Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2293787	06/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's Choice Of Danville	159 Executive Drive, Suite E, Danville, VA	

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
D0000	An announced CLIA Initial survey was conducted at A Woman's Choice of Danville on June 3, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400- 42 C.F.R. 493-1250 Condition: Analytic Systems. D6000- 42. C.F.R.493-1403 Moderate Complexity Laboratory Director.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the laboratory's policy and procedures (P&P), manufacturer's package insert, lack of documentation, daily patient testing log, and interviews, 1) The laboratory director failed to review and approve the P&P's provided for review during the survey on 06/03/24. Refer to D5407; the laboratory failed to 2) document positive and negative quality control (QC) materials for the Rh Anti-D testing each day of patient testing. Refer to D5449; and 3) document and monitor the refrigerator and room temperatures according to the manufacturer's instructions Refer to D5413.
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 the review of the laboratory's policy and procedures (P&P), lack of documentation, and interviews, the laboratory director failed to review and approve eight of eight P&P's provided for review during the survey on 06/03/24. Finding include: 1. Review of the laboratory's P&P revealed lack of documentation of review and approval by the laboratory director for the following: "Medical Staff Laboratory Duties, HCG Urine Pregnancy, Rh Testing Policy and Procedure, Blood Collection Technique, Quality Assurance, Proficiency Testing, Room and Refrigerator Temperatures, and Clinical Laboratory Competency Testing. " 2. An interview with the senior clinical manager on 06/03/2024 at 10:30 AM revealed the laboratory began Rh- Anti D typing patient testing on 02/29/24. 3. An exit interview with the senior clinical manager on 06/03/2024 at 11:25 AM confirmed the findings. A phone conference with the laboratory director on 06/03/2024 at 11:50 AM confirmed the findings.
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 the review of the manufacturer's package insert, laboratory's policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to document and monitor the refrigerator and room temperatures according to the manufacturer's instructions from 02/29/24 up to the date of survey on 06/03/24. Finding include: 1. Review of the ALBAclone Anti-D Blend reagent package insert revealed instructions for storage of reagent at 2-8 degrees Celsius. In addition, the package insert provided instructions for performing the slide technique to include "incubate the test for 5 minutes at 18-24 degrees Celsius." 2. Review of the laboratory's P&P revealed a "Policy and Procedure for Refrigerator and Room Temperature" providing instructions for monitoring and documenting the refrigerator and room temperatures (lacked documentation of approval by the laboratory director). Refer to D5407. 3. The surveyor requested to review the refrigerator and room temperature logs from 02/29/24 up to the date of survey on 06/03/24. The logs were not available for review. In an interview with the senior clinical manager on 06/03 /2024 at 10:30 AM, they stated, "We don't have the logs today. The original clinical manager failed to implement the logs." 4. An exit interview with the senior clinical manager on 06/03/2024 at 11:25 AM confirmed the findings. A phone conference with the laboratory director on 06/03/2024 at 11:50 AM confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedures (P&P), lack of documentation, daily patient testing logs, and interviews, the laboratory failed to document positive and negative quality control (QC) materials for the Rh Anti-D testing each day of patient testing from 02/29/24 up to the date of survey on 06/03/24, resulting 451 patients. Findings include: 1. Review of the P&P, "Rh Testing Policy and Procedure" (lacked documentation of approval by the laboratory director, Refer to D5407), revealed to following statements, "Testing Anti-D is a daily process. Make sure after testing the Anti-D with the controls, results are place on the lab sheet before clinic begins." 2. The surveyor requested to review the documentation of the daily positive and negative QC materials for the Rh Anti-D typing. In an interview with the senior clinical manager on 06/03/2024 at 10:30 AM, they stated, "We don't have the logs today. The original clinical manager failed to implement the logs." 3. Review of daily patient testing logs revealed 451 patients were resulted between 02/29/24 up to the date of survey on 06/03/24. 4. An exit interview with the senior clinical manager on 06/03/2024 at 11:25 AM confirmed the findings. A phone conference with the laboratory director on 06/03/2024 at 11:50 AM confirmed the findings.
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 the review of the laboratory's policy and procedures (P&P), manufacturer's package insert, lack of documentation, daily patient testing log, and interviews, the laboratory director failed to provide analytical oversight of the Rh Anti-D typing test platform from 02/29/24 up to the date of survey on 06/03/24. Refer to D6020.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's package insert, laboratory's policy and

	procedures (P&P), daily patient testing logs, lack of documentation, and interviews, the laboratory director failed to ensure 1) the documentation of positive and negative quality control (QC) materials for the Rh Anti-D testing each day of patient testing. Refer to D5449; and 2) ensure the documentation and monitoring of the refrigerator and room temperatures according to the manufacturer's instructions. Refer to D5413.