Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0883911	06/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Alexandria	2839 Duke Street, Building 3, Alexandria, 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 Whole Woman's Health & Family Center on June 28, 2022 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 and include two (2) Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6063 -42 CFR. 493.1421 Condition Testing Personnel.
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the facility's Blood Bank Rh Factor proficiency testing (PT) documentation, and interviews, the laboratory failed to submit PT testing results to American Proficiency Testing Institute (API) for one (1) of 1 event reviewed for 2022. Findings include: 1. Review of the laboratory's API immunohematology PT documentation revealed that the laboratory failed to return their first enrolled event of calendar year 2022. API report stated "Test results were not received by American Proficiency Institute". The inspector inquired regarding the PT report outlined above. The office manager stated on 6/28/22 at approximately 2:00 PM, "We did not send the results in for grading. The staff did not refrigerate the samples and thought that they had set out too long before the error was noted." The inspector requested to review corrective action of self grading for the five (5) Rh Factor proficiency testing challenges. No documentation was available for review. 2. An exit interview with the facility manager on 6/28/22 at approximately 2:30 PM confirmed the above findings.
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 a tour, review of the facility's laboratory test logs, quality assurance policy, and an interview, the laboratory failed to document quality control for Anti-D Rh tests on fifteen of forty-four days of patient testing during the four months reviewed (timeframe: February 2022 to June 28, 2022). See D5449.
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 a tour, review of the facility's laboratory test logs, quality assurance (QA) policy, and an interview, the laboratory failed to document Anti-D Rh quality control (QC) on fifteen (15) of forty-four (44) days of patient testing during the four (4) months reviewed (timeframe: February 2022 to June 28, 2022). Findings include: 1. During a tour of the facility's laboratory testing area, the inspector noted moderate complexity Doctor's Kit DKS RhD with Eldoncard Rhesus Factor and RhD quality control (QC) kits stored and in use for RhD antigen detection. 2. Review of the facility's patient laboratory test logs from February 2022 to the date of the survey on 6 /28/22 revealed 44 days of testing utilizing the Eldoncard Rhesus Factor RhD kits outlined above. The inspector noted the following 15 days with no QC documentation and number of patients tested: 3/04/22- three (3) 3/08/22 - 3 3/11/22 - four (4) 3/12/22 - 3 3/15/22 - one (1) 3/18/22 - two (2) 3/22/22- 3 3/26/22 - 3 3/28/22 - 1 3/29/22 - 1 4 /04/22 - 2 4/05/22 - 3 4/08/22 - 3 4/09/22 - 4 4/16/22 - 2 A total of 15 days with no QC documentation while reporting thirty-eight (38) patient Anti-D Rh results. The inspector requested to review the QC documentation on the dates of patient testing outlined above. No documentation was available for review. 3. Review of the laboratory's QA policies revealed a QC protocol that stated "Rh controls are to be documented daily before any client sample testing is done." 4. An exit interview with the facility manager on 6/28/22 at approximately 2:30 PM confirmed the above findings.
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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for four of six testing personnel responsible for reporting moderate complexity RhD antigen patient test results during the review timeframe of February 2022 to the date of the initial inspection on June 28, 2022. 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, and interviews, the laboratory director (LD) failed to retain documentation of education qualifications for four (4) of six (6) testing personnel (TP) from February 2022 to the date of the initial inspection, on June 28, 2022. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed 6 TP listed as qualified to perform moderate complexity RhD antigen patient immunohematology testing. 2. Review of the available laboratory personnel records for evaluation of education documentation revealed: TP A and TP B - no records of education; TP C and TP D - foreign diplomas for secondary level (Ethiopia). (See Personnel Code Sheet.) The inspector requested to review the documentation of education for TP A, B and for US education equivalency records for TP C and D. The records were not available for review. 3. An exit interview with the facility manager on 6/28/22 at approximately 2:30 PM and a follow up email interview on 6/30/22 at approximately 9:45 AM confirmed the above findings.