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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>46D1086950      | <b>(X3) Date Survey Completed</b><br>11/18/2020 |
| <b>Name of Provider or Supplier</b><br>Wee Care Pediatrics Syracuse  | <b>Street Address, City, State</b><br>1792 W 1700 S Suite 102, Syracuse, UT |   |
| 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>   |
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| <b>D5461</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(6)(g)</p> <p>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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on patient test records review, quality control records review, lack of documentation, and interview with staff, the laboratory failed to ensure quality control was performed prior to testing patient samples when a new lot number of Piccolo hepatic panel cartridges and Solana Group A Strep were placed into use for 2 of 11 new lot numbers of reagents reviewed, (Solana lot number 149638 and Piccolo 9084AC3 and 0091AC3.) Findings include: 1. Patient test records review included patient 12282009 was tested on 10/30/2020 for Group A Strep using lot number 149638. Patient test records review included patient 01152020 on 01/21/2020 using hepatic panel lot number 9084AC3 for total and direct bilirubin and patient 09202020 on 09/25/2020 using hepatic panel lot number 0091AC3 for direct bilirubin tests. 2. Quality control records review failed to include documentation the laboratory checked Solana lot number 149638 prior to testing patient 12282009 on 10/30/2019 and failed to perform Piccolo quality control prior to testing patients 01152020 on 01/21/2020 using lot number 9084AC3 and patient 09202020 on 09/30/2020 using lot number 0091AC3. 3. In an interview with staff on 11/18/2020 at approximately 11:15 A.M. staff confirmed the quality control record failed to include documentation quality control was performed prior to testing patient specimens when there were replacements of testing reagents.</p> |