Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0964390	10/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Womens Wellness	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 on-site CLIA recertification survey was conducted at Professional Medical Services, PC on October 27, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The survey included an entrance interview on 10/14/2020 and virtual record review conducted on 10/26/2020. The laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D6000 - 42 CFR. 493.1403 Condition: Moderate complexity laboratory director.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2019 and 2020 immunohematology proficiency testing (PT) records, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for three (3) of six (6) events reviewed. *REPEAT DEFICIENCY 1. Review of the laboratory's American Association of Bioanalysts (AAB) immunohematology PT records, a total of six (6) events for ABO/Rh Group (Anti-D Rh typing), revealed no LD or TP signed

	attestation statements for: 2019 Event 2, 2019 Event 3, 2020 Event 3. The inspector requested to review the LD and TP attestation documentation for the PT events listed above. No documentation was available for review. 2. In an interview with the lead testing personnel, on 10/27/20 at approximately 2:30 PM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, 2019 and 2020 immunohematology proficiency testing (PT) documentation, and an interview, the laboratory director failed to ensure that the quality assurance (QA) policies for PT attestations by testing personnel and director were maintained during the twenty-four (24) months reviewed. See D6021.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, 2019 and 2020 immunohematology proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director (LD) failed to ensure that the quality assurance (QA) policies were maintained during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written and approved QA policy ("Quality Assessment Procedures") that included protocols that the LD would oversee the proficiency testing program to include testing personnel (TP) rotation and signed attestations by LD and TP. 2. Review of the laboratory's American Association of Bioanalysts (AAB) immunohematology PT records, a total of six (6) events for ABO/Rh Group (Anti-D Rh typing), revealed no LD and TP signed attestation statements for: 2019 Event 2, 2019 Event 3, 2020 Event 3. The inspector requested to review the attestations. No records were available for review. The inspector requested to review QA corrective action documentation for the lack of attestations outlined above. No QA corrective action was available for review. 3. In an interview with the lead testing personnel, on 10/27/20 at approximately 2:30 PM, the above findings were confirmed.