Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2092552	03/27/2024
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation, and interview with TP (testing personnel) #1 on 3/27/24, the laboratory failed to update the procedure manual with instructions for the urine hCG (human chorionic gonadotropin) kits currently in use in the laboratory. Findings: Review of the laboratory's policies and procedures revealed manufacturer's instructions for the "hCG 2IU Test Disk" and the "Rapid Response Human Chorionic Gonadotropin hCG Test Cassette (Urine)". During a tour of the laboratory at approximately 11:50 a.m., the surveyor observed "Henry Schein One Step+ hCG Urine Cassette Test" and "dBest One Step Rapid Test" kits in the laboratory, available for use." Manufacturer's instructions for these tests were not included in the laboratory's procedure manual. During interview at approximately 12:00 p.m., TP #1 confirmed the laboratory currently uses Henry Schein One Step+ hCG Urine Cassette Test and dBest One Step Rapid Test.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedure manual and interview with TP #1 on 3 /27/24, the laboratory's policies and procedures were not signed and dated by the current laboratory director. Review of the laboratory's procedure manual revealed a coversheet which stated "... Lab Director will review and sign the Policy and Procedure Manual yearly or as new Policies are put in place throughout the year." Review of the laboratory's procedure manual revealed the policies and procedures were signed by the previous laboratory director, but had not been signed and dated by the current lab director. During interview at approximately 9:45 a.m., TP #1 confirmed that the current laboratory director had not signed and dated the laboratory's policies and procedures. This deficiency was cited on the previous survey 7/9/21.
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, review of 2022, 2023, and 2024 Rh(D) logs, and interview with TP #1 on 3/27/24, the laboratory failed to document the results of Rh(D) quality control testing for 24 days of patient testing from 2/15/24-3/27/24 when approximately 120 patients were tested. Findings: Review of the laboratory's "POLICY & PROCEDURE FOR QUALITY ASSURANCE" revealed "... 1. Everyday controls will be done and written on lab sheets before the start of every clinic (Rh positive and negative *documented in slot 1 and 2* ...". Review of the 2023 and 2024 Rh(D) logs revealed the laboratory discontinued patient Rh(D) testing 10/21/23. Patient Rh(D) testing resumed 2/15/24. Review of Rh(D) logs from 2/15/24 - 3/27/24 revealed the laboratory documented the lot number and expiration date for Rh(D) positive and negative controls on each log, but failed to document the results obtained. Approximately 120 patients were tested on 24 days of testing when quality control results were not documented. During interview at approximately 12:30 p.m., TP #1 stated they tested positive and negative Rh(D) controls each day that patients were tested. She stated they had updated the logs, and she confirmed the Rh(D) quality control results were not documented on the logs. This deficiency was cited on the previous survey 7/9/21. .
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 policies and procedures, review of quality assessment records, review of personnel records, and review of quality control records 3/27/24, the laboratory director failed to ensure the laboratory's quality assessment program was effective at identifying and correcting problems and preventing recurrence. Findings: Review of the laboratory's POLICY & PROCEDURE FOR QUALITY ASSURANCE" revealed "... 4. At the end of each month the Director of Patient Services will complete quality assurance checklist and corrective action (if any) and will be documented. ... 6. The lab director will review quality assurance checklist /corrective action (if any) and sign, twice per month. ..." Review of quality assessment records revealed the laboratory had completed the checklist, but the checklist failed to identify and prevent recurrence of problems identified during the survey in the following areas: 1. Procedure manual (see D1001, D5407); 2. Personnel training and competency (see D6029, D6054); 3. Quality control (see D5551). This deficiency was cited on the previous survey 7/9/21.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of job descriptions, review of personnel records, and interview with TP #1 on 3/27/24, the laboratory director failed to ensure that prior to testing patient specimens, 2 of 6 testing personnel (TP #5, TP #6) received training appropriate for the services offered and had demonstrated that they could perform all testing operations reliably to provide accurate patient test results. Findings: Review of the laboratory director's job description revealed "... The Lab Director is responsible for: ... Assuring Lab Staff Personnel folders verify eligibility and training ...". Review of personnel records revealed no documentation of training for TP #5 (hired in September 2022). Review of personnel records revealed TP #6 (hired in December 2023) had an initial "competency assessment" in January 2024 which indicated completion of training, but no documentation of the training. During interview at approximately 10:50 a.m., TP #1 confirmed there were no training records available for TP #5 and TP #6. This deficiency was cited on the previous survey 7/9/21.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with TP #1 on 3/27/24, the technical consultant (laboratory director) failed to perform and document annual competency evaluations for 2 of 6 TP (TP #1, TP #4) in 2022 and 2023. Findings: Review of the laboratory's "Policy for Clinical Laboratory Competency Testing" revealed "Laboratory Competency testing will be performed by ... Laboratory Director or Registered Nurse with Bachelors of Science Degree. Clinical Competency Assessment for all testing personnel will be completed after their 90 day probationary period and each year from that date. Once completed Clinical Assessment will be filed in testing personnel file. ..." Review of personnel records revealed there were no records of competency evaluations for TP #1 or TP #4 during 2022 and 2023. During interview at approximately 10:45 a.m., TP #1 confirmed the 2022 and 2023 competency evaluations were not in the personnel files for TP #1 and TP #4.