Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2092552	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's Choice Of Greensboro, Inc	2425 Randleman Road, Greensboro, 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
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 review of the laboratory's policies and procedures and review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records 7/12/18, the laboratory failed to retain all proficiency testing records for at least two years. The laboratory's "PROFICIENCY TESTING" policy states "... Employees will do the testing as they would on a daily basis Lab director will sign Place a copy of package insert of proficiency testing will be placed in the lab book ..." Review of 2016, 2017, and 2018 API proficiency testing records revealed the laboratory did not have the following records available for review during the survey: a. the signed attestation statement for the 2017 1st event; b. the signed attestation statement and the report form used to record proficiency testing results for the 2018 1st event.
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 procedure manual review, observation, and interview with TP (testing personnel) 7/12/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory's "Rh Testing Policy & Procedure" states "... Test must incubate for 5 minutes using timer at 18c-24c (room temperature) with occasional mixing. ... If temperature are below 18c RH view box light will be used, room temperature will be adjusted and rechecked in 30 minutes with timer. ..." The room temperature listed in the laboratory's procedure was not consistent with the manufacturer's instructions for use of the Anti-D ALBAclone reagent. The "Anti-D blend ALBAclone" product insert states "... RECOMMENDED TECHNIQUES This reagent and the specimen(s) to be tested should be at 20-24 degrees C prior to testing. ... Slide Technique ... 3. Mix well by rocking the slide for approximately 30 seconds and incubate the test FOR 5 MINUTES at 20-24 degrees C with occasional mixing. ... ". 2. The laboratory's "QUALITY CONTROL FOR RhD TYPING" procedure states "... Procedure ... 3. Add 1 drop of red blood cells suspended to 30-45% in group homologous plasma/serum: To the '+' or 'pos' labeled slide add 1 drop of red cells from the RhD positive control blood vial. To the '-' or 'neg' labeled slide add 1 drop of red cells from the RhD negative control blood vial. 4. Mix well..." The laboratory's quality control procedure did not include use of the Anti-D ALBAclone reagent which must be added to the slide prior to adding the control blood sample. 3. The procedure manual contained a product insert for the "CLIAwaived Inc. Pregnancy Urine Test (Cassette) and a generic "HCG URINE PREGNANCY TEST" procedure written by the laboratory and dated 3/2015. During a tour of the laboratory at approximately 10:00 a.m., surveyors observed test kits for the "Rapid Response Human Chorionic Gonadotropin hCG Test Cassette Urine" and the "Instant -View Pregnancy Urine Cassette Test". During interview at approximately 10:10 a.m., TP #5 stated that they currently use the "Rapid Response Human Chorionic Gonadotropin hCG Test Cassette Urine" for the initial visit and the "Instant -View Pregnancy Urine Cassette Test" for the follow-up. She stated she was not familiar with the other two urine pregnancy test procedures in the procedure manual.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed,

	as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and random review of 2016, 2017, and 2018 daily logs 7/12/18, the laboratory failed to perform and document a positive and a negative control each day of patient testing for Rh(D). The "QUALITY CONTROL FOR RhD TYPING" procedure states "Introduction ... A positive and a negative control should be tested each day of use. To fulfill these requirements, Anti-D reagent will be tested with a known RhD positive sample and a known RhD negative sample once each day, before the testing of patient samples begins. ..." The "POLICY & PROCEDURE FOR QUALITY ASSURANCE" states "... 1. Everyday controls will be done and written on lab sheets before the start of every clinic (Rh positive and negative ...". Random review of the Rh(D) daily logs revealed the laboratory failed to perform and document positive and negative controls each day that patients were tested. Examples: 1. December 2017 - positive control result not documented 1 of 19 days of testing: a. 12/15/17 - 10 patients tested. 2. February 2018 - positive and negative control results not documented 1 of 20 days of testing: a. 2/1/18 - 5 patients tested. 3. April 2018 - positive and negative control results not documented 8 of 20 days of testing: a. 4/2/18 - 9 patients tested; b. 4/5/18 - 8 patients tested; c. 4/6/18 - 5 patients tested; d. 4/7/18 - 13 patients tested; e. 4/9/18 - 13 patients tested; f. 4/12/18 - 4 patients tested; g. 4/13/18 - 12 patients tested; h. 4/19 /18 - 2 patients tested. 4. April 2018 - positive control results not documented 2 of 20 days of testing: a. 4/16/18 - 8 patients tested; b. 4/26/18 - 4 patients tested. 5. April 2018 - negative control results not documented 1 of 20 days of testing: a. 4/28/18 - 9 patients tested. 6. May 2018 - positive and negative control results not documented 3 of 21 days of testing: a. 5/17/18 - 4 patients tested; b. 5/19/18 - 5 patients tested; c. 5 /26/18 - 10 patients tested. 7. May 2018 - positive control results not documented 3 of 21 days of testing: a. 5/18/18 - 4 patients tested; b. 5/24/18 - 2 patients tested; c. 5/25 /18 - 11 patients tested. 8. May 2018 - negative control results not documented 3 of 21 days of testing: a. 5/2/18 - 3 patients tested; b. 5/10/18 - 5 patients tested; c. 5/11/18 - 12 patients tested. This deficiency was cited on the previous survey 8/24/16.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2016, 2017, and 2018 room and refrigerator temperature logs, the laboratory failed to take and document corrective action for room and refrigerator temperatures outside acceptable limits. The laboratory's "Temperature and Humidity Policy" states "... will keep a temperature and humidity log that will be completed daily at the start of every day... If the staff should find that the temperature or humidity is not within range, she will notify the Director of Patient Services so that the thermostat can be regulated to fit the correct parameters." Review of 2016, 2017, and 2018 room temperature logs revealed the room temperature recorded by the laboratory was outside the acceptable range of 21 - 24 degrees Celsius (69.8 - 75.2 degrees Fahrenheit) for 314 of 514 days from 9/1 /16 - 7/12/18 with no corrective action documented. Review of 2016, 2017, and 2018

	refrigerator temperature logs revealed the refrigerator temperature recorded by the laboratory was outside the acceptable range of 2 - 8 degrees Celsius (35.6 - 46.4 degrees Fahrenheit) for 37 of 514 days from 9/1/16 - 7/12/18 with no corrective action documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test result form and interview with TP (testing personnel) 7/12/18, the laboratory's test report did not include all required information. Review of the "PREGNANCY TERMINATION RECORD" form used to record the results of the Rh(D) antigen, urine pregnancy, and hemoglobin testing performed by the laboratory included the name of the laboratory, but did not include the address. During interview at approximately 1:10 p.m., TP #2 stated that the address probably was on the form at one time, but had disappeared as the form was updated.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records 7/12/18, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure all proficiency testing results were reviewed to identify any problems requiring corrective action (see D6018). 2. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6021). 3. The laboratory director failed to ensure patient Rh (D) test results were reported only when the system was functioning properly (see D6025). 4. The laboratory director failed to ensure that an approved, complete, and current procedure manual was available to all testing personnel (see D6031).
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 the laboratory's policies and procedures and review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records 7/12/18, the laboratory director failed to ensure all proficiency testing results were reviewed to identify any problems requiring corrective action. The laboratory's "PROFICIENCY TESTING" policy states "... When results come back, they should be reviewed, signed and dated by the lab director, then placed in the lab book. ..." Review of 2016, 2017, and 2018 API proficiency testing records revealed the following results had not been signed and dated by the laboratory director to indicate review: a. 2016 2nd and 3rd events; b. 2017 1st, 2nd, and 3rd events; c. 2018 1st event.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2016, 2017, and 2018 laboratory records 7/12/18, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. The laboratory's "POLICY & PROCEDURE FOR QUALITY ASSURANCE" (dated 8/2016) states "Upon arrival of the testing staff: 1. Everyday controls will be done and written on lab sheets before the start of every clinic (Rh positive and negative, Hematology, room /refrigerator temperatures). 2. Check expiration dates on all controls on all testing controls. Report to manager/lab director of any expired or about to expire controls. 3. At the end of everyday manager will review lab sheet and then place in lab book. 4. At the end of each month the Director of Patient Services will complete quality assurance checklist and corrective action (if any) will be documented. 5. Lab director will review monthly quality assurance checklist/corrective action (if any) and sign. Staff is aware of documentation policy. Management/nurse will closely renew QA program weekly, lab director will also sign and review monthly." Review of the laboratory's "Monthly Quality Assurance Checklist" from September 2016 - June 2018 revealed the laboratory had not documented that corrective action was needed for any items listed. The checklist was not an effective tool for the laboratory to identify and correct problems identified during the survey. Examples: 1. The checklist states "... Required controls, calibrations, and maintenance have been performed. Control documents have been reviewed and signed. ... Maintenance documents have been reviewed and signed. Corrective actions were implemented and reviewed to ensure resolutions and prevention of recurrences. ..." The laboratory noted Y (yes) for all items. Review of 2016, 2017, and 2018 daily quality control/patient logs and

	review of 2016, 2017, and 2018 temperature logs revealed: a. The laboratory failed to perform and document Rh(D) controls each day that patient specimens were tested (see D5551); b. The laboratory failed to take corrective action for room and refrigerator temperatures outside the acceptable limits (see D5785). c. Quality control and maintenance records had not been signed and dated by the laboratory director to indicate review. 2. The checklist states "... PT test results have been reviewed. ... Review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records revealed the laboratory director had not signed and dated the results to document review (see D6018).
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, random review of 2016, 2017, and 2018 daily logs, and review of 2016, 2017, and 2018 temperature logs 7/12 /18, the laboratory director failed to ensure patient results were reported only when the system was functioning properly. 1. The laboratory failed to perform and document a positive and a negative control each day of patient Rh(D) testing (see D5551). 2. The laboratory failed to ensure room temperature was within the manufacturer's specified acceptable limits each day that patient Rh(D) testing was performed (see D5785).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with TP (testing personnel) 7/12/18, the laboratory director failed to ensure that an approved, complete, and current procedure manual was available to all testing personnel for all aspects of the testing and reporting process. Findings: 1. Review of the laboratory's procedure manual revealed the policies and procedures had not been signed by the current laboratory director to indicate review and approval. During the exit interview at approximately 1:40 p.m., TP #2 confirmed the laboratory's procedures had not been signed and dated by the current laboratory director. 2. The procedure manual was not complete and current for the testing performed (see D5403).