

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115970	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Advocare West Morris Pediatrics	Street Address, City, State 151 Rt 10, Suite 105, Succasunna, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain NJCLL for 2023. The Supervisor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 5/23/23 that the laboratory did not have a NJCLL license for 2023.</p>
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 Technical Supervisor (TS), the laboratory failed to check each lot number and shipment of BBL Bacitracin Discs for negative reactivity from 3/25/23 to the date of the survey. The findings include: 1. There was no evidence that the laboratory used a</p>

beta-hemolytic streptococcal species belonging to groups B, C, D and/or G to demonstrate lack of zone formation for a negative control. 2. The TS confirmed on 5/23/23 at 11:00 am that negative QC was not performed.