Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715437	04/28/2022
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with Testing Person One, the afternoon of the day of survey, the laboratory did not have procedures to ensure testing of Rh proficiency test samples was performed by additional staff only after the results were reported to the proficiency test provider. Findings: 1. Proficiency test records show that Rh testing was performed by two testing persons April 13, 2022 (first test event 2022) and December 8, 2021 (third test event of 2021), the samples were tested by two different people and there was no documentation and no policy to show that the testing performed by the second person was performed after the results were already submitted to the proficiency test provider; and 2. This was confirmed with Testing Person One during the survey exit.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with Testing Person One on the afternoon of the day of survey, the laboratory did not maintain a record of each specimen tested by the laboratory and did not have records of the director review of

	the proficiency test providers evaluation and the test providers scores for each sample tested for Rh testing. Findings: 1. The laboratory director did not document review for individual test scores of events 1, 2 and 3 of 2021 and event 3 of 2020 (the lab failed to participate with this event); 2. The laboratory did not maintain a record showing each test score for each sample tested for events 1, 2 and 3 of 2021; and 3. This was confirmed with Testing Person One at the survey exit.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory written procedure and interview with Testing Person One on the afternoon of the day of survey, the procedure did not include instructions to positively identify the patient at the time of blood collection for Rh testing. Findings: 1. The written procedure did not state how the phlebotomist identifies the patient prior to collection of blood for Rh testing; and 2. This was confirmed with Testing Person One during survey exit.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of testing records and interview with Testing Person One on the afternoon of the survey, the laboratory director did not document corrective actions taken when Rh quality control testing was not performed November 8, 9 and 11, 2021. Findings: 1. The laboratory performs positive and negative quality control

	checks for the anti-D reagent each day of patient testing; 2. During the days of November 8, 9 and 11, 2021, the laboratory was using a card test to perform Rh testing; 3. There was no record that quality control testing was performed for these days in November and there was no written corrective action showing a review of patient test results and retesting if needed and there was no retraining of testing staff documented; 4. On November 11, 2021 one patient was tested; on November 9, 2021, 3 patients were tested and on November 8, 2021, five patients were tested; and 4. This was confirmed with Testing Person One during survey exit.