

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0125381	<b>(X3) Date Survey Completed</b>  05/04/2021
<b>Name of Provider or Supplier</b>  Advocare North Brunswick Pediatrics	<b>Street Address, City, State</b>  1950 State Route 27, North Brunswick, 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 MC5-B in 2019 and D1-C in 2020. The TP #1 listed on CMS form 209 confirmed on 5/4/21 at 1:15 pm that the laboratory did not maintain AT for PT.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform the CA from January 2020 to the date of the survey. The findings include: 1. One out of two TP did not have a CA performed in the calendar year 2020. 2. TP #1 listed on CMS form 209 confirmed on 5/4/21 at 1:30 pm that the CA was not performed .

**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 the surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review Throat Culture (TC) results obtained from the College of American Pathologists (CAP) in the calendar years 2019 and 2020. The findings include: 1. There was no review documented for MC5-A and MC5-C in 2019 2. There was no review documented for D1-A and D1- B in 2020 3. The TP #1 listed on CMS form 209 confirmed on 5/4/2021 at 1:15 pm that the laboratory did not review all PT results.