

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0964390	(X3) Date Survey Completed 06/05/2018
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 Professional Medical Services, PC on June 5, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Deficiencies are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report form (CMS 209), and an interview, the laboratory failed to rotate proficiency testing among the three (3) testing personnel for three (3) of the six (6) events reviewed. Findings include: 1. The review of the American Association of Bioanalysts (AAB) PT records revealed that the testing personnel (TP) A performed 3rd event in 2016 and the 1st and 2nd events in 2017. (See attached personnel code list.) 2. Review of the CMS 209 laboratory personnel form revealed three (3) testing personnel performing testing in 2016 and up to the date of survey on June 5, 2018. 3. An interview with the primary testing personnel at approximately 4:00 PM confirmed that the laboratory failed to rotate the AAB PT events among all testing personnel for the events specified above.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination,</p>

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 review of proficiency testing (PT) records and an interview, the laboratory failed to maintain the attestation statement and submitted results for the 3rd event in 2017. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT records revealed that the laboratory did not have documentation of the attestation statement and submitted results for the 3rd event in 2017. 2. An interview the primary testing personnel at approximately 4:00 PM confirmed that the laboratory failed to maintain the documents specified above for the 3rd event in 2017.

D2154

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(b)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on the review of proficiency testing (PT) records and an interview, the laboratory failed to achieve satisfactory performance, a score of 100%, in the specialty of Immunohematology (Anti-D Rh typing) for the 3rd event in 2016. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT records revealed that the laboratory received a score of 80% for the 3rd event in 2016 for the Anti-D Rh typing. 2. An interview the primary testing personnel at approximately 4:00 PM confirmed that the laboratory did not receive a satisfactory score of 100% in the specialty of Immunohematology for the 3rd event in 2016.

D2160

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(e)

(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on the review of proficiency testing (PT) records for the specialty of Immunohematology (Anti-D Rh typing) and an interview, the laboratory failed to have documentation of remedial actions for the unsatisfactory score of 80% for the 3rd event in 2016. Findings include: 1. Review of the American Association of

Bioanalysts (AAB) PT revealed that the laboratory received a score of 80% for the 3rd event in 2016. There was no documentation of remedial actions performed for the unsatisfactory event. 2. An interview the primary testing personnel at approximately 4:00 PM confirmed that the laboratory did not perform and document remedial actions for the above-specified event.