

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0116272	(X3) Date Survey Completed 04/13/2021
Name of Provider or Supplier Advocare Sinatra & Peng Pediatrics	Street Address, City, State 169 Minebrook Road, Bernardsville, 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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(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.</p> <p>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 BBL Bacitracin Discs for positive and negative reactivity from 04/05/18 to the date of the survey. The findings include: 1. There was no documentation provided to show laboratory checked for growth inhibition for positive QC or lack of inhibition for negative QC. 2. The laboratory performed approximately 300 Throat Culture tests per year 3. The TP #1 listed on CMS form 209 confirmed on 04/13/21 at 11:20 am that QC was not performed.</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</p>

	<p>manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>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 batch of Throat Culture (TC) media for its ability to support growth and as appropriate, select or inhibit specific organisms from 4/05/18 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 04/13/21 at 11:30 am that the laboratory did not check the QC of the TC media.</p>
<p>D5803</p>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Electronic Medical Records (EMR), Test Results (TR) and interview with the Testing Personnel (TP), the laboratory failed to have all tests performed in the EMR from 04/05/18 to the date of survey. The finding includes: 1. One out of ten EMR reviewed did not have a TR. 2. The TP #1 as listed on CMS form 209 confirmed on 4/13/21 at 11:40 am that all TR were not in the EMR.</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 into the Electronic Medical Record for Throat Culture tests from 04/05/18 to the date of survey. The TP #1 as listed on CMS form 209 confirmed on 04/13/21 at 11:45 am that the laboratory did not have the procedure mentioned above.</p>
<p>D6020</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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the established QC program was maintained for laboratory services provided from 04/05/18 to the date of the survey. The Testing Personnel (TP) #1 listed on CMS form 209 confirmed on 04/13/21 at 11:45 am the LD did not ensure the QC plan was maintained.

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 (PF) and interview with the Testing Personnel (TP) , the Laboratory Director (LD) failed to have appropriate training documentation for all TP performing laboratory testing from 04/05/18 to the date of survey. The finding includes: 1. The laboratory did not have training records for TP # 5 listed on the CMS form 209. 2. The TP #1 as listed on CMS form 209 confirmed on 04/13/21 at 11:15 am the above records were not on file.