

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2146458	(X3) Date Survey Completed 07/24/2025
Name of Provider or Supplier Women's Center Of Fort Lauderdale, Llc	Street Address, City, State 2161 E Commercial Blvd Ste 400, Fort Lauderdale, 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
D0000	An announced CLIA recertification survey was conducted at WOMEN'S CENTER OF FORT LAUDERDALE, LLC from 07/18/2025 to 07/24/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 CFR 493.1421 Laboratory Testing Personnel.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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: Based on record review and staff interview, the Laboratory failed to have one out of two testing personnel (TP) rotate through the testing of Proficiency Testing (PT) in the Specialty of Immunohematology in 2024 and 2025. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 07/17/2025 revealed the laboratory had two TP listed (TP#1 and TP#2). 2-Review of personnel records for TP#2 revealed that she had competency evaluation on 2024 and 2025. 3-Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT records for 2024 (first, second and third event) and 2025 (first and second event) in the specialty of Immunohematology, revealed that TP#2 had no PT participation. 4-During an interview on 07/18/2025 at 12:30 PM, with TP#1 she explained that both TPs do the PT and confirmed that there was no documentation that TP#2 participated in PT during this period.</p>
D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to submit the Proficiency Testing (PT) results for Immunohematology specialty in one out of five events reviewed for 2024 and 2025 and failed to do a review of the results. Findings included: 1-Review of American Association of Bioanalysts /Medical Laboratory Evaluation (AAB/MLE) PT records for 2024 (first, second and third event) and 2025 (first and second event) in the specialty of Immunohematology, revealed that the laboratory failed to submit the results for the first event of 2024 for the test of Rhesus (RH) factor and this resulted in a 0% score due to fail to submit PT results on time, the due date for this event was 02/23/2024. 2-Review of laboratory handwritten results note (Note#1) for that event showed results with no date and an undated note that stated" Results not submitted, write lab deviation report. No patients were harmed." 3- Review of the "LABORATORY DEVIATION REPORT FORM" signed on 02/24/2024 by the Laboratory Director stated that the laboratory failed to submit the results for the first event of 2024, two employees will be responsible for making sure results are entered in a timely matter." 4-Review of Note#2 written in the page of the AAB/MLE instructions for the 1st event of 2024, revealed, "Keep results once summary is issued 3 weeks make self-evaluation." The laboratory had no documentation that made a comparison with the results for a self-evaluation. 5-During an interview on 07/18/2025 at 12:35 PM, with TP#1 she explained that she did an online review of the results and confirmed that she did not have documentation of this review.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the Laboratory failed to verify the education of 1 out of 2 Testing Personnel performing the Rhesus (Rh) factor test. See D6065

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree

in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify the education of 1 out of two testing personnel (TP). Findings included: 1-Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 07/14/2025 listed 2 TP (TP#1 and TP#2). 2-Review of employee files revealed that TP#2 had Competency evaluations in 2024 and 2025 and the diploma was a copy of a Foreign High School Diploma, no equivalence for that diploma submitted. 3-Review of Patient log for the years 2024 to 2025, she did testing for Rhesus (RH) factor during this period. 4-During an interview on 07/18/2025 at 12:35 PM with TP#1, she confirmed that the laboratory failed to have documentation to proof that the TP#2 fulfill the minimum education requirement.