

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0964390	(X3) Date Survey Completed 06/16/2026
Name of Provider or Supplier Virginia Womens Wellness	Street Address, City, State 224 Groveland Road - 2nd Floor, Virginia Beach, VA	
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 Virginia Womens Wellness on June 16, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Virginia Womens Wellness was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
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 documentation review and interviews, the laboratory failed to retain proficiency testing (PT) attestation statements signed by the testing personnel and laboratory director documenting that proficiency testing samples were tested in the same manner as patient specimens for six (6) of 6 PT events reviewed. Findings include: 1. In an interview at 9:30 am, the inspector inquired about attestation and documentation of PT testing by testing personnel. The laboratory director (LD) stated that PT samples and their results were documented along with patient results on the Quality Control and Daily Laboratory Log with the testing personnel's initials. 2. Review of the laboratory's American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) PT documentation for the 2nd and 3rd events of 2024, all

	2025 events, and the 1st event in 2026 (a total of 6 events) revealed the lab failed to retain the attestation statements signed by the testing personnel and LD for all 6 events reviewed. 3. In an exit interview at 11:25am, the LD confirmed the above findings.
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 a review of Center for Medicaid and Medicare Services CASPER 0155 report, proficiency testing (PT) documentation, and interviews, the laboratory failed to participate in one (1) of 6 PT events reviewed resulting in unsatisfactory PT performance and a score of 0 % for the testing event. Findings include: 1. A pre-survey review of the Center for Medicaid and Medicare Services CASPER 0155 report revealed the laboratory received a score of 0% for the ABO/RHO specialty and analyte 875 D (RHO) for the 2026 Event 1. 2. During an interview at 9:30am, the Laboratory Director stated they had missed testing and submitting the first PT event in 2026 because the event samples were not received at the building. 3. Review of the laboratory's American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) PT result evaluations for the 2nd and 3rd events of 2024, all 3 events in 2025, and the 1st event in 2026 (a total of 6 events) revealed a score of 0% for 2026's Event 1 due to failure to submit results. 4. The failure to participate in 2026 Event 1 was confirmed in an exit interview with the Laboratory director at 11:25 am.