

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0702489	<b>(X3) Date Survey Completed</b>  06/06/2022
<b>Name of Provider or Supplier</b>  Advocare Pediatric Health	<b>Street Address, City, State</b>  470 Stillwells Corner Rd, Freehold, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> 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 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 and document the physical characteristics of the media no the date of the survey. The findings include: 1. There was no documented evidence the above mentioned QC was performed on SSA lot # 502927. 2. The TP #8 listed on CMS form 209 confirmed on 6/6/22 at 11:00 am that the laboratory did not perform QC as stated above.</p>
<b>D5803</b>	<p><b>TEST REPORT</b> 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 the surveyor review of the Final Reports (FR), Work Records (WR) and</p>

interview with the Testing Personal (TP), the laboratory failed to have WR on three the out of five FR reviewed from 2/20/22 to the date of the survey. The TP #8 listed on CMS form 209 confirmed on 6/6/22 at 11:01 am that the laboratory did not maintain all work records..

**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:

a) Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Covid 19 testing accurately from on the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement stating "This test has not been FDA cleared or approved; The test has been authorized by FDA under an Emergency Use Authorization (EUA). 2. The TP #8 listed on the CMS 209 form confirmed on 03/25/21 at 2:30 pm that COVID 19 tests were not reported accurately.

b) Based on surveyor review of the Test Report (TR) and interview with the TP, the laboratory failed to ensure that the interpretation of COVID 19 test was on the TR on the date of survey. The finding includes: 1. The TR failed to include interpretation of COVID 19 results as found in the Manufacturers Package Insert (MPI). 2. The MPI stated "Negative results do not rule out COVID 19 and should not be used as the sole basis for treatment or patient management decisions." 3. The TP #8 listed on the CMS 209 form confirmed on 6/6/21 at 10:35 am that COVID 19 tests were not reported accurately.