Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0244179	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's Choice Of Charlotte	421 N Wendover Road, Charlotte, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the 2018, 2019, 2020, and 2021 API (American Proficiency Institute) PT (proficiency testing)records and absence of documentation 5/5/21, the laboratory failed to maintain all PT records and failed to ensure the director and testing personnel signed the attestation statement. Findings: Review of 2018, 2019, 2020, and 2021 API PT records revealed: 1. The laboratory failed to maintain the PT report forms with graded results for the following events: a. 2018 3rd Immunology /Immunohematology test event; b. 2019 2nd Immunology/Immunohematology test event; c. 2020 3rd Immunology/Immunohematology test event; 2. The laboratory failed to ensure the director and/or testing personnel signed the attestation statements for the following events: d. 2018 2nd Immunology/Immunohematology test event; e. 2019 1st Immunology/Immunohematology test event; f. 2019 3rd Immunology /Immunohematology test event; g. 2020 2nd Immunology/Immunohematology test event (only signed by testing personnel and clinic manager); h. 2020 3rd Immunology /Immunohematology test event (only signed by testing personnel and clinic manager); i. 2021 1st Immunology/Immunohematology test event.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, review of manufacturer's instructions, review of laboratory records and the absence of documentation, and interview with the clinic manager 5/5/21, the laboratory failed to monitor and document the conditions required for accurate and reliable test performance. Findings: The laboratory's "Policy and Procedure for Refrigerator and Room Temperature" states, "Refrigerators and Rooms that contain regulated reagents and medications must have the temperature monitored to ensure proper temperatures are kept. A thermometer will be placed inside the lab room, and lab refrigerator that contain medication and reagents... Lab Room temperature range should be between 20 degrees C(Celsius)- 31 degrees C(68 degrees F(Fahrenheit)-87 degrees F)." The laboratory's procedure states an incorrect room temperature range that is not consistent with the manufacturer's instructions dated 4-7-2020 for the RhD testing. The ALBAclone Anti-D blend blood grouping reagent instructions revealed under "Slide technique... incubate the test at 18-24 degrees C for 5 minutes with occasional mixing...." Review of the laboratory's temperature records revealed Room temperature documentation was not available for Room #1 and Room #2 where RhD slide testing was performed after December 2, 2020 until April 2021. Approximately 1,262 patients were tested during this time-frame. At approximately 12 p.m., the clinic manager stated the room temperatures were recorded for the lab area until the end of 2020 when testing was moved into Room #1 and Room #2. She confirmed room temperatures were not being monitored or documented in Room #1 or Room #2.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of procedures, review of manufacturer's instructions, review of 2018, 2019, 2020, and 2021 Rh(Rhesus) Slide test QC(quality control) and patient testing logs 5/5/21, the laboratory failed to document Rh QC each day patients were tested. Findings: The laboratory's procedure "Quality control for RhD Typing" states, " In

	order to show that testing is in a state of control, and to ensure that reagents are operating as expected, daily quality control should be performed on each reagent. 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 begin." The Anti-D blend ALBAclone manufacturer's 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..." Random review of 2018, 2019, 2020, and 2021 Rh QC and patient logs revealed the laboratory failed to document positive and negative control on 14 days between 1/25/20 and 4/21 /20 when approximately 164 patients were tested and reported: a. 1/25/20 - 21 patients tested; b. 1/28/20 - 12 patients tested; c. 1/29/20 - 6 patients tested; d. 1/30/20 - 3 patients tested; e. 1/31/20 - 14 patients tested; f. 3/10/20 - no positive control - 23 patients tested; g. 3/11/20 - no positive control -11 patients tested; h. 3/12/20 - no positive control - 5 patients tested; i. 3/13/20 - no positive control -7 patients tested; j. 3/14/20 - no positive control - 12 patients tested; k. 3/17/20 - no positive control - 13 patients tested; l. 3/18/20 - no positive control - 15 patients tested; m. 3/19/20 - no positive control - 9 patients tested; n. 4/21/20 - 13 patients tested.
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 laboratory's procedures, review of manufacturer's instructions, and review of 2018, 2019, 2020 and 2021 Temperature logs 5/5/21, the laboratory failed to ensure corrective action was taken when refrigerator readings were outside the acceptable limits. Findings: Review of the laboratory's " Policy and Procedure for Refrigerator and Room Temperature" states, "....Refrigerator temperature range should be between 2 degrees C(Celsius) - 8 degrees C(35 degrees F(Fahrenheit)- 46 degrees F)... A Temperature Control Log used to document the 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..." The Anti-D blend ALBAclone manufacturer's insert states under Storage, "The reagent should be stored at 2-8 degrees C." Review of Refrigerator Temperature logs where Anti-D reagents were stored revealed refrigerator temperatures were documented outside of acceptable limits of 2-8 degrees C with no corrective action for the following: a. 9 days in April 2019; b. 12 days in May 2019; c. 11 days in March 2020; d. 12 days in April 2020; e. 16 days in May 2020; f. 11 days in June 2020; g. 11 days in July 2020; h. 13 days in August 2020; i. 3 days for Fridge #1 and 10 days for Fridge #2 in September 2020; j. 4 days for Fridge #1 and 11 days for Fridge #2 in October 2020; k. 2 days for Fridge #1 and 5 days for Fridge #2 in November 2020; l. 5 days for Fridge #1 in December 2020; m. 2 days for Fridge #1 and 4 days for Fridge #2 in January 2021; n. 3 days for Fridge #1 and 3 days for Fridge #2 in February 2021; o. 4 days for Fridge #1 and 2 days for Fridge #2 in March 2021; p. 4 days for Fridge #2 in April 2021.

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 2018, 2019, 2020, and 2021 laboratory records 5/5/21, the laboratory director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action (See D6018). 2. The laboratory director failed to ensure quality control testing was performed and documented on each day patient testing was performed and failed to ensure the laboratory's QA program was established and maintained to identify and correct problems as they occurred (See D6022). 3. The laboraotry director failed to evaluate the testing personnel competency as required (See D6046). 4. The laboratory director failed ensure all testing personnel met the minimum education requirements for performing moderate complexity testing (See D6065).
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 procedures, review of 2018, 2019, 2020, and 2021 API(American Proficiency Institute) PT (proficiency testing) records, and absence of documentation 5/5/21, the laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Findings: The laboratory's Proficiency Testing procedure states, " When results come back, they should be reviewed, signed and dated by the lab director, then placed in the lab book." Review of 2018, 2019, 2020, and 2021 API PT records revealed the laboratory director failed to review, sign and date the PT results for the following test events: a. 2018 2nd Immunology/Immunohematology; b. 2018 3rd Immunology/Immunohematology; c. 2019 1st Immunology/Immunohematology; d. 2019 2nd Immunology /Immunohematology; e. 2020 2nd Immunology/Immunohematology; f. 2020 3rd Immunology/Immunohematology; g. 2021 1st Immunology/Immunohematology.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures and Quality Assurance checklist, review of laboratory records and the absence of QA (quality assurance) records 5/5/21, and the deficiencies cited at D5413 and D5445, the laboratory director failed to ensure Rh quality control testing was performed and documented on each day patient testing was performed and failed to ensure the laboratory's QA program was established and maintained to identify and correct problems as they occurred. Findings: The laboratory's "Quality Assurance" Procedure states, "Upon arrival all of the testing staff: 1. Everyday controls will be done and written on lab sheet before the start of every clinic(Rh(positive and negative), hematology, room/refrigerator temperature.)..... 5. At the end of each month clinic manager and lab consultant will complete quality assurance checklist and corrective action(if any) will be documented...6. Lab director will review monthly quality assurance checklist/corrective action (if any)and sign." Review of the monthly Quality Assurance checklist in the laboratory's procedure manual revealed the laboratory should review records for Personnel, Procedure manual, Quality Control, Patient Test Management, Proficiency Testing, Communications, and Quality Assurance Plan on a monthly basis. Review of the laboratory records 5/5/21 revealed there was no monthly QA checklist documentation with the laboratory director's review since the last survey in August 2018 to April 2021, a total of 32 months. The laboratory's QA program failed to identify and correct problems in Quality Control testing(See D5413, D5445).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, review of personnel records and absence of documentation 5/5/21, the technical consultant(laboratory director) failed to evaluate the competency of 2 of 6 TP(testing personnel #1 and #2). Findings: The laboratory's procedure "Policy for Clinical Laboratory Competency Testing" states, "Laboratory Competency testing will be performed by AWC 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 that TP#1 was hired on 6/9/20. There was no semiannual competency assessment completed for TP#1 during the first year of testing patient specimens. Review of personnel records revealed that TP#2 was hired on 10/4/19. There was no semiannual or annual competency assessment completed for TP#2 in 2020.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 5/5/21 and the deficiency cited at D6065, the laboratory failed to verify the minimum education requirements for performing moderate complexity testing. Findings: See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and laboratory records, absence of documentation, and interview with the clinic manager 5/5/21, the laboratory failed to verify that 4 of 6 TP(testing personnel) met the minimum education requirements for performing moderate complexity testing. Findings: Review of personnel records revealed TP#1 had a CMA(Certified Medical Assistant) certificate only and TP#3, TP#5, and TP#6 had no education documentation for review. Review of laboratory logs revealed that TP#1, TP#3, TP#5 and TP#6 had performed patient testing. Interview with the clinic manager at approximately 12:00 p.m.confirmed the education documentation for TP#1, TP#3, TP#5, and TP#6 was not on file.