

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115970	(X3) Date Survey Completed 06/12/2018
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 Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA on six out of six TP in the calendar year 2017. The TP #2 listed on CMS form 209 confirmed on 6/12 /18 at 10:20 am that CA was not performed in 20017.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Work Records, Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that test results were accurately transcribed on the FR from 6/9/16 to the date of survey. The findings</p>

include: 1. A review of the Throat Culture Log (TC) and FR revealed: a. On 4/2/18 patient KL had a negative TC but the laboratory reported positive on the FR. b. Patient SP - 3124407 had a positive rapid strep but the laboratory reported negative on the FR. 2. The TP #2 listed on CMS form 209 confirmed on 6/12/18 at 11:30 am that the laboratory did not transcribe results accurately.

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:
Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for Throat Cultures from 6/9/16 to the date of survey. The TP #2 listed on CMS form 209 confirmed on 6/12/18 at 11:35 am that the TRD was not on the FR.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

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.

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 have a procedure to verify manually entered results into electronic medical records for accuracy from 6/9/16 to the date of survey. The TP # 2 listed on CMS form 209 confirmed on 6/15/18 at 11:15 am that the laboratory did not have the procedure mentioned above.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

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 Director (LD) failed to ensure that PT samples were tested for Throat Culture (TC) tests in 2017 and 1-2018. The TP #2 listed on CMS form 209 confirmed on 6/15/18 at 11:30 am that the LD did not ensure PT TC samples were tested.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have training documented for one out of one new TP from 6/9/16 to the date of the survey . The TC # 2 listed on the CMS form 209 confirmed on 6/12/18 at 10:10 am that all TP did not have training records.