

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0952088	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Womens Center Of Hyde Park Llc	Street Address, City, State 4602 N Nebraska Ave, Tampa, 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 Hyde Park LLC on 07/09/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, it was determined the individual testing or examining of the samples failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for five (2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023) of six (1st and 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023) for D(RHO) Typing testing. Findings included: 1. Review of proficiency records for 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023 for D(RHO) Typing testing failed to include indication of who performed the proficiency testing or an attestation that the testing was integration of the samples into the patient workload using the laboratory's routine methods. 2. Testing Personnel A confirmed on 7/09/2025 at 11:15 a.m. there was no indication of who performed the proficiency testing or an attestation that the testing was integration of the samples into the patient workload using the laboratory's routine methods 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023 for D(RHO) Typing testing.</p>
D2014	TESTING OF PROFICIENCY TESTING SAMPLES

(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples for five (2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023) of six (1st and 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023) for D(RHO) Typing testing. Findings included: 1. Review of proficiency records for 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023 for D(RHO) Typing testing failed to include the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. 2. Testing Personnel A confirmed on 7/09/2025 at 11:15 a.m. there was no documentation of the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples for 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023 for D(RHO) Typing testing.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, it was determined the laboratory failed to and evaluate the results obtained on proficiency testing for two (1st event of 2024 and 1st event of 2025) of six (1st and 2nd event 2025, 1st, 2nd, and 3rd event of 2024, and 3rd event of 2023) for D(RHO) Typing testing. Findings included: 1. Review of 1st event of 2024 and 1st event of 2025 records failed to include an evaluation of the results from the proficiency company. 2. The Laboratory Policy and Procedure Manual approved by the Laboratory Director 1/2/2025 included under, duties and responsibilities of the Laboratory Director, all proficiency reports are reviewed to evaluate the laboratory's performance. 3. Testing Personnel A confirmed on 7/09/2025 at 11:15 a.m., there was no evidence of evaluation of the results obtained on proficiency testing for the 1st event of 2024 and 1st event of 2025 for D(RHO) Typing testing.