference laboratory when tests were performed offsite. 2. The TR did not have the report date. 3. The TP # 1 listed on the CMS form 209 confirmed on 1/8/2020 at 11:30 am that the TR failed to include all the required information.

<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Range (RR) for Throat Culture (TC) tests from 12/5/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 12:00 pm that TC tests did not have a RR on the TR.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verifying manually entered results from the accession log to the laboratory information system from 12/5/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 11:30 am that the laboratory did not have the procedure mentioned above.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 12/5/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/8/2020 at 11:20 am that a QA plan had not been established.</p>