Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715437	09/26/2019
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
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 record review and interview, the laboratory (lab) did not monitor and evaluate quality control testing for Rh testing. The lab failed to ensure that quality control test results met the laboratory's criteria for acceptability prior to reporting patient test results for Rh testing (refer to D5481 for findings); the lab failed to ensure that corrective action procedures were established and maintained and adequately document corrective actions after identifying problems in the interpretation of the serum control results for the Rh positive quality control red cell testing (refer to D5783 for findings).
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 record review and interview with laboratory (lab) staff, the lab's written procedure did not include instructions to positively identify the positive and negative quality control samples. Findings: 1. The lab used whole blood collected from staff as positive and negative controls for the Rh test performed on patient samples; 2. The procedure for identifying the control samples did not include an identifier or code showing that the control samples in use (positive and negative) were collected from specific staff members who had an Rh type on record; 3. This was confirmed during interview with staff on the day of survey; and 4. The written procedures did not have instructions to use the date of collection and an identifier (see cite 2 above) to assign the positive and negative control samples a lot number that uniquely identifies the controls.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not document the lot number and expiration date of the positive and negative Rh quality control samples on the testing worksheet. Findings: 1. The lab collects blood from staff members to use as positive and negative controls for the Rh test; 2. The lab did not document the lot number (a unique identifier for each control [positive and negative] that can be related to the date the specimen was collected and the person the blood was collected from) on the Rh test log and did not document the expiration date of the positive and negative quality control samples on the test log; and 3. This was confirmed during interview with staff on the day of survey.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) did not ensure that quality control test results met the laboratory's criteria for acceptability prior to reporting patient test results for Rh testing. Findings: 1. Rh testing procedures instruct the lab to test a serum control alongside every Rh test, both patient and control. The serum control is performed to check for false positive test results (the serum control contains everything that the anti-D reagent contains, except for the anti-D). A positive serum control means a false positive reaction in the Anti-D (Rh) test that requires further investigation; 2. The lab did not investigate why the serum control for the positive red blood cell control was interpreted as positive (instead of negative as expected) on the test log at the time of testing, and the lab did not investigate this same problem during monthly reviews of Rh testing records; 3. On September 30, 11, 10, 9, 8, 5, 3 and 2, 2018; 9 of 13 serum control results (positive control) were interpreted and documented as positive; 4. On August 28, 27, 26, 22, 20, 19, 15, 14, 13, 12, 8, 5 and 4, 2018; 13 of 13 serum control results (positive control) were interpreted and documented as positive; 5. On July 29, 25, 23, 22, 18, 17, 16 10, 9, 8 and 6, 2018, 11 of 11 serum control results (positive control) were interpreted and documented as positive; 6. On June 28, 27, 26, 25, 24, 17, 11, 10, 9, 6, 5, 4 and 3, 2018; 13 of 13 serum control results (positive control) were interpreted and documented as positive; 7. The reporting of positive results for the serum control for the Rh positive control red cells continued as far back as January 2018 and was not immediately identified as a quality control failure by staff or upon quality assurance reviews of testing records or through competency check reviews that involve observation of staff performing quality control tests and reporting of those results; 8. On October 16 and 9, 2018, 2 days of 12 days of testing, quality control test results for the Rh test were not performed and recorded on the Rh testing records; and 9. In December 2017, the lab did not document positive and negative quality control test results for 8 of 8 days of testing (December 19, 18, 17, 11 10, 5, 4, 3, 2017).
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director did not ensure that corrective action procedures were established and maintained and well documented to ensure accurate and reliable patient testing. Findings: 1. Rh testing procedures instruct the lab to test a serum control alongside every Rh test, both patient and control. The serum control is performed to check for false positive test results as it is a solution that the anti-D is suspended in, but not containing anti-D. A positive serum control means a false positive reaction in the Anti-D (Rh) test requiring further investigation; 2. The lab did not immediately investigate the positive interpretation of the serum control performed for the positive control red cells, the lab did not identify this problem and investigate in a timely manner through monthly reviews of Rh testing records; 3. From October 30, 2018 going back to January 2018, testing staff routinely

	recorded the serum control for the Anti-D test on the positive quality control red cells as positive. See D5481 for findings; 4. The lab director did not take corrective actions in a timely manner and allowed the problem to continue for 10 months before identification and correction; 5. The laboratory identified the problem in October 2018 and conducted retraining for lab staff, The lab did not maintain detailed minutes of the retraining and did not have records showing competency or follow up assessments of staff to ensure staff understood the principle behind the Rh test and all related procedures (as described during interview with staff on the day of survey); 6. The laboratory did not document direct observations of staff performing and documenting test results to ensure procedures were followed; and 7. The lab did not have documentation to show staff passed a knowledge skills evaluation for the Rh testing.
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 record review and interview, the laboratory director did not provide adequate direction for Rh testing to ensure that it is conducted in an accurate and reliable manner; The director failed to establish and maintain quality control procedures and quality assurance procedures (see D6022); The lab director failed to ensure that staff training and competency review checks ensured testing personnel understood and interpreted test reactions in an accurate and reliable manner (see D6029 and D6030).
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 record review, the laboratory (lab) director did not ensure that quality control and quality assurance procedures were established and maintained to ensure accurate and reliable patient testing. Findings: 1. Rh testing procedures instruct the lab to test a serum control alongside every Rh test, both patient and quality control tests. The serum control is performed to check for false positive test results, in addition to testing the patient or control cells with anti-D reagent, the lab also tests the patient or control cells with a solution containing everything in the anti-D reagent except for the anti-D, therefore a positive serum control means something in the serum control reacted to cause a false positive reaction; 2. From October 30, 2018 going back to January 2018, testing staff routinely recorded the serum control for the Anti-D as positive (instead of negative as expected), for the positive control red cells. See D5481 for findings; 3. The lab director did not ensure that quality control procedures

	were observed and interpreted by staff according to lab procedures; and 4. The lab director's performance of quality assurance activities, such as record review, competency evaluations and training of staff for the Rh test did not identify errors in Rh quality control testing in a timely manner, as incorrect results were reported for 10 months.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review, the laboratory (lab) director did not ensure that lab staff were properly trained to observe, interpret and report test results for Rh controls. Findings: 1. Written procedures for the Rh test, instruct lab staff to test a serum control alongside of every Rh test. The serum control is performed to check for false positive test results and is a solution containing everything the anti-D reagent contains, except for anti-D, if the serum control is positive, a false positive reaction has occurred and the test is invalid; 2. From October 30, 2018 going back to January 2018, testing staff routinely recorded the serum control for the Anti-D positive control check as positive. See D5481 for findings; 3. In January 2018, the lab records show that a card test in use for Rh testing was replaced with a slide test. The card test and slide test operate under similar principles, but the addition of test reagents and steps in completing the test are different. The director did not ensure that staff were properly trained and evaluated to understand the principle of the test and how to interpret and troubleshoot problems or unexpected reactions that may occur during testing; and 4. When the problem concerning the reporting of the control serum for the Rh positive control as positive was identified in October 2018, the lab director did not have a detailed record documenting the retraining and follow up competency reviews showing staff were adequately trained and evaluated in the performance of the Rh test.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director did not ensure that testing personnel competency reviews and training were adequate to ensure staff performed and documented quality control for Rh testing in an accurate and reliable manner. Findings: 1. Written procedures for the Rh test, instruct lab staff to test a serum control alongside of every Rh test. The serum control is performed to check for false positive test results and is a solution containing everything the anti-D reagent contains, except for anti-D, if the serum control is positive, a false positive reaction has occurred and the test is invalid; 2. From October 30, 2018 going back to January 2018, testing staff routinely recorded the serum control for the Anti-D positive control check as positive. See D5481 for findings; 3. Competency reviews performed by the lab director and training by the lab director for the Rh test failed to identify problems in Rh quality control testing and did not ensure that staff were properly trained to perform, interpret and report observed results for Rh quality control testing; 4. When the error was identified in November of 2108, retraining of staff was conducted, as described during interview with staff on the day of survey, but there was no comprehensive documentation to show that staff were interviewed to determine why the errors occurred. The lab did not have records showing the retraining material and process that was performed and did not have records showing that staff were again evaluated for competency by observations of testing and reporting results, problem solving skills and knowledge of the Rh test (such as reading the Rh testing package inserts and demonstrating knowledge of the principles involved with the testing).