| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>10D0897753 | (X3) Date Survey Completed<br><br>04/02/2024 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>A Womans World Medical Center Inc | **Street Address, City, State**<br><br>503 S 12th St, Fort Pierce, FL | |
| 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** | A recertification survey was conducted on April 2, 2024. A Woman's World Medical Center clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory logs, and interview, the laboratory failed to report the temperature of the refrigerator and the Rh (Rhesus) typing box each day of testing from 12/16/2023 to 12/30/2023. Findings: During a tour of the laboratory on 04/03 /2024, the Anti-D for Rh factor typing was in the refrigerator. The Daily Temperature Log noted the "Refrigerator Temp. Range 36 - 45 degrees" Fahrenheit and "Rh Box Temp. Range 45 - 50 degrees." Review of "Daily Temperature " showed the last temperature taken of the refrigerator and Rh typing box for 2023 was on 12/13/2023. Review of the Daily Laboratory Log showed 10 patients on 12/16/2023, 14 patients on 12/18/2023, 11 patients on 12/23/2023 and 14 patients on 12/30/2023 were tested for Rh. On 04/02/2024 at 10:45 AM, the Laboratory Owner acknowledged the temperatures for the refrigerator and the Rh Typing Box were not recorded. |