

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115970	(X3) Date Survey Completed 03/25/2021
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
D5209	<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: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the laboratory failed to follow the CA procedure for all employees who perform Throat Culture testing from 6/12/18 to the date of the survey. The findings include: 1. The CA was not performed on two out of six TP in 2019. 2. The CA was not performed on one out of six TP in 2020. 3. The TP # 2 listed on CMS form 209 confirmed on 3/25/2021 at 11:00 am the laboratory did not perform a CA on all employees.</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</p>

	<p>Testing Personnel (TP), the laboratory failed to check each lot number and shipment of BBL Bacitracin Discs for positive and negative reactivity from 6/12/2018 to the date of the survey. The findings include: 1. There is no documentation provided to show a presence of a zone of growth inhibition for a positive control. 2. There is no documentation provided to show a lack of zone formation for a negative control. 3. Approximately 15 specimens per day from 6/12/18 to the date of the survey were affected by a lack of QC records. 4. The TP #2 listed on CMS form 209 confirmed on 03/25/2021 at 11:00 am that QC was not performed.</p>
<p>D5477</p>	<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 manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Throat Culture media for sterility from 6/12/18 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 3/25/21 at 10:30 am the laboratory did not perform the above QC.</p>
<p>D5807</p>	<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: Based on the surveyor review of the Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to have an accurate Reference Ranges (RR) for Throat Culture (TC) tests from 06/12/18 to the date of the survey. The findings include: 1. A review of the TR revealed the RR was listed as "Negative, Presumptive, Not Performed" 2. The TP #2 listed on CMS form 209 confirmed on 3/25/21 at 10:30 am that these TC tests did not have accurate RR on the TR.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel, (TP) the Laboratory Director (LD) failed to ensure that Throat Culture (TC) PT performed with the College of American Pathologists (CAP) was reviewed and evaluated by the appropriate staff for all events in 2019 and 2020. The TP # 2 listed on CMS form 209 confirmed on 03/25/2021 at 9:45 am that the LD did not ensure review and evaluation of PT results listed above

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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 Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the education and training records were available on the date of the survey. The findings include: 1. Education records were not available for one of six TP. 2. Three out of six TP did not have training records. 3. The TP #2 listed on CMS form 209 confirmed on 03/25/2021 at 10:00 am that all education and training records were not available.