

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0964390	(X3) Date Survey Completed 08/11/2022
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	<p>An announced on-site CLIA recertification survey was conducted at Professional Medical Services, PC on August 11, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to perform annual ABO/Rh Group Anti-D Rh typing competency evaluations for one of six testing personnel (TP) in calendar year 2021. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC. The LD identified six TP responsible for non waived ABO/Rh Group Anti-D Rh typing during the 21 months of review (timeframe: November 2020 to the date of the survey on August 11, 2022). 2. Review of the laboratory personnel files revealed that TP A lacked a 2021 annual Anti-D Rh typing competency assessment. The inspector requested to review the competency assessment documentation. No record was available for review. (See Personnel Code Sheet.) 3. An exit interview with the office manager on 8/11/22 at approximately 2 PM confirmed the above findings.</p>

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, and an interview, the laboratory failed to retain documentation of education qualifications for one of six testing personnel responsible for reporting moderate complexity ABO/Rh Group Anti-D Rh typing test results during the timeframe of January 2022 to the date of the inspection on August 11, 2022. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interviews, the laboratory director (LD) failed to retain documentation of education qualifications for one of six testing personnel (TP) from January 2022 to the date of the inspection, on August 11, 2022. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the LD identified six TP as qualified to perform moderate complexity Anti-D Rh patient immunohematology typing. 2. Review of the available laboratory personnel records of TP B for evaluation of education documentation revealed no record. TP B's personnel record indicated initial training and patient Anti-D Rh testing began January 2022. 3. The inspector requested to review education documentation for TP B. The records were not available for review. The office manager stated at approximately 1 PM, "I asked for the education records from our main office and from the employee repeatedly but have not received them to date." 4. An exit interview with the office manager on 8/11/22 at approximately 2 PM confirmed the above findings