

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0116925	<b>(X3) Date Survey Completed</b> 06/15/2023
<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>D3003</b>	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of where Bacteriology testing was performed and the lack of decontamination records and interview with the Testing Personnel(TP), the laboratory failed to ensure contamination of laboratory work areas were minimized from 3/23/21 to the date of inspection. The TP #1 as listed on the CMS-209 form confirmed the laboratory failed to ensure contamination of laboratory work areas where minimized.</p>
<b>D3009</b>	<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. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 6/19/23 that the laboratory did not have a NJCLL license for 2023.</p>
<b>D5401</b>	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

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 follow all procedures written for "Taxo A QC Kit (#3137)" from 3/23/21 to the date of the survey. The findings include: 1. The procedure "Taxo A QC Kit (#3137)," stated "Note: Quality control should be performed and results recorded each week patient tests are done." 2. There was no documented evidence the above mentioned procedure was performed. 3. The TP #1 listed on CMS-209 confirmed on 6/15/23 at 11:00 am that the laboratory did not follow the PM.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of culture media and interview with the Testing Personnel (TP), the laboratory failed to discard expired culture media used for Bacteriology tests from 05/09/2023 to the date of survey. The findings include: 1) 1 unopened 10 pack of Hardy Diagnostics Selective Strep Agar, Lot # 150746, Expiration date of 05/09/2023 was observed. 2) The TP #1 listed on CMS-209 form confirmed on 6/15/23 at 12:10 pm that laboratory failed to discard expired culture media.

**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 Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR had all the required information from 05/25/16 to the date of survey. The finding includes: 1. The laboratory failed to include a FR date on 10/10 FR 2. The laboratory failed to have a final result in the

"Result" section in 4/10 FR. 3. The laboratory failed to have a reference range value in 4/10 FR. 4. The TP #1 listed on the CMS form 209 confirmed on 6/15/23 at 12:10 PM that all the required information 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 establish a procedure for verifying manually entered results into the Electronic Medical Record from 06/12/18 to the date of survey. The TP #1 as listed on CMS form 209 confirmed on 6/19/23 at 12:15 pm that the laboratory did not have the procedure mentioned above. Note: This is the third time citation has been observed.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Quality Assurance (QA) program for verifying manually entered results into the Electronic Media Record from 6/12/18 to the date of survey. The TP#1 as stated on CMS-209 form confirmed on 6/15 /23 at 11:45 AM that a QA program was not established.