| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0706472 | 12/22/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Partners Of Augusta Llc | 1303 Dantignac Street Ste 2600, Augusta, GA | |

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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| **D0000** | On February 24, 2024 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations. |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on document review and staff interview during the lab tour, the laboratory failed to document inspections of the 4oz eyewash bottles appropriately and there was no flush eyewash equipment installed in the laboratory to protect against accidental chemical and biohazard facial contamination, as required by CLIA from 2022 to 2023. Findings: 1. A review of maintenance records revealed that the laboratory failed to document (weekly instead of daily) inspections of the 4oz eyewash bottle. Also, there was no eyewash flush equipment installed in the lab to protect against accidental biohazard and chemical contamination from 2022 to 2023. 2. Interviews with staff and lab director at approximately 2:00 PM on 12/22/2023 confirmed the laboratory failed to document inspections of the eyewash bottleon a weekly basis and no flush eyewash equipment present in the laboratory at the time of survey 12/22/2023. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 |

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| | through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>A review of the procedure manual and an interview with staff and lab director, the laboratory failed to have a Quality Assurance (QA) policy for the laboratory specific to the specialty of Urine and Throat cultures by (URICULT by AIDIAN) in 2022 and 2023. Findings: 1.) Procedure manual review revealed that the clinic does not have a Quality Assurance (QA) policy specific to Urine and Throat cultures by (URICULT by AIDIAN) testing currently performed in the laboratory in 2022 and 2023. 2.) An interview with staff and lab director at approximately at 1:30 PM, on 12/22/2023, in the review room confirmed that the clinic did not have a written (QA) policy specific to the current moderate complexity testing performed in the laboratory in 2022 and 2023. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly or quaterly basis that cover pre-analytic, analytic and post analytic phases of laboratory testing in 2022 and 2023. Findings: 1. Daily maintenance logs including: Room Temperature, Humidity, Refrigerator and Freezer logs had the incorrect normal ranges and no facility location addresses on the logs. 2. No evidence that maintenance logs were reviewed and signed by the Laboratory Director in 2022 and 2023. 3. An interview with staff and lab director on 12/22/2023, at approximately 1:00 PM, in the review room confirmed the lack of adequate QA oversight of the laboratory in 2022 and 2023. |
| **D6022** | 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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on documents review and interview with staff, the Lab Director failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 and 2023. Findings: 1. Standard Operating Procedures (SOP), QA, proficiency testing (PT) and maintenance logs ( Room |

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| | Temperature, Refrigerator and QC) review revealed the lab director did not review and sign ALL of the above documents in 2022 and 2023. 2. An interview with the laboratory director and staff in the review room on 12/22/2023 at approximately 2:40 PM, confirmed the lab director failed to ensure proper (QA) (Pre-analytic, Analytic and Post analytic phases) oversight of the lab in 2022 and 2023. |