Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1011716	04/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Reproductive Health, Inc	700 E Hebron Street, Charlotte, NC	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records and review of 2016, 2017, and 2018 patient Rh(D) logs 4 /12/18, the laboratory failed to test proficiency samples in the same manner that patient specimens are routinely tested. Review of 2016, 2017, and 2018 API proficiency testing records and review of daily patient logs revealed proficiency samples were not documented on the daily patient Rh(D) testing logs in the same manner as patients for the the following test events: 1. 2017 1st, 2nd, and 3rd test events; 2. 2018 1st test event.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed

	by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records and interview with the owner 4/12/18, the laboratory failed to maintain a copy of all proficiency testing records for at least two years. Findings: Review of 2016, 2017, and 2018 API proficiency testing records revealed the laboratory failed to maintain copies of signed attestation statements for the following proficiency testing events: a. 2016 2nd and 3rd events; b. 2017 2nd and 3rd events. During interview at approximately 11:40 a.m., the owner stated that she was unsure where the attestation statements might be if they were not in the manual.
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 procedure manual review and interview with the owner 4/12/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual contained multiple procedures for urine pregnancy testing, and it was unclear which one was current. Examples: a. "R Medical One-Step Strip HCG Urine Pregnancy Test"; b. "'RAPID RESPONSE' LOW SENSITIVITY URINE PREGNANCY TEST"; c. "Immunocept-D urine pregnancy test (LSUPT)"; d. hCG 2 IU Test Disk product insert. 2. The procedure manual contained a "BLOOD GROUP (RH) SLIDE METHOD Anti-D Blend ALBAclone" procedure written by the laboratory. The procedure stated "... Materials: ... Room temp MUST be between 18-24 degrees C Procedure: Room temperature must be between 18-24 degrees C ..." The room temperature listed in the laboratory's procedure was not consistent with the manufacturer's instructions for use of the Anti-D ALBAclone reagent. The "Anti-D blend ALBAclone" product insert states "... PROCEDURES ... This reagent and the

	specimen(s) to be tested should be at 20-24 degrees C prior to testing. ... Slide Technique ... 3. Mix well by rocking the slide for approximately 30 seconds and incubate the test at 20-24 degrees C for 5 minutes with occasional mixing. ...". 3. The procedure manual contained a "MICROHEMATOCRIT" procedure, but during interview at approximately 9:50 a.m., the owner stated they no longer perform hematocrit. 4. The procedure manual contained four Anti-D quality control procedures. 5. The procedure manual contained two venipuncture procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2016, 2017, and 2018 patient logs, and interview with the owner 4/12/18, the laboratory failed to monitor refrigerator temperature each day the clinic was open to ensure proper storage of the Anti-D reagent. Manufacturer's instructions for the "Anti-D blend ALBAclone" reagent state "... STORAGE The reagent should be stored at 2-8 degrees C. ... LIMITATIONS ... False positive or false negative results can occur due to ... improper storage of materials ... ". Review of 2016, 2017, and 2018 daily patient Rh (D) logs revealed the refrigerator temperature was documented on the logs. There was no documentation available to indicate that refrigerator temperatures were recorded on days that patient Rh(D) testing did not occur. During interview at approximately 3:15 p.m., the owner confirmed that the laboratory does not document the refrigerator temperature on all days the clinic is open. She stated they document the refrigerator temperature only on the days that patient Rh(D) testing is performed - usually Tuesday, Wednesday, Friday, and Saturday.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2016, 2017, and 2018 temperature logs and review of 2016, 2017, and 2018 patient Rh(D) logs, the laboratory failed to document that any corrective action was taken for room temperatures outside acceptable limits for performance of the Rh(D) test. Manufacturer's instructions for the "Anti-D blend ALBAclone" blood grouping reagent state "... PROCEDURES ... This reagent and the specimen(s) to be tested should be at 20-24 degrees C prior to testing. ... Slide Technique ... 3. Mix well by rocking the slide for approximately 30 seconds and incubate the test at 20-24 degrees

	C for 5 minutes with occasional mixing. ... LIMITATIONS ...samples stored and tested at below 20 degrees C may exhibit false positive reactions... False positive or false negative results can occur due to ... improper reaction temperature...". Review of 2016, 2017, and 2018 temperature logs and patient Rh(D) testing logs revealed room temperatures recorded were below 20 degrees C (Celsius) on the following days when patient Rh(D) testing was performed: 1. 2016 a. March 4 (18 patients), 5 (11 patients), 8 (18 patients), 19 (20 patients), 22 (10 patients), 25 (17 patients), 20 (9 patients); b. April 2 (13 patients), 5 (9 patients), 6 (2 patients), 12 (18 patients), 13 (10 patients), 15 (15 patients), 16 (17 patients); c. May 7 (12 patients); d. June 3 (8 patients), 11 (10 patients), 18 (12 patients), 17 (13 patients), 21 (10 patients), 22 (5 patients). 2. 2017 a. October 4 (7 patients); b. November 7 (7 patients), 25 (4 patients); c. December 1 (9 patients), 5 (7 patients), 9 (9 patients), 13 (3 patients), 15 (9 patients), 16 (9 patients), 22 (10 patients). 3. 2018 a. January 2 (12 patients), 6 (13 patients), 9 (11 patients), 20 (11 patients), 27 (16 patients), 30 (6 patients); b. February 3 (15 patients), 10 (10 patients).
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 review of the laboratory's policies and procedures and interview with the owner 4/12/18, the laboratory director failed to establish a detailed, specific policy or procedure for evaluating the competency of testing personnel. The laboratory's "Quality Assurance Plan" states "Personnel files will be monitored in January and June of each year. Competency of each employee who performs lab testing will be reviewed with results documented appropriately in personnel files. ..." The "Quality Assurance Plan" did not include how the competency evaluations are conducted, the criteria used for evaluation, the threshold for acceptable performance, and how unacceptable evaluations are handled. During interview at approximately 1:25 p.m., the owner confirmed the laboratory did not have a detailed, specific competency evaluation policy.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic,

	and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the laboratory's test list provided during the survey, interview with the owner, and review of personnel records 4/12/18, the laboratory director failed to specify in writing the current laboratory duties and responsibilities for 2 of 2 testing personnel (TP). Findings: 1. The "Laboratory Testing Policy" (signed by the laboratory director 5/12/17) states "The following tests have been requested by (the laboratory director) to be standard procedure for each category of patient. Walk in High sensitivity urine test: R-Medical 1 strip test Low sensitivity urine test: 15 days late for period CHG IU test disc Abortion patients ... If no IUP visualized, first do a low sensitivity urine test (Hcg2 IU test disc), then complete a high sensitivity urine test (R-Medical 1 strip) if low sensitivity is negative. Positive serum pregnancy test is acceptable if performed at (the laboratory) ... Hematocrit or hemoglobin Rh typing ..." Review of the laboratory's test list provided during the survey revealed the laboratory currently performs only one pregnancy test (Henry Schein One Step +). In addition, the laboratory performs hemoglobin, but no longer performs hematocrit. During interview at approximately 9: 50 a.m., the owner confirmed that the laboratory performs only one type of pregnancy test and she verified the laboratory now performs hemoglobin instead of hematocrit. 2. The testing personnel job duties and responsibilities had not been updated to reflect the laboratory's current test menu. a. Review of the personnel file for TP #1 revealed a "LABORATORY PERSONNEL" document (signed by TP #1 5/3/16 and signed by the owner 5/3/17) which stated "The Laboratory Personnel are responsible for doing laboratory work-ups on each patient as indicated in standing orders. ... HCG and UCG pregnancy tests, hematocrit readings, and RH factor procedures shall be performed pre-operatively, as indicated. ... A UCG and RH control is to be performed each morning at the start of the shift. ..." Another copy of the "LABORATORY PERSONNEL" document was signed by TP #1 and the owner 4/10/18. b. Review of the personnel file for TP #2 revealed a "LABORATORY TESTING PERSONNEL JOB DESCRIPTION" document which stated "Each Testing Personnel is authorized to perform: Rh testing Urine pregnancy slide test Urine pregnancy dipstick test Hematocrit / Hemoglobin Blood draw Proficiency Testing Supervision is not required for specimen processing, test performance or results reporting. Director review is not required prior to reporting test results. Director review is required prior to any changes in brands or procedures." The document was not signed or dated.