Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715437	02/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Care-Clinics For Abortion & Reproductive Excellenc	10401 Old Georgetown Road Suite 104, Bethesda, MD	

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
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 review of the federal report for unsuccessful proficiency testing (PT) results and review of the comparative evaluation report from American Proficiency Institute (API), the laboratory failed to successfully participate in the API PT program for immunohematology testing, in which the laboratory is certified under CLIA (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 review of the federal report for unsuccessful proficiency testing (PT) results and review of the comparative evaluation report from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the same analyte in two out of three consecutive testing events. 1. Failure to attain a score of at least 100% of acceptable responses for D (Rh) typing is unsatisfactory performance. 2. The laboratory received the following scores from API for D (Rh) typing: a. 80% in the 2022 3rd PT event b. 60% in the 2022 1st PT event
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 federal report for unsuccessful proficiency testing (PT) results and review of the comparative evaluation report from American Proficiency Institute (API), the laboratory director failed to ensure an approved corrective action plan was followed when immunohematology PT results were found to be unsatisfactory (D6019).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the federal report for unsuccessful proficiency testing (PT) results and review of the comparative evaluation report from American Proficiency Institute (API), the laboratory director failed to ensure that an approved corrective action plan was followed when immunohematology PT results were found to be unsatisfactory in the 2022 1st PT event. Findings: 1. The laboratory failed to achieve satisfactory performance for D (Rh) typing in two out of three consecutive PT events (cross-refer to tag D2162): a. 80% in the 2022 3rd PT event b. 60% in the 2022 1st PT event