Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0401385	04/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Of Minnesota	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
D0000	A recertification survey was completed on April 5, 2022. During the survey, it was determined that Immediate Jeopardy existed for the following condition-level deficiency: Analytic Systems - 42 CFR 493.1250 .
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. 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 two of five PT events from late 2020 through 2022 were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 04/05/22. 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. The Rhesus Factor (Rh) PT samples were tested by multiple testing personnel (TP) prior to the event submission deadline for two of five PT events events reviewed as indicated on attestation statements. See below. 2021 - 1st Immunohematology event Submission deadline: 04/14/21 Samples: RH-01 through RH-05 Tested by: TP1, TP2, and former TP EG and AL on 04/05/21 2022 - 1st Immunohematology event Submission deadline: 04/13/22 Samples: RH-01 through RH-05 Tested by: TP1, TP2, and TP3 on 03/29/22 5. In an interview at 12:50 p.m. on 04/05/22, TP1 indicated patient specimens would not be tested multiple times and confirmed the above finding. .
D3037	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 04/05/22. 2. The laboratory performed Rhesus Factor PT using the American Proficiency Institute (API) provider. 3. The following PT documentation was not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. Event: 2020 3rd Immunohematology event Missing Item: Attestation Statement Event: 2021 2nd Immunohematology event Missing Item: Attestation Statement Event: 2021 3rd Immunohematology event Missing Item: Attestation Statement 4. In an interview at 12:47 p.m. on 04/05/22, TP1 confirmed the above findings. .
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 investigate one unacceptable Immunohematology proficiency testing (PT) result in 2021. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 04/05/22. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory received one unacceptable PT result of 15 Rhesus Factor (Rh) testing challenges in 2021. See below. 2021 3rd Immunohematology event Sample: RH-15 Laboratory Result: Negative API expected result: Positive 4. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing procedure located in the CLIA manual. 5. Investigation of the unacceptable Rh PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:52 p.m. on 04/05/22, TP1 confirmed the above finding. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of five proficiency testing (PT) results when the laboratory received a zero score for non-participation. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 04/05/22. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory failed to submit results to API for five Rhesus Factor (Rh) PT samples prior to the submission deadline for the 2020 Immunohematology second testing event. API assigned a zero score for failure to participate. 4. The laboratory discovered the issue and completed testing on the five samples on 09/17/20 as indicated in laboratory records. A self-evaluation of the five results was not found during review. The laboratory was unable to provide a self-evaluation of the results upon request. 5. Evaluation of non-graded PT results was required as established in the laboratory's Proficiency Testing procedure found in the CLIA manual. 6. In an interview at 12:45 p.m. on 04/05/22, TP1 confirmed the above finding. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of laboratory policies and procedures, patient testing and quality control logs, direct observation, and interview with laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to perform quality control each day of patient testing for an Immunohematology test. See D5449 .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) testing on five of seven days of patient testing between 02/21/22 and 03/31/22 for a qualitative Immunohematology test. Findings are as follows: 1. The laboratory performed Rhesus Factor (Rh) Immunohematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 04/05/22. 2. An Eldon Biologicals EldonBag RhD-25 containing EldonCards with lot number 21251 and expiration date 2023-06-28 was observed as present and available for use during the tour. 3. Rh QC testing with a

	positive and a negative control material was required upon receipt of new testing kits as established in the Eldon Card Rh Test procedure and on each day of patient testing as established in the Quality Assurance procedure. Both procedures were located in the laboratory's CLIA manual. 4. An Individualized Quality Control Plan (IQCP) to reduce the required daily QC frequency for Rh testing was not found in the laboratory's records. The laboratory indicated an IQCP for this test system had not been completed. 5. The Daily Laboratory Log included QC and patient testing information. The log indicated Rh QC was not performed on five of seven days of Rh testing between 02/21/22 and 03/31/22 and a total of 35 patient samples received Rh testing over those five days. See below. Date Number of tests 02/21/22 1 03/10/22 4 03/17/22 11 03/24/22 12 03/31/22 7 6. In an interview at 1:03 p.m. on 04/05/22, TP1 confirmed the above finding.