Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2178760	09/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Of South Bend	3511 Lincoln Way West, South Bend, IN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to: 1) ensure the laboratory director and individual performing proficiency testing (PT) signed the attestation statements for Rhesus Factor (Rh) PT during two of two PT testing events reviewed (event 1, 2020 and event 2, 2020) (refer to D2009); and 2) test PT samples the same number of times it tests patient samples for Rh during one of two PT events reviewed (event 2, 2020) (refer to D2010).
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director and individual

	performing proficiency testing failed to sign the attestation statements for Rhesus Factor (Rh) proficiency testing (PT) for two of two PT testing events reviewed (event 1, 2020 and event 2, 2020). Findings included: 1. Review of "Proficiency Testing" policy/procedure, approved by the laboratory director on 2-7-2020, indicated the policy/procedure did not require the laboratory director and individual performing the proficiency test to sign the PT attestation statement to indicate the routine integration of the PT samples into the patient workload, using the laboratory's routine methods. 2. Review of PT documentation indicated the attestation statements for Rh were not signed by the laboratory director nor were they signed by the individual who performed the PT test during PT testing events 1 and 2, 2020. 3. In interview on 9-14-2020 at 2:42 PM, SP1, Administrative Coordinator, acknowledged the PT attestation statements for Rh testing were not signed by the laboratory director and the individual who performed the test during PT testing events 1 and 2, 2020.
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, the laboratory failed to test proficiency testing (PT) samples the same number of times it tests patient samples for Rhesus Factor (Rh) during one of two PT events reviewed (event 2, 2020). Findings included: 1. Review of "Proficiency Testing" policy/procedure, approved by the laboratory director on 2-7-2020, read: "The laboratory testing personnel are instructed to analyze these specimens exactly as they would analyze routine client specimens, and the results are submitted to the proficiency testing agency." 2. Review of PT documentation indicated the "attestation statement" for Rh during PT testing event 2, 2020 included the typed names of SP1, Administrative Coordinator, and SP3, Testing Person, as the individuals who performed the PT test. 3. In interview on 9-14-2020 at 2:42 PM, SP1 indicated each of the proficiency samples for Rh during the PT event 2, 2020 were tested by SP1 and SP3 on the same date, prior to submitting the test results to the proficiency testing provider.
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, the laboratory failed to verify the accuracy of one of one analyte assigned a proficiency testing (PT) score that did not reflect the laboratory test performance during one of two PT testing events reviewed (event 1, 2020). Findings included: 1. Review of "Proficiency Testing" policy/procedure, approved by the laboratory director on 2-7-2020, did not require the laboratory to verify the accuracy of a PT score that did not reflect the laboratory's test performance

	during a PT testing event. 2. Review of PT documentation for Rhesus Factor (Rh) during PT testing event 1, 2020 indicated the following: a. The "Performance Summary" indicated the laboratory received a PT score of "100%" during the PT testing event. The "Performance Summary" indicated the "Lab Reported Test Problem" in the "Notes" section for the testing event. b. The "Submitted Result Form" during the testing indicated FedEx did not deliver the first kit shipped and refused to deliver the replacement kit that was shipped. The "Submitted Result Form" further read "Test Problem Reported" for each of the five PT samples. c. The "Comparative Evaluation" indicated the PT performance was "Not Graded" for each of the five PT samples during the PT testing event. 3. In interview on 9-14-2020 at 11:57 AM, SP2, Clinic Manager, indicated the Rh proficiency testing samples for event 1, 2020 were shipped via United Parcel Service (UPS). SP2 indicated UPS refused to initially deliver the PT samples and the samples were held by UPS for a few days. When UPS finally delivered the PT samples, they were unusable. SP2 indicated the proficiency testing provider was notified of the unusable samples and the laboratory received a second shipment of PT samples. 4. In interview on 9-14-2020 at 3:17 PM, SP1, Administrative Coordinator, confirmed the laboratory received a second shipment of PT samples for Rh, but the samples were used for training purposes and not tested to verify the accuracy of the Rh testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to demonstrate it can obtain performance specifications comparable to those established by the manufacturer for accuracy and precision for one of one test reviewed (Rhesus Factor). Findings included: 1. Review of policies and procedures indicated the laboratory did not establish a policy/procedure for performance specifications. 2. Review of laboratory documentation indicated the laboratory did not demonstrate it could obtain accuracy and precision comparable to the accuracy and precision established by the manufacturer for Rh testing. 3. Review of patient records indicated the laboratory performed Rh testing for patients, without demonstrated accuracy and precision, as follows: a. Patient #2 (4-24-2020) b. Patient #6 (9-11-2020) c. Patient #7 (9-10-2020) d. Patient #11 (8-14-2020) e. Patient #12 (7-17-2020) f. Patient #15 (4-17-2020) g. Patient #16 (3-27-2020) h. Patient #17 (4-3-2020) 4. In interview on 9-14-2020 at 12:30 PM, SP2, Clinic Manager, confirmed the laboratory did not test accuracy and precision for performance specifications prior to testing patient samples.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to have one of two technical consultants meet the qualification requirements (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on document review and interview, one of two technical consultants failed to be qualified (SP4). Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209) did not indicate SP4 was a technical consultant. The form further indicated SP1, Administrative Coordinator, was a testing person. 2. Review of personnel records indicated the following: a. SP4 performed the competency assessments for SP1 and SP3, Testing Person, on 5-22-2020. b. SP4 had a high school diploma and did not qualify as a technical consultant. c. SP1 had a high school diploma and did not qualify as a technical consultant. 3. Review of patient records indicated SP3 performed patient testing as follows: a. Patient #6 (9-11-2020) b.

	Patient #7 (9-10-2020) c. Patient #11 (8-14-2020) d. Patient #12 (7-17-2020) e. Patient #15 (4-17-2020) e. Patient #16 (3-27-2020) f. Patient #17 (4-3-2020) 4. In interview on 9-14-2020 at 4:06 PM, SP1 acknowledged SP4 had performed the competency assessments for SP1 and SP3. SP1 further acknowledged SP4 had a high school diploma. SP1 indicated SP4 no longer worked as this laboratory and SP1 would be performing future competency assessments. SP1 acknowledged they had a high school diploma.