Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0964390	08/10/2020
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 unannounced, off-site CLIA proficiency test desk review was conducted for Professional Medical Services, PC on August 10, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's American Association of Bioanalysts proficiency testing (PT) records and interviews, the laboratory failed to attain satisfactory performance (a score of 100 percent acceptable responses) for

	immunohematology in two consecutive ABO and RHo (D Group) module testing events reviewed, resulting in unsuccessful PT performance (review: first and second events of calendar year 2020). See 2163.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on an off-site desk review of proficiency testing (PT) records, and interviews, the laboratory failed to attain satisfactory performance (a score of 100 percent acceptable responses) for immunohematology in two (2) consecutive ABO/Rh Group (Anti-D Rh typing) testing events in calendar year 2020, resulting in unsuccessful PT performance. Findings include: 1. Review of the laboratory's American Association of Bioanalysts (AAB) ABO and RHo (D) Groups PT Modules revealed unsatisfactory scores for the following consecutive events: AAB 2020 Event 1: ABO/Rh Group = 0 % and D (Rho) Typing = 0%; AAB report noted "results not reported to AAB for five of five challenge samples resulting in score of zero"; AAB 2020 Event 2: ABO/Rh Group = 60% and D (Rho) Typing = 60%, challenge specimens #9 and #10 graded as incorrect, AAB report noted "results score is below CMS limit"; resulting in an unsuccessful PT performance. 2. In telephone interviews with AAB technical support specialist on 8/10/20 at approximately 11:30 AM, practice's office manager and nurse manager on 8/12/20 at 1:00 and 3:00 PM, the above findings were confirmed.