Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128596	06/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Alliance	4100 Duval Road Building 2, Suite 201, Austin, TX	

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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found a CFR 42 493.1 through 493.1780: 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Review of Immunohematology proficiency testing records for 2022 and interview of facility personnel found the laboratory failed to ensure that proficiency testing results were reviewed and evaluated for one of one testing events. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2022 found no documentation of the review of the 2022 Immunology /Immunohematology 1st event. The performance Review page had no date of review or signature of reviewer. 3. Interview of testing person one on the CMS Laboratory Personnel Report conducted June 21, 2022 at 10:37 AM confirmed the laboratory did not evaluate results in this event stating she assumed that they did not have to be reviewed if they did not fail the event.
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: Review of Immunohematology proficiency testing records for 2022 and interview of facility personnel found the laboratory director failed to ensure that proficiency testing results were reviewed and evaluated for one of one testing events. (See D 6018)
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: Review of personnel files and interview of facility personnel found the laboratory director failed to ensure that all testing personnel had received the appropriate training prior to testing patient specimens. (See D 6066)
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: Review of laboratory records and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties of five of five testing personnel. The findings included: 1. Review of laboratory records found no written delegation of duties for testing personnel. 2. Interview of testing person one on the CMS report 209 Laboratory Personnel report confirmed during interview conducted June 21, 2022 at 10:02 AM that there was no written delegation of duties for testing personnel available for review.
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 a review of the Laboratory Personnel Report, policies and procedures, personnel records and staff interview, it was revealed that one of five testing personnel did not have the appropriate documented training required to perform moderate complexity testing using the Eldon Doctor's Kit DKS RhD test kit. (see D6066).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report, policies and procedures, personnel records and staff interview, it was revealed that one of five testing personnel did not have the appropriate documented training required to perform moderate complexity testing using the Eldon Doctor's Kit DKS RhD test kit. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory designated five testing personnel performing non-waived testing. 2. Review of training records found no documentation of training for use of the Eldon Doctor's Kit DKS RhD test kit for testing person one (designated as primary trainer). 3. Interview of testing person one conducted June 21, 2022 at 10:11 AM confirmed there was no documentation of training for her using the Eldon Doctor's Kit DKS RhD test kit.