Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0883911	09/28/2023
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 unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Whole Woman's Health Alexandria on September 28, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation, D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity, Laboratory Director. Specific deficiencies cited are as follows.
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 an off-site Proficiency Testing (PT) desk review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2023, the CASPER 0153D Unsatisfactory and Unsuccessful PT Report and interview, the laboratory failed to participate in API D (Rho) proficiency testing for two (2) of 2 consecutive testing events in 2023 resulting in unsuccessful performance (Refer to D2162).
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 an off-site Proficiency Testing desk review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, CASPER 0153D Unsatisfactory and Unsuccessful PT Report and interview, the laboratory failed to submit PT testing results to API within the specified time frame for D (Rho) Type testing in two (2) of 2 events for 2023 resulting in unsuccessful performance. The findings include: 1. Review of the laboratory's 2023 API Immunohematology PT records for Events 1 and 2 (a total of 2 events) revealed the laboratory failed to return results for API 2023 D (Rho) Type Events 1 and 2. The API report stated "0% Failure to Participate" for Events 1 and 2. 2. Review of the laboratory's CASPER Report 0153D revealed the following 2023 Rh events with results of less than 100%: 2023 Event 1 Rh = 0%, 2023 Event 2 Rh = 0%, resulting in unsuccessful performance. 3. In a telephone interview with the clinical manager on September 28, 2023, at approximately 9:35 AM, the findings were confirmed. The clinical manager stated they were informed by the testing personnel they received the wrong samples for testing and that they were going to contact API to order the correct ones.
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 review of the laboratory's plan of correction (POC) submitted on July 29, 2022, Proficiency Testing (PT) record review, and interview, the laboratory director failed to follow the submitted POC and ensure Rho PT results were submitted to the American Proficiency Institute by the testing deadline (See D2162 and D6017).
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on an off-site review of the laboratory's Plan of Correction (POC) (submitted on July 29, 2022), American Proficiency Institute (API) proficiency testing (PT) records, the CASPER 0153D Unsatisfactory and Unsuccessful PT Report and interview, the laboratory director failed to follow the submitted POC and ensure PT testing results were submitted to API within the specified time frame for D (Rho) Type testing for two (2) of 2 consecutive events in 2023 (see D2159). The findings include: 1. Review of the laboratory's POC revealed the following statements, "The Laboratory Director will complete a staff inservice with the Clinic Manager and all laboratory personnel on Monday July 25, 2022 and review proper laboratory proficiency testing sample storage and how to complete testing. 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." 2. Review of the laboratory's 2023 API Immunohematology PT records for Events 1 and 2 (a total of 2 events) revealed the laboratory failed to return results for API 2023 D (Rho) Type Events 1 and 2 . The API report stated "0% Failure to Participate" for Events 1 and 2. 3. In a telephone interview with the clinical manager on September 28, 2023, at approximately 9:35 AM, the findings were confirmed. The clinical manager stated they were informed by the testing personnel they received the wrong samples for testing and that they were going to contact API to order the correct ones.