

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0116925	<b>(X3) Date Survey Completed</b>  03/23/2021
<b>Name of Provider or Supplier</b>  Advocare Morristown Pediatrics	<b>Street Address, City, State</b>  261 James Street, Suite 1g, Morristown, 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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>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 maintain Attestation Statements (AT) for Throat Culture tests performed with the College of American Pathologists (CAP) for events D1-A 2020 and D1- C 2020. The TP #4 as listed on CMS form 209 confirmed on 3/23/21 at 1:15 pm that the laboratory did not maintain AT for PT.</p>
<b>D5807</b>	<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:</p>

	<p>Based on the surveyor review of the Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to have accurate Reference Ranges (RR) for Throat Culture (TC), Rapid Flu and Rapid Strep tests from 06/12/18 to the date of the survey. A review of the TR revealed the RR was listed as "Negative, Presumptive, Not Performed" The TP #4 as listed on CMS form 209 confirmed on 3/23/21 at 2:00 pm that these tests did not have accurate Reference Ranges on the TR.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> 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 from 06/12/18 to the date of survey. The TP #4 as listed on CMS form 209 confirmed on 03/23/21 at 2:15 pm that the laboratory did not have the procedure mentioned above.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files, Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to perform CA from 06/12/18 to the date of survey. The findings include: 1. The CA was not performed by the TC. 2. The TP #4 performed CA on TP #1, TP #2, TP #3 and TP # 5. 3. TP #1 performed the CA for TP # 4 4. TP #4 and TP #1 were not qualified to perform CA 5. The TP #4 as listed on CMS form 209 confirmed on 03/23 /21 at 1:15 pm that the CA was not performed by the TC.</p>