

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0432111	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Whole Woman's Health Of Peoria Llc	Street Address, City, State 7405 N University St #D, Peoria, IL	
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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to test PT samples in the same manner as it tests patient specimens when analyzing and reporting PT results for Rhesus Factor (Rh) typing in 2016 through 2017. Findings Include: 1. The laboratory failed to test PT samples with the same methodology used for patient specimens when analyzing and reporting PT results for Rhesus factor (Rh) typing in 2016 through 2017. See D2006. 2. The laboratory failed to test Rhesus factor (Rh) typing proficiency testing (PT) samples by personnel who routinely perform testing in the laboratory in 2016 through 2017. See D2007.</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the</p>

laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and personnel interviews; the laboratory failed to test PT samples with the same methodology used for patient specimens when analyzing and reporting PT results for Rhesus Factor (Rh) typing in 2016 through 2017. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the log, "Test Procedures", which indicated Rh testing using the slide method was instated on 02-24-2016. 2. Interview with the technical consultant on 02-14-2018, at 11:30 am confirmed that all TP routinely use the slide method for Rh typing of patients. 3. Review of proficiency testing (PT) documentation for all six events in 2016 through 2017 for Rh testing indicated the tube method was used for PT. 4. Interview on 02-14-2018 with the TC at 11:30 am confirmed that immunohematology testing for Rh typing in 2016 through 2017 was performed using the tube method and not the slide method currently performed by the laboratory testing personnel for patient testing.

D2007

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

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

This STANDARD is not met as evidenced by:

Based on review of laboratory records and personnel interviews; the laboratory failed to test Rhesus factor (Rh) proficiency testing (PT) samples by personnel who routinely perform testing in 2016 through 2017. Findings Include: 1. Review of the laboratory's policy and procedure manual identified testing personnel authorizations, which documented 4 of 4 (TP#1-4) current testing personnel, listed on the CMS-209, who were authorized to perform slide Rh typing. 2. Interview with the TC on 02-14-2018 at 11:30 am confirmed that 6 of 6 PT events for Rh typing in 2016 through 2017 had been performed by the TC/TP#1. 3. On survey date 02-14-2018, at 1:15 pm testing personnel (TP) #4 confirmed 1 of 4 TP who were authorized to perform Rh testing had participated in PT in 2016 through 2017.

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 review of laboratory records and personnel interviews; the laboratory failed to demonstrate it can obtain performance specifications for Rhesus factor typing using the slide method prior to reporting patient testing results. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the log, "Test Procedures", which indicated Rh testing using the slide method was instated on 02-24-2016. 2. Surveyor requested verification of performance specifications for slide Rh typing on 02-14-2018 at 10:30 am from TP#4 and the TC confirmed at 11:30am on 02-14-2018 that no verification of performance for Rh typing using the slide method had been performed. 3. On survey date 02-14-2018, at 1:15 pm, the above findings were confirmed by testing personnel (TP) #4.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of laboratory records and personnel interviews; the laboratory director failed to ensure 6 of 6 proficiency testing (PT) events in 2016 through 2017 were reviewed by the appropriate staff. Findings Include: 1. Review of proficiency testing performance records for Rhesus factor typing found the laboratory failed to review 6 of 6 testing events in 2016 through 2017. 2. On survey date 02-14-2018, at 1:15 pm the findings were confirmed by testing personnel #4.