| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 31D1011572 | 08/15/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pedia-Care Physicians Llc | 290 Norwood, Deal, 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 |
|---|---|
| **D2021** | BACTERIOLOGY<br>CFR(s): 493.823(b)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel (TP), the laboratory failed to participate in PT for Bacteriology from the American Proficiency Institute (API) for calendar year 2022. TP#1 confirmed on 8/15/23 at 10:45 am that the laboratory did not participate in Bacteriology PT from API for calendar year 2022. |
| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>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 calendar year 2023. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 8/3/23 that the laboratory did not have a NJCLL license for 2023. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), there was no QC procedure for the inhibition ability of Selective Strep Agar (SSA) media from 7/12/21 to date of the survey. The TP #1 confirmed on 8/15/23 at 11:38 am there was no QC procedure for the inhibition ability of Selective Strep Agar (SSA) media |
| **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 a discontinuance date for procedures not performed in the laboratory from 7/12/21 to the date of survey. The finding includes: 1. There were no discontinuance dates for Urine culture procedures in the PM. 2. The TP #1 as listed on the CMS-209 form confirmed on 8/15/23 at 10: 45 am that a discontinuance date was not documented. |
| **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 and interview with Testing Personnel (TP), the laboratory failed to check each new lot number and |

| | |
|---|---|
| | shipment of Selective Strep Agar (SSA) media for it ability to inhibit specific organisms from 7/12/21 to the date of the survey. The TP #1 confirmed on 8/15/23 at 11:30 am the laboratory did not perform the above mentioned QC on SSA media. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Lab Log Book, Test Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to maintain an accurate record system for Bacteriology tests from 7/12/21 to the date of the survey. The findings include: 1. All Bacteriology TR from 7/12/21 to date of survey did not have a culture read time or date. 2. The TP#1 confirmed at 11:45 am on 8/15/23 the laboratory did not maintain accurate record system. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel l(TP), the Laboratory Director (LD) failed to ensure PT samples were tested for Bacteriology from the American Proficiency Institute (API) for calendar year 2022. TP #1 confirmed on 8/15/23 at 11:45 am that the LD did not ensure PT samples for Bacteriology were tested for calendar year 2022. |