Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0938247	11/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's Choice Of Raleigh	3305 Drake Circle, Raleigh, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory records, absence of records and interview with clinic manager 11/08/24, the laboratory failed to establish a policy for technical consultant (TC) competency assessment and also failed to assess the competency of the TC in 2022, 2023 and 2024, a period of approximately 3 years. Findings: Review of laboratory records revealed no documentation of a policy TC competency assessment. Review of laboratory records revealed a statement on facility letterhead, "I have reviewed the competencies for AWR Technical Consultant (name entered) for 2021, that have been performed.". The statement was signed by the previous laboratory director. There was no documentation of a policy for the performance of TC competency. There was no documentation of TC competency assessments in 2022, 2023 and 2024. During exit interview at approximately 12:30 p.m., the clinical manager confirmed there was not a specific policy for performing TC competency. She also confirmed there was no documentation of TC competency assessments in 2022, 2023 and 2024.
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 procedure, review of 2023 and 2024 laboratory room temperature logs and review of 2024 "Consultation Lab Sheets" 11/08/24, the laboratory defined the correct room temperature range for the laboratory but failed to ensure the defined room temperature range was correct on the room temperature logs and the "Consultation Lab Sheets". Findings: Review of laboratory procedure "Policy and Procedure for Refrigerator and Room Temperature" revealed "Lab Room temperature range should be between 20C-31C (68F-87F)". Review of 2023 and 2024 laboratory room temperature logs revealed a room temperature range of "18C - 24C". Review of 2024 "Consultation Lab Sheets" revealed a room temperature range of "18C - 24C".
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 laboratory records and interview with clinical manager 11/08/24, the laboratory director (LD) failed to review and sign their approval of the laboratory procedure manual prior to assuming the position of LD in March of 2023. Findings: Review of laboratory records revealed a facility letterhead stating "AWC Lab Director will review and sign the Policy and Procedure Manual yearly or as new Policies are put in place throughout the year.". The form was signed by the previous LD 07/31/21. It was also signed by the current LD 08/21/24, approximately 17 months after assuming the position of LD. During exit interview at approximately 12:30 p.m., the clinical manager confirmed there was no documentation the LD reviewed and signed their approval of the laboratory procedure manual prior to assuming the position of LD in March of 2023. .
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with clinic manager 11/08/24, the laboratory director (LD) failed to specify in writing the duties delegated to the technical consultant (TC) when they assumed the position of LD in March of 2023. Findings: Review of laboratory records revealed a signed statement from the previous LD in which competency assessments were delegated to the TC in 2019. There was no documentation of the duties delegated to the TC by the current LD. During exit interview at approximately 12:30 p.m., the general manager confirmed there was no documentation of the duties delegated to the TC by the current LD.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records and review of 2023 and 2024 testing personnel (TP) competency records, the technical consultant (TC) failed to ensure TP either participated in external PT, internal blind testing of samples or testing of previously analyzed specimens each year as part of their annual competency assessment. Findings: Review of 2023 and 2024 API PT records revealed the following: a. TP #1 participated in the second PT event of 2023, there was no documentation of participation in 2024. b. TP #2 participated in the first PT event of 2024, there was no documentation of participation in 2023. c. TP #3, no documentation of PT participation in 2023 or 2024. d. TP #4, no documentation of PT participation in 2023 or 2024. Review of 2023 and 2024 TP competency records revealed the no documentation of internal blind testing or testing of previously analyzed specimens for the following TP: a. TP #1, no documentation in 2024. b. TP #2, no documentation in 2023. c. TP #3, no documentation in 2023 or 2024. d. TP #4, no documentation in 2023 or 2024.