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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0716772 | <b>(X3) Date Survey Completed</b><br><br>04/17/2025 |
| <b>Name of Provider or Supplier</b><br><br>All Womens Health Center Of Tampa Inc   | <b>Street Address, City, State</b><br><br>3330 W Kennedy Blvd, Tampa, FL   |   |
| 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>D0000</b>              | An announced CLIA recertification survey was conducted at All Women's Health Center of Tampa, Inc. on 04/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:  |
| <b>D2007</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview, the laboratory failed to test proficiency test samples in the same manner patient tests were performed for one (test event 1 of 2025) of six test events (2023 - 2025) performed for the analyte, Rh type. Findings included: Review of the CMS-209 Laboratory Personnel Report, signed by the Lab Director on 03/13/2025, listed five testing persons. The proficiency testing was reviewed for two events in 2023, three events in 2024, and one event in 2025 for the analyte "Rh type". The "RH TYPING LOG SHEET" dated 03/26/2025 noted testing person(s) A, B, C, and E performed the proficiency testing for five of five proficiency test samples (RH-1 through RH-5) for the analyte Rh type. The American Proficiency Attestation Statement stated, "The undersigned certify that, as closely as possible, these proficiency samples were tested in the same manner as patient specimens." It was signed by the Lab Director and testing person(s) A, B, C, and E documenting that each testing person tested sample RH-1, RH-2, RH-3, RH-4, and RH-5. The Administrator was interviewed on 04/17/2025 at 11 a.m. They confirmed four testing persons ran the proficiency testing samples. Additionally, they confirmed patient samples are normally only ran by one testing person.</p> |
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**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to monitor the room temperature to ensure it was maintained within the established acceptable temperature range per the manufacturer instructions for two years (04/1/2023 through 04/17/2025). Findings included: A tour of the lab was conducted 04/17/2025 at 9:15 a. m. The anti-D (Anti-Rh) reagent was on the countertop. Manufacturer instructions for the anti-D reagent, with a revision dated of March 1998, stated "May be at room temperature [15 to 30 degrees Celsius] while in use." There was no documentation the lab monitored the room temperatures from 04/01/2023 through 04/17/2025. The Administrator was interviewed on 04/17/2025 at 11:45 a.m. and confirmed the laboratory leaves the anti-D reagent at room temperature when patient testing is performed and does not monitor the room temperature.