

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0401385	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier Whole Woman's Health Of Minnesota	Street Address, City, State 8053 E Bloomington Fwy, Bloomington, MN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee and Testing Personnel failed to attest to the integration of proficiency testing samples into the routine patient workload. Findings are as follows: 1. The laboratory performed Vaginal Preparation microscopic examinations under the specialty of Microbiology and Rh testing under the specialty of Immunohematology as confirmed by the Clinic Manager (CM) during a tour of the laboratory on 05/17/18 at 1:15 p.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The Laboratory Director (LD) or designee and Testing Personnel failed to attest to the integration of PT samples into the routine patient workload for 2 of 11 API PT events reviewed in the January 2016 through May 2018 timeframe. See below. Event Specialty missing attestation 2017-2 Immunohematology 2017-2 Microbiology 4. In an interview on 05/17/18 at 2:50 p.m., the CM confirmed the above finding.</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, 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</p>

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 document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing result records. Findings are as follows: 1. The laboratory performed Vaginal Preparation microscopic examinations under the specialty of Microbiology and Rh testing under the specialty of Immunohematology as confirmed by the Clinic Manager (CM) during a tour of the laboratory on 05/17/18 at 1:15 p.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute PT provider. 3. Laboratory testing records from 10 of 11 PT events completed in the January 2016 through May 2018 timeframe were not found. The laboratory was unable to provide the missing documents upon request. 4. In an interview on 05/17/18 at 3:00 p.m., Testing Personnel 1 (TP1) confirmed the above finding. TP1 explained she entered the results directly into the online submission program and did not retain the hand written testing result documents for the PT events.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Vaginal Preparation microscopic examinations under the specialty of Microbiology and Rh testing under the specialty of Immunohematology as confirmed by the Clinic Manager (CM) during a tour of the laboratory on 05/17/18 at 1:15 p.m. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory received unacceptable PT results from API for the samples listed below. Event ID Lab Result API expected 2016-3 VA-03 Yeast seen No yeast seen 2016-3 RH-15 Positive Negative 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 05/17/18 at 2:50 p.m., the CM confirmed a documented evaluation of the unacceptable results was not performed.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples at least annually. Findings are as follows: 1. The laboratory performed Rh testing under the Specialty of Immunohematology as confirmed by the Clinic Manager (CM) during a tour of the laboratory on 05/17/18 at 1:15 p.m. 2. Requirements to assess testing personnel competency via blind testing using previously analyzed specimens, blind samples or proficiency testing samples were not found in the CLIA procedure manual. Documentation of blind testing was not included on the annual assessment form. 3. Laboratory records indicated 2 of 4 testing personnel (TP) were not assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples in 2016. In 2017, 3 of 5 TP were not assessed in this manner. See below. TP performed proficiency testing as indicated by "x" TP 2016 2017 1 2 x 3 4 N/A x 5 x x *N/A - not applicable, newly hired in 2016 4. In an interview on 05/17/18 at 2:55 p.m., the CM confirmed the above finding.