| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>41D0702228 | **(X3) Date Survey Completed**<br><br>09/12/2023 |
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| **Name of Provider or Supplier**<br><br>Pediatric Associates, Inc | **Street Address, City, State**<br><br>450 Veterans Memorial Parkway Ste 10, East Providence, RI | |

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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| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples in the specialties of Chemistry and Hematology. Findings include: 1. Record review on 09/12/2023 of the laboratory's College of American Pathologists (CAP) 2022 PT records revealed: a. The attestation sheet for Urinalysis and Clinical Microscopy Event B contained the signatures of both Testing Personnel 1 (TP1) and Testing Personnel 2 (TP2). b. The Hematology and Automated Differential Event B attestation sheet contained both signatures of TP1 and TP2. 2. Record review on 09/12/2023 of the laboratory's CAP 2023 PT records revealed: a. The attestation sheets for Urinalysis and Clinical Microscopy Events A and B contained the signatures of both TP1 and TP2. b. The Hematology and Automated Differential Event A attestation sheet contained both signatures of TP1 and TP2. 3. Interview with TP1 on 09/12/2023 at 9:55 AM confirmed the above findings. TP1 stated, "We ask each other if they concur. We don't separate them or determine who is going to do which PT sample. I wouldn't be |

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| | able to tell you who did what one. We don't do that with patients, only one of us reads patient samples." 4. The laboratory performs 314 Chemistry and 17,637 Hematology tests annually. |
| **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 observation, record review, and staff interview, the laboratory failed to follow the approved "Confirmatory Test for Group A Strep from Plated Culture of TSA Blood Agar" procedure in the specialty of Microbiology. Findings include: 1. Surveyor observation on 09/12/2023 at 11:30 AM of the laboratory's incubator containing 2 patient culture plates for Group A Streptococcus confirmatory testing revealed: a. 2 of 2 plates were not streaked in a manner to obtain isolated colonies. b. 1 of 2 plates had been swept to obtain specimen for Sekisui Osom Strep A testing. 2. Record review on 09/12/2023 of the laboratory's "Confirmatory Test for Group A Strep from Plated Culture of TSA Blood Agar" procedure states, "Using a sterile swab select a beta hemolytic colony and perform the rapid test according to the manufacturer's instructions." 3. Record review on 09/12/2023 of the Sekisui Osom Strep A Test package insert states, "Lightly touch 1-3 suspect colonies (showing characteristic beta hemolysis) using a sterile swab. Do not sweep the plate." 4. Interview with Testing Personnel 1 on 09/12/2023 at 12:30 PM confirmed the above findings. 5. The laboratory performs 1,296 tests annually in the specialty of Microbiology. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>A. Based on record review and staff interview, the laboratory failed to include a procedure for corrective action when quality control (QC) results are out of the acceptable range in the specialty of Hematology. Findings include: 1. Record review on 09/12/2023 of the laboratory's procedure manual revealed it did not contain a procedure for corrective action to take when Hematology QC is out of acceptable range. 2. Interview with Testing Personnel 1 (TP1) on 09/12/2023 at 10:30 AM revealed the lab does not have a procedure for corrective action. TP1 stated, "We just rerun it." 3. The laboratory performs 17,637 tests annually in the specialty of Hematology. B. Based on record review and staff interview, the laboratory failed to include reference ranges in the procedure manual for Complete Blood Count (CBC). Findings include: 1. Record review on 09/12/2023 of the laboratory's procedure manual revealed it did not contain reference ranges for CBC. 2. Interview with TP1 on 09/12/2023 at 12:30 PM confirmed the findings in B1 above. 3. The laboratory performs 17,637 tests annually in the specialty of Hematology. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to include an external positive and negative control on each day of patient testing for the Sekisui Osom Strep A Test. Findings include: 1. Record review on 09/12/2023 of the laboratory's Sekisui Osom Rapid Strep quality control (QC) records from 12/8/2021 through 09/05/2023 revealed QC was only performed when a new lot was opened and /or monthly. 2. Record review on 09/12/2023 of the laboratory's procedure manual revealed it did not contain an approved Individual Quality Control Plan (IQCP) for performing QC less frequently than the Clinical Laboratory Improvement Amendments requirements. 3. Staff interview on 09/12/2023 at 12:30 PM with Testing Personnel 1 (TP1) confirmed the above findings. TP1 stated, "I do not know what an IQCP is." 4. The laboratory performs 1,296 tests annually in the specialty of Microbiology. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to perform quality control (QC) checks on each lot number and/or shipment of media for sterility and ability to support and/or inhibit growth in the specialty of Microbiology. Findings include: 1. Record review on 09/12/2023 of the laboratory's "Culture Media Checklist" for 10/13/2021 through 09/06/2023 revealed the laboratory did not check each lot number and/or shipment of media for sterility and ability to support and/or inhibit growth for: a. 69 of 69 new lots and/or shipments of Blood Agar (Tryptic Soy Agar with 5% sheep blood) plates. b. 56 of 56 new lots and/or shipments of Blood Agar (Tryptic Soy Agar with 5% sheep blood)/Eosin-Methylene Blue Agar Biplates. 2. Record review on 09/12/2023 of the laboratory's procedure manual revealed it did not contain an approved Individual Quality Control Plan (IQCP) for performing QC less frequently than the Clinical Laboratory Improvement Amendments requirements. 3. Staff interview on 09/12/2023 at 11:30 AM with Testing Personnel 1 (TP1) confirmed the above findings. TP1 stated, "This is the way we have always been doing it." TP1 also stated, "I do not know what an IQCP is." 4.. The laboratory performs 1,296 tests in the specialty of Microbiology annually. |