

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0401385	<b>(X3) Date Survey Completed</b>  02/13/2024
<b>Name of Provider or Supplier</b>  Whole Woman's Health Of Minnesota	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Whole Women's Health of Minnesota laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on February 13, 2024. The following standard-level deficiencies were cited: 493.801 Enrollment and testing of samples 493.1291 Test report 493.1407 Laboratory director responsibilities .
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Immunohematology proficiency testing (PT) samples from five of six PT events in 2022 and 2023 were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Rhesus Factor (Rh) testing under the specialty of Immunohematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 02/13/24. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The Proficiency Testing procedure found in the CLIA Manual indicated PT samples would be tested in the same manner as patient specimens. 4. Rh PT samples were tested by multiple testing personnel (TP) in five of six PT events events completed in 2022 and 2023 as indicated on API attestation statements. See below. 2022 - 1st Immunohematology event Tested by: TP5 and former TP KS and JO on 03/29/22 2022 - 3rd Immunohematology event Tested by: TP6 on 11/29/22 and TP5 and TP6 on unknown date* 2023 - 1st Immunohematology event Tested by: TP4 on 003/28/23 and TP4 and TP5 on 04/03/23 2023 - 2nd Immunohematology event Tested by: TP5 on 08/09/23</p>

and TP6 on 08/08/23 2023 - 3rd Immunohematology event Tested by: TP3 and TP4 on 12/01/23 5. In an interview at 11:20 a.m. on 02/13/24, TP1 confirmed the above finding and indicated patient specimens would not be tested by multiple TP or on multiple days. \*The 2022 - 3rd Immunohematology event attestation statement was dated 04/03/23 by the laboratory director, TP5, and TP6. \*\*This is a repeat deficiency from the 04/05/22 survey\*\* .

**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 document review and interview with laboratory personnel, the laboratory failed to retain required proficiency testing (PT) testing records from six of six testing events in 2022 and 2023. Findings are as follows: 1. The laboratory performed Rhesus Factor (Rh) testing under the specialty of Immunohematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 02/13/24. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. Test result, testing personnel, and test kit lot number and expiration date testing records from three of three API PT events completed in 2022 were not found. Testing personnel, test kit lot number and expiration date testing records were not found for three of three API PT events in 2023. The laboratory was unable to provide the missing documentation upon request. 4. In an interview at 11:15 a.m. on 02/13/24, TP1 confirmed the above finding. TP1 explained testing personnel entered the PT result on the API provided result sheet. No other documentation was completed. The API result sheets from 2022 were not retained. \*\*This is a repeat deficiency from the 05/17/18 survey and the 04/05/22 survey (at D3037).\*\* .

**D5821**

**TEST REPORT**  
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish a written corrected reports procedure. Findings are as

follows: 1. The laboratory performed Rhesus Factor (Rh) testing under the specialty of Immunohematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 02/13/24. 2. An Eldon Biologicals EldonBag RhD-25 containing Eldon Cards was observed as present and available for use during the tour. 3. A corrected reports procedure was not found during review of laboratory policies and procedures located in the CLIA Manual. The laboratory was unable to provide a corrected reports procedure upon request. 4. In an interview at 12:50 p.m. on 02/13/24, TP1 confirmed the above finding. .

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on document review and interview with laboratory personnel, the laboratory director failed to ensure proficiency testing (PT)samples were tested as required. Findings are as follows: 1. The laboratory performed Rhesus Factor (Rh) testing under the specialty of Immunohematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 02/13/24. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory director failed to ensure Immunohematology proficiency testing (PT) samples from five of six API PT events in 2022 and 2023 were tested consistent with the number of times the laboratory routinely tested patient specimens. See D2010 4. During an interview at 11:20 a.m. on 02/13/24. TP1 confirmed the above finding. .