| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D0925635 | 04/24/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advocare Pediatric Health | 69 West Main Street, Freehold, 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP) the laboratory failed to have a complete Quality Control (QC) procedure for Bacteriology tests from 2/1/22 to 4/24/24. The findings include: 1. There were no QC procedures for checking each batch of Selective Strep Agar (SSA) media for its ability to support growth and inhibit specific organisms. 2. TP #1 as listed on the CMS-209 form confirmed on 4/24/24 at 11:25 am that the PM failed to have a complete QC procedure for Bacteriology tests. |
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| **D5409** | PROCEDURE MANUAL<br>CFR(s): 493.1251(e)<br><br>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to record discontinuance dates for procedures not in use in the laboratory from 1/6/23 to 4/24/24. The finding includes: 1. The PM had multiple procedures for performing throat cultures and Bacitracin Quality Control (QC). 2. The laboratory had a final procedure in use for throat cultures and Bacitracin QC, but failed to put discontinuance dates on the procedures no longer in use. 3. The TP #1 as listed on the CMS-209 form confirmed on 4/24/24 at 12:15 pm that discontinuance dates were not documented. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of culture media and interview with the Testing Personnel (TP), the laboratory used and failed to discard expired culture media used for Bacteriology tests from 4/5/24 to 4/24/24. The findings include: 1. One opened pack of Hardy Diagnostics Selective Strep Agar, Lot # 619475 with an expiration date of 4/5/24 was observed. 2. The laboratory used expired culture media for three patients during the aforementioned timeframe. 3. TP #1 listed on the CMS-209 form confirmed on 4/24/24 at 12:10 pm that laboratory used and failed to discard expired culture media. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records, the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Selective Strep Agar (SSA) media for its ability to inhibit specific organisms from 2/1/22 to 4/24/24. The findings include: 1. The laboratory failed to use at least one organism to confirm the inhibitory characteristic |

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| | of SSA media. 2. TP #1 as listed on the CMS-209 form confirmed on 4/24/24 at 11:45 am, the laboratory failed to perform the above mentioned QC on SSA media. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Electronic Medical Records (EMR), Manual Accession Log Entries (MALE) and interview with the Testing Personnel (TP), the laboratory failed to ensure that laboratory results are accurately and reliably transcribed manually and into the EMR from 9/13/23 to 4/24/24. The findings include: 1. Two out of Eight MALE did not have both a final result and time and reported date documented. 2. Two out of Eight MALE did not have a time and reported date documented. 3. Three out of Eight patient EMR did not have a collection time for documented for throat culture specimens. 4. Five out of Eight patient EMR did not have collection times that matched the MALE for throat culture specimens. 5. TP # 1 as listed on CMS form 209, confirmed on 4/24/24 at 11:50 am, that the laboratory failed to ensure that laboratory results are accurately and reliably transcribed manually and into the EMR. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of a Quality Assessment (QA) records, review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to maintain the QA program to assure the quality of laboratory services for the calendar year of 2022. The findings include: 1. The QA plan in the PM states "QA Review must be reviewed at a minimum of once a year." 2. There was no documented evidence the QA plan was followed in calendar year 2022. 3. TP #1 as listed on the CMS-209 form, confirmed on 4/24/24 at 11:30 am, the LD failed to maintain the QA program. |