Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0883911	**(X3) Date Survey Completed** 05/21/2024
Name of Provider or Supplier Whole Woman's Health Alexandria	**Street Address, City, State** 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 off-site CLIA proficiency testing desk review of Whole Woman's Health Alexandria was completed on May 21, 2024 by a Medical Facilities Inspector of 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 found not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation. D6000 - 42 C.F.R. 493.1403 Condition-Laboratories performing moderate complexity testing: Laboratory Director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and American Proficiency Institute (API) records for 2023 (Events one, two and three), and 2024 (Event one), the laboratory failed to successfully participate in a proficiency testing program approved by Health and Human Services (HHS) for the Immunohematology subspecialty of ABO Group and D (RHO) typing and the analyte D (RHO). Refer to D2162 and D2163.
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and American Proficiency Institute (API) evaluation reports for 2023 (Events one, two and three), and 2024 (Event one), the laboratory failed to achieve satisfactory performance (100%) for the analyte D (RHO) for three of four events reviewed. The laboratory had unsatisfactory scores for D (RHO) for 2023 Event one (1), 2023 Event two (2), and 2024 Event one (1) resulting in non-initial unsuccessful participation. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2023 Event 1: D (RHO) = 0%, 2023 Event 2: D (RHO) = 0%, 2024 Event 1: D (RHO) = 80%. 2. A review of the laboratory's 2023 and 2024 API PT scores for the analyte D (RHO) confirmed the above findings resulting in non-initial unsuccessful participation for the analyte D (RHO).
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and American Proficiency Institute (API) evaluation reports for 2023 (Events one, two and three), and 2024 (Event one), the laboratory failed to achieve satisfactory performance (100%) for the Immunohematology subspecialty of ABO Group and D (RHO) typing for three of four events reviewed. The laboratory had unsatisfactory scores for ABO Group and D (RHO) typing for 2023 Event one (1), 2023 Event two (2) and 2024 Event one (1) resulting in non-initial unsuccessful participation. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2023 Event 1: ABO/RHO = 0%, 2023 Event 2: ABO/RHO = 0%, 2024 Event 1: ABO /RHO = 80%. 2. A review of the laboratory's 2023 and 2024 API PT scores for the subspecialty ABO Group and D (RHO) typing confirmed the above findings resulting in non-initial unsuccessful participation for the Immunohematology subspecialty ABO Group and D (RHO) typing.

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 proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and the American Proficiency Institute (API) 2023 (Events one, two and three), and 2024 (Event 1) result reports, the laboratory director failed to provide overall management and direction of laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and American Proficiency Institute (API) 2023 (Events one, two and three), and 2024 (Event 1) result reports, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program for the Immunohematology subspecialty ABO Group and D (RHO) typing and the analyte D (Rho) for three of four events. Refer to D2162 and D2163.