

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0718790	(X3) Date Survey Completed 07/17/2025
Name of Provider or Supplier All Womens Health Center Of North Tampa Inc	Street Address, City, State 14498 University Cove Pl, 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 All Women's Health Center of North Tampa, Inc. on 07/15/2025 - 07/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Lab Director failed to establish a policy to be onsite once every six months and document the onsite visits. Findings included: 1. The lab's policies and procedures were reviewed. There was no policy to reflect the Lab Director would be onsite at least once every six months or how an onsite visit would be documented. 2. The Lab Director confirmed the above via electronic communication on 07/16/2025 at 1:35 p.m.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant failed to perform competency evaluations on four of four testing personnel (#A - #D) who performed moderate complexity testing in the subspecialty of ABO Group & Rh Group for two of two years (2023 - 2024) reviewed. Findings included: 1. The Laboratory Personnel Report, form CMS-209, signed and dated by the Lab Director on 07/09/2025, was reviewed. Four testing personnel were listed (#A - #D) as performing moderate complexity testing. The form listed the Lab Director as the Technical Consultant. 2. The previous recertification survey CMS-209, signed and dated by the Lab Director on 05/03/2023 was reviewed. The same testing personnel (#A - #D) were listed as performing moderate complexity testing. 3. Competency assessments for 2023 and 2024 were reviewed for testing personnel (#A - #D). The Technical Consultant did not complete competencies in 2023 or 2024. 4. An interview was conducted with the President of the organization on 07/15/2025 at 1:50 p.m. They confirmed the above listed testing personnel required an annual competency and the Technical Consultant wasn't completing them. 5. The Lab Director, who was also the Technical Consultant, confirmed via electronic communication on 07/16/2025 at 1:35 p.m. the data above.