Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0938247	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's Choice Of Raleigh	3305 Drake Circle, Raleigh, NC	

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
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 2017, 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records, review of personnel records and review of laboratory testing records 6/4/19, the laboratory failed to ensure all testing personnel (TP) performed PT. Review of 2017, 2018 and 2019 API PT records revealed TP#5 was the only TP to perform PT. Review of testing records and personnel records revealed TP #1 was hired in October of 2017, TP #3 was hired December of 2018 and TP #4 was hired in November of 2018. TP#1, TP#3 and TP#4 failed to perform PT. In addition, TP who were documented on laboratory testing records during 2018, but were no longer employed, had not performed PT.
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: Based on review of laboratory procedure manual and review of manufacturer's instructions for rhesus D antigen (RhD) testing 6/4/19, the laboratory's procedure manual was not complete and current for the RhD testing performed. Review of laboratory procedure manual and manufacturer's instructions revealed the laboratory had two procedures for RhD testing, and both procedures failed to follow the manufacturer's instructions (see D5411).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory procedure manual, and testing personnel (TP) interview 6/4/19, the laboratory failed to follow manufacturer's instructions for rhesus D antigen (RhD) testing. Review of manufacturer's instructions for RhD testing, ALBAclone Anti-D blend blood grouping reagent, revealed under "Slide Technique...1. Add 1 drop of blood grouping reagent ... 2. Add 1 drop of whole blood...3. Mix well by rocking the slide for approximately 30 seconds and incubate the test at 20-24 degrees Celsius (C) for 5 minutes with occasional mixing. Review of laboratory procedure manual revealed the following two procedures for RhD testing: 1. "Rh Testing Policy & Procedure" which states "... One drop of Albaclone Anti-D reagent placed on glass slide follow by one drop of the patient's blood. Slide will then be mixed well with stir stick and then rocking the slide for approximately 30 seconds. Test must incubate for 5 minutes using timer at 18c-24c (room temperature) with occasional mixing." The procedure fails to follow manufacturer's instructions. The manufacturer's instructions do not include mixing with a stir stick before rocking the slide. And the manufacturer's instructions state to incubate the test at 20-24 degrees C not 18-24 degrees C. 2. "Protocol for Administering Rh Test" which states "...Add 2 drops of blood to the one drop of reagent that is already on the glass slide. Mix thoroughly with a toothpick over an oval area. Lift the slide up to the light and rock back and forth to receive your results. Test results may be interpreted immediately upon completion of test." The procedure fails to follow manufacturer's instructions. The manufacturer's instructions state 1 drop of blood grouping reagent and 1 drop of whole blood. The manufacturer's instructions also state to incubate the test after rocking for 5 minutes at 20-24 degrees C. Interview with TP#2 at approximately 11:00 am confirmed the laboratory mixes with a stir stick first, then rocks the slide and interprets the test. The TP did not state that the test was

	incubated for 5 minutes after rocking the slide. The laboratory performs approximately 3500 RhD tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of rhesus D antigen (RhD) quality control (QC) records and review of RhD antigen testing records 6/4/19, the laboratory failed to document the acceptability of control materials used for RhD testing. The laboratory utilizes blood drawn from testing personnel (TP) as negative and positive controls for the RhD testing procedure. Review of laboratory procedure "Rh Testing Policy & Procedure" revealed "Positive/Negative Controls (Blood Samples). Positive /negative samples must be drawn every 30 days...THIS SHOULD ALSO BE PLACED ON RH CONTRO; LOG SHEET LOCATED IN THE LAB BOOK." Review of 2018 RH Control Logs revealed the laboratory drew blood for RhD quality control on 7/3/18 which expired on 8/3/18. The next entry for blood draw was on 9/18 /18. The laboratory failed to document the blood draw due on 8/4/18. This deficiency was previously cited under D6072 in 2014.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records, review of laboratory quality assessment records, and interview with facility manager 06/04 /2019, the laboratory director failed to ensure the laboratory's corrective action plan was followed when PT results were found to be unacceptable or unsatisfactory. The laboratory PT policy "PROFICIENCY TESTING(4/18/11)" states "If less then 100% is scored, then employee who performed test needs to be retrained and retested. (Make

	notation in QA)." Review of API 2018 Immunology/Immunohematology - 1st Event PT records revealed the laboratory scored an unacceptable result for sample RH-05, resulting in an overall score of 80%. The less than 100% score was reviewed by laboratory director. There was no documentation of corrective action. Review of 2018 quality assessment records revealed no documentation of corrective action for the less than 100% score on the API PT 2018 Immunology/Immunohematology - 1st event. Interview with facility manager at approximately 12:30 p.m. confirmed the laboratory did not follow the corrective action plan, she stated they were under the impression that if they scored 80% or above nothing needed to be done.