Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2092552	07/09/2021
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
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 policies and procedures and interview with the clinic manager 7/9/21, the laboratory failed to ensure that all procedures were approved by the current laboratory director. Review of the laboratory's procedure manual revealed the procedures were not signed and dated by the current laboratory director. During the exit interview at approximately 4:05 p.m., the clinic manager confirmed that the laboratory's procedures had not been signed by the current laboratory director.
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 manufacturer's instructions, review of the laboratory's policies and procedures, and random review of 2019, 2020, and 2021 daily logs 7/9/21, the laboratory failed to perform and document a positive and a negative control each day of patient testing for Rh(D). The QUOTIENT "BLOOD GROUPING REAGENT Anti-D blend ALBAclone" product insert states "... QUALITY CONTROL Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations. ..." The "Protocol for Administering Rh Test" procedure states "... A control must be done daily before performing this test. This is achieved by testing cells known to be negative and positive for the relevant antigen. Test reagent by using confirmed Positive and Negative blood specimens. ..." The "Rh Testing Policy & Procedure" states "... Testing Anti-D is a daily process. Make sure after testing the Anti-D with the controls, results are placed on lab sheet before clinic begins. ..." 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. 2 of 20 days in December 2019 (12/26, 12/30) positive and negative controls not documented - 21 patients tested. 2. 4 of 22 days in January 2020 (1/4, 1/6, 1/7, 1/10) positive and negative controls not documented - 51 patients tested. 3. 1 of 21 days in February 2020 (2/13) positve control not documented - 11 patients tested. 4. 1 of 22 days of testing in March 2021 (3/27) positive and negative controls not documented - 8 patients tested. This deficiency was cited on the previous survey 7/12/18.
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 random review of 2019, 2020, and 2021 room and refrigerator temperature logs 7/9/21, the laboratory failed to take and document corrective action for room and refrigerator temperatures outside acceptable limits. The laboratory's "Policy and Procedure for Refrigerator and Room Temperature " states "... A Temperature Control Log used to document temperatures daily. If at any time the thermometer reads an out of range temperature the testing personnel will document that temp, check gauges for temp control inside refrigerator and AC control unit. Adjust if needed and recheck temps in 30 minutes. IF temps are still out of range all medications and reagents will be tested for accuracy and moved to a safe temperature. Clinic Manager will be notified of discrepancies. ... " 1. Random review of 2019, 2020, and 2021 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) on the following days with no corrective action documented: a. 8 of 27 days in October 2019 (10/17, 10/18, 10/19, 10/22, 10/24, 10/26, 10/29, 10/31) - 54 patients tested. b. 12 of 27 days in October 2020 (10/2, 10/4, 10/5, 10/6, 10/7, 10/9, 10/10, 10/17, 10/20, 10/21, 10/24, 10 /28) - 83 patients tested. c. 6 of 21 days in April 2021 (4/1, 4/2, 4/3, 412, 4/29, 4/30) - 73 patients tested. 2. Random review of 2019, 2020, and 2021 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) on the following days with no corrective action documented: a. 2 of 23 days in March 2019 (3/4, 3/9) -

	33 patients tested. b. 6 of 26 days in April 2020 (4/3, 4/6, 4/10, 4/16, 4/27, 4/28) - 75 patients tested. c. 2 of 24 days in February 2021 (2/6, 2/19) - 30 patients tested. This deficiency was cited on the previous survey 7/12/18.
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 3 random patient charts (RHS010489, YH050784, CS122781) and interview with the clinic manager 7/9/21, 3 of 3 test reports did not include the address of the laboratory. Review of 3 random patient charts (RHS010489, YH050784, CS122781) revealed the form used by the laboratory to record the results of the Rh(D), urine pregnancy, and hemoglobin testing included the laboratory's name, but did not include the address. During interview at approximately 3:30 p.m., the clinic manager confirmed that the laboratory's address was not included on patient test reports. She stated they could stamp the blank test report forms with the laboratory's address before use. This deficiency was cited on the previous survey 7/12 /18.
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 2019, 2020, and 2021 laboratory records 7/9/21, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure that testing personnel competency evaluations were performed by a person who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory (see D6004). 2. The laboratory director failed to ensure that all graded proficiency testing results were reviewed to identify any problems requiring corrective action (see D6018). 3. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6021). 4. The laboratory director failed to ensure patient Rh(D) test results were reported only when the system was functioning properly (see D6025). 5. The laboratory director failed to ensure the laboratory employed a qualified technical consultant (see D6028). 6. The laboratory director failed to ensure all testing personnel were trained and the training was documented prior to testing patient specimens (see D6029). This deficiency was cited on the previous survey 7/12/18.

D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. 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 the clinic manager 7/9/21, the laboratory director failed to ensure that testing personnel competency evaluations were performed by a person who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. The laboratory's "Policy for Clinical Laboratory Competency Testing" states "Laboratory Competency testing will be performed by ... Laboratory Director or Registered Nurse with Bachelors of Science Degree. ..." Review of personnel records revealed that 2019, 2020, and 2021 competency evaluations for 5 of 5 testing personnel were performed and signed by the clinic manager as "Reviewer". The clinic manager confirmed during interview at approximately 4:15 p.m. that she does not meet the qualification requirements to serve as technical consultant in a moderate complexity laboratory.
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 2019, 2020, and 2021 API (American Proficiency Institute) proficiency testing records 7/9/21, the laboratory director failed to ensure that graded proficiency testing results were reviewed to identify any problems requiring corrective action for 5 of 7 testing events. 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 2019, 2020, and 2021 API proficiency testing records revealed that 3 of 3 testing events (1st, 2nd, 3rd) in 2019 and 2 of 3 testing events (1st, 3rd) in 2020 were not signed and dated by the laboratory director to indicate review. This deficiency was cited on the previous survey 7/12/18.
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 2019, 2020, and 2021 laboratory records 7/9/21, 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" 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 *documented in slot 1 and 2*, 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. The lab director will review all AB lab sheets twice per month and will ensure that all API proficiency testing statements are signed and documented correctly. 6. The lab director will review quality assurance checklist/corrective action (if any) and sign, twice per month. 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 January 2019 - July 2021 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 reviewed for all Quality Control Problems to ensure resolutions and prevent recurrence. ..." The laboratory noted Y (yes) for all items. Review of 2019, 2020, and 2021 daily logs and review of 2019, 2020, and 2021 temperature logs revealed: a. The laboratory failed to perform and document positive and negative 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). 2. The checklist states "... PT test results have been reviewed. ... Review of 2019, 2020, and 2021 API (American Proficiency Institute) proficiency testing records revealed the laboratory director had not signed and dated all results to document review (see D6018). This deficiency was cited on the previous survey 7/12 /18.
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 2019, 2020, and 2021 daily logs, and review of 2019, 2020, and 2021 temperature logs 7/9 /21, 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 and refrigerator temperatures were within acceptable limits each day that patient Rh(D) testing was performed (see D5785). This deficiency was cited on the previous survey 7/12/18.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on the deficiencies cited at D6033 and D6034 and review of personnel records 7 /9/21, the laboratory director failed to ensure the laboratory employed a qualified technical consultant. Review of personnel records revealed the laboratory did not have anyone on staff at the time of the survey who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. There was no documentation available to indicate that anyone employed by the laboratory had the training or experience to serve as technical consultant in a laboratory performing moderate complexity Rh(D) testing (see D6033, D6034).
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 personnel records and interview with the clinic manager 7/9/21,

	the laboratory director failed to ensure that prior to testing patient specimens, 5 of 5 testing personnel received appropriate training and demonstrated that they could perform all testing operations reliably to provide and report accurate Rh(D) patient test results. Review of personnel records revealed a "Verification of Orientation for Clinical Staff... " document for each testing personnel signed by the testing personnel and the clinic manager. The document included the following items: "I have been given a thorough tour of the facility" "I have read and understand the (facility) 'Emergency Plan'." "I know where the facility's evacuation route is posted." "I have read and understand the Policy and Procedure Manual." "I understand the regulation governing the operation of (the facility) which are given by the NC Division of Facility Services." "I have received, read, and fully understands aspect of the detailed job description for the position I am fulfilling." There was no training documentation for Rh(D) testing available for review. During interview at approximately 4:10 p.m., the clinic manager confirmed the personnel records did not include documentation of training for all aspects of Rh(D) testing from specimen collection through result reporting. She stated personnel were trained, but the training was not documented.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiency cited at D6034 and review of personnel records 7/9/21, the laboratory failed to have personnel in place who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the clinic manager 7/9/21, the laboratory failed to have personnel in place who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. Review of personnel records revealed the laboratory did not have anyone on staff at the time of the survey who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. There was no documentation available to indicate that anyone employed by the laboratory had the training or experience to serve as technical consultant in a laboratory performing moderate complexity Rh(D) testing. During the exit interview at approximately 4:15 p.m., the clinic manager confirmed that they did not have a qualified technical consultant.