

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0883911	<b>(X3) Date Survey Completed</b>  01/17/2024
<b>Name of Provider or Supplier</b>  Whole Woman's Health Alexandria	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>An announced CLIA recertification survey was conducted at Whole Woman's Health Alexandria on January 17, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA CONDITION Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems; D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity, Laboratory Director, and D6063 - 42 C.F.R. 493-1421 Condition: Moderate Complexity, Testing Personnel. Specific deficiencies cited are as follows:</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, lack of documentation, and an interview, the laboratory failed to retain PT result reviews and attestation statements signed by the laboratory director (LD) and testing personnel (TP) for two (2) of five (5) Immunology/Immunochemistry D (rho) events during the eighteen months reviewed from July 2022 until the date of the survey on January 17, 2024. The findings include: 1. Review of the laboratory's American Proficiency Institute (API)</p>

PT documentation revealed no PT results and signed attestation statements for the following two events: 2022 API Immunology/Immunochemistry-2nd Event-D (Rho) -a lack of result review or attestation signatures for LD and TP; 2022 API Immunology /Immunochemistry-3rd Event-D (Rho)-a lack of result review or attestation signatures for LD and TP. The surveyor requested to review the PT results review and attestation documentation for the events listed above. The laboratory provided no documentation for review. 2. In an exit interview with the Interim Director and Clinic Manager on January 17, 2024, at approximately 12:00 PM, the above findings were confirmed.

**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 laboratory tour, review of the laboratory's policies and procedures, quality control (QC) and quality assurance records, July 2022 plan of correction, lack of documentation and interviews, the laboratory failed to: 1. follow their established policy to perform and document QC for D (Rho) typing each day of patient testing (See D5449) REPEAT DEFICIENCY; 2. follow their quality assurance plan and July 29, 2022 plan of correction.

**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:  
**\*\*REPEAT DEFICIENCY \*\*** Based on a laboratory tour, review of the laboratory's policies and procedures, "Daily Laboratory Log Sheet", quality assurance (QA) policy, and an interview, the laboratory failed follow their established policy to perform and document quality control (QC) for D (Rho) testing on three (3) days of patient testing in the eighteen months reviewed from July 2022 until the survey on January 17, 2024. The findings include: 1. During a tour of the facility's laboratory testing area, the surveyor noted moderate complexity Doctor's Kit DKS RhD with Eldoncard Rhesus Factor and Immunocor Panoscreen quality control (QC) kits stored and in use for D (Rho) typing. 2. Review of the laboratory's "Daily Laboratory Log Sheets" from July 2022 until the date of the survey on January 17, 2024 revealed the following 3 days with no QC documentation and number of patients tested: 02/18 /2023-1 patient tested; 08/04/2023-2 patients tested; 08/24/2023-1 patient tested. A total of 3 days with no QC documentation while reporting 4 patient D (Rho) typing

results. The surveyor requested to review the QC documentation for the above listed dates. The laboratory provided not documentation for review. 3. Review of the laboratory's QA policies revealed a QC protocol that stated "Quality control samples must be analyzed each day patient specimens are analyzed. The assay results of the quality control specimens must be recorded on the Daily Laboratory Log Sheet." 4. In an exit interview with the Interim Director and Clinic Manager on January 17, 2024, at approximately 12:00 PM, the above findings were confirmed.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policies and procedures, the plan of corrections (POC) submitted on 07/29/2022, available quality assurance (QA) documents, lack of documentation, and interviews, the laboratory failed to follow the quality assurance plan defined in the policies and the POC submitted on 07/29/2022 for sixteen (16) of the eighteen (18) months reviewed from July 2022 until December 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance", with the following statements: "QUALITY CONTROL TESTING-"Quality control samples must be analyzed each day of patient specimens are analyzed." (See D5449 and D6020.) "PROFICIENCY TESTING-Survey summaries of laboratory performance are returned to the clinic by the proficiency testing agency for evaluation. The laboratory director must review the survey report and date and initial it to document that such review took place." (See D2015 and 6018.) QUALITY ASSURANCE MONITORING-The quality assurance program monitors and evaluates the overall quality of the laboratory testing personnel at Whole Woman's Health in the following ways: 1. Whole Woman's Health has Quality Assurance Committee which meets quarterly. The committee is comprised of the Laboratory Director, the Executive Administrator and the Nurse Supervisor. 2. The Quality Assurance Committee is responsible for...C. Proficiency Testing... Reviewing the proficiency testing results. D. Assuring the adequacy and competency of the testing staff through-Hiring and personnel policies that include: 1. Hiring appropriately trained and certified personnel... 3. All Quality Assurance Committee meetings and actions are documented in minutes and memos. A. Minutes and Memos of the Quality Assurance Committee meetings are available and kept on file in the Nurse Supervisor's office." (See D6021.) 2. Review of the POC submitted on 07/29 /2022 revealed the following statements, " D2159 The Clinic Manager is responsible for ensuring that laboratory proficiency testing is stored correctly once received. The Laboratory Director is responsible for monitoring ongoing compliance, including review of laboratory proficiency testing on a quarterly basis...D5449 The Clinic Manager and Laboratory Director are responsible for monitoring ongoing compliance for daily laboratory controls for each day patient specimens are tested with the Clinic Manager reviewing the Daily Laboratory Log on a weekly basis and Laboratory Director on a quarterly basis. If no controls are made available due to manufacturer backorder or shipment delay, no patient testing may be performed on site....D6065 To ensure on going compliance, the Clinic Manager will complete a monthly staff file audit and submit documentation of completion of audit to the Associate Director of

Clinical Services monthly." 3. Review of the laboratory's records revealed a lack of documentation of the following: Quarterly Quality Assurance Committees meeting's minutes from July 2022 until November 2023. (A quarterly meeting was held on 11/17 /2023); Quarterly proficiency testing (PT) review from July 2022 until December 2023; Quarterly daily quality control review by the Laboratory Director from July 2022 until December 2023; Monthly staff file audit from July 2022 until December 2023. The surveyor requested to review the above listed quality assurance documents. The laboratory provided no documentation to review. 4. In an exit interview with the Interim Director and Clinic Manager on January 17, 2024, at approximately 12:00 PM, the above findings were confirmed.

**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 a laboratory tour, review of the laboratory's policies and procedures, quality control (QC) and quality assurance records, July 2022 plan of correction, lack of documentation and interviews, the laboratory director failed to: 1. follow the laboratory's established policy to document review of the laboratory's performance in proficiency testing events (See D6018); 2. ensure the July 2022 plan of correction and established QC policies were followed (See D6020); 3. ensure the laboratory's Quality Assurance policy was followed (See D6021).

**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 a review the laboratory's policies and procedures, proficiency testing (PT) documentation and an interview, the laboratory director (LD) failed follow the laboratory's established policy to document review of the laboratory's performance in Immunology/Immunochemistry PT events for two (2) of five (5) events from July 2022 until the date of the survey on January 17, 2024. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation revealed a lack of documentation of the PT results review for the following two events: 2022 API Immunology/Immunochemistry-2nd Event-no results reviewed by the LD, 2022 API Immunology/Immunochemistry-3rd Event-no results reviewed by the LD. The surveyor requested to review the PT results review for the above listed events. The laboratory provided no documentation for review. 2. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance", with the following

	<p>statements, "PROFICIENCY TESTING-Survey summaries of laboratory performance are returned to the clinic by the proficiency testing agency for evaluation. The laboratory director must review the survey report and date and initial it to document that such review took place." (See D2015.) 3. In an exit interview with the Interim Director and Clinic Manager on January 17, 2024, at approximately 12:00 PM, the above findings were confirmed.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) documentation, plan of correction (dated 7/29/2022), daily logs, lack of documentation, and interview, the Laboratory Director failed to ensure the July 2022 plan of correction and established QC policy to perform QC each day of patient testing were maintained for D (Rho) testing for three days from July 2022 until the date of the survey on January 17, 2024 (see D5449 <b>**REPEAT DEFICIENCY**</b>).</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Quality Control (QC) records, Quality Assurance (QA) records, July 2022 plan of correction and interviews, the Laboratory Director failed to ensure the July 2022 plan of correction and established QA policy was followed and maintained from July 2022 until the date of the survey on January 2024 (See D5791, D6020 and D6065).</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

**\*\*REPEAT DEFICIENCY\*\*** Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one (1) of two (2) new testing personnel responsible for reporting D (Rho) blood typing from July 2022 until the date of the survey on January 17, 2024 (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:

**\*\*REPEAT DEFICIENCY\*\*** Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one (1) of two (2) new testing personnel responsible for reporting D (Rho) blood typing from July 2022 until the date of the survey on January 17, 2024 (See Personnel Code Sheet). The findings include: 1. Review of the CMS 209 form revealed the laboratory director identified two new testing personnel (TP), that included TP A, as responsible for patient D (Rho) typing from July 2022 until the date of the survey on January 17, 2024. 2. Review of the available personnel documents for TP A revealed no education documentation. Review of the laboratory personnel records revealed TP A was hired on 07/11/2023 and initial training and sign off for patient testing was verified/signed by the technical consultant (laboratory director) on 11/17/2023. The surveyor requested to review education records for TP A. The laboratory provided no education documentation for review. 3. In an exit interview with the Interim Director and Clinic Manager on January 17, 2024, at approximately 12:00 PM, the above findings were confirmed.