Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219450	07/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Of Baltimore	7648 Belair Rd, Baltimore, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the lab did not have written procedures for staff to follow when they transcribe results (Rh) obtained from testing performed the previous day onto the patient record for the current day. Findings: 1. When a patient has an Rh test performed and reported within 24 hours, the lab will transcribe the results onto the current patient log so that the test is not repeated; 2. Staff transcribing the test result onto the patient log, record that the result was obtained from testing performed on the previous day; 3. According to staff, the test results can only be transcribed to the current visit when testing was performed

	within 24 hours; 4. The lab did not have a written policy stating that transcription of test results can only be done when the previous testing was performed within 24 hours, and the lab did not have a written procedure to make a notation that transcribed results were obtained from testing performed the previous day; and 5. Findings were confirmed during interview with staff on the day of survey. B. Based on observation and interview with laboratory (lab) staff, the lab did not have manufacturer instructions for the current anti-D reagent in use for patient Rh testing. Findings: 1. The lab replaced their anti-D reagent with that of a different manufacturer (new anti-D), and on the day of survey, the surveyor observed the new anti-D in the refrigerator for use; 2. The lab did not have a manufacturer's package insert for the new anti-D reagent; 3. The lab did not have documentation showing that it reviewed the manufacturer's instructions for the new anti-D, ensuring that test methods, test conditions and use of the new anti-D product had not changed; and 4. Findings were confirmed during interview with staff on the day of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not ensure that Rh testing reagent (anti-D) was not used past expiration. Findings: 1. The lab did not maintain a daily record of the Anti-D in use for each day of patient testing to include the manufacturer name, product name, lot number and expiration date; and 2. Findings were confirmed during interview with lab staff on the day of survey
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not take corrective action and performed patient testing, when Rh quality control test results did not meet the laboratory's criteria for acceptability. Findings: 1. On December 21, 2018, the lab did not record the Rh quality control result for red cell reagent III (negative check). Fourteen patient tests were performed ; 2. On December 5, 2018, the lab did not record the Rh quality control result for red cell reagent III (negative check). twenty patient tests were performed; 3. On August 24, 2018, the Rh quality control results for red cell reagents I (positive check), II (positive check) and III (negative check), all failed to meet the lab's criteria for acceptability and were reported as testing negative for reagents I and II and positive for reagent III. Thirteen patient tests were

	performed; 4. On July 30, 2018, the Rh quality control test results for red cell reagents I (positive check), II (positive check) and III (negative check), all failed to meet the lab's criteria for acceptability and were reported as testing negative for reagents I and II and positive for reagent III. 12 patient tests were performed; 5. On March 23, 2018, the Rh quality control result for red cell reagent III (negative check) was reported as testing positive. Sixteen patient tests were performed; 6. On November 15, 2017, the Rh quality control result for red cell reagent III (negative check) was not documented. Twelve patient tests were performed; 7. Corrective actions were not taken and documented when the quality control results failed to meet the laboratory's criteria for acceptability; and these findings were confirmed during interview with staff on the day of survey.