Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2092855	10/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Femhealth Usa- Carafem Washington, Dc	5530 Wisconsin Ave Suite 1200, Chevy Chase, 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
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 did not have a written procedure for performing patient Rh testing. Findings: 1. During interview with lab staff at noon on the day of survey, staff stated that the written procedure for performing the Rh test was documented within the check list used for evaluating competency of testing persons; and 2. The competency checklist was not a complete description of the performance of the Rh test and did not include: a. Step-by-step procedures for testing and recording the results of the external controls (with both anti-D and auto test results) each day of patient testing, including the expected results, the

	interpretation of the control results and corrective actions that the lab must take if the results fail to meet the labs criteria for acceptability or if the lab is unable to test controls. The external control is different from the auto control, the external control is a known Rh positive or known Rh negative reagent used to check the accuracy of the test system, and the auto control is used to check for unexpected agglutination); b. Step-by-step procedures to identify the patient and collect the capillary blood to be used for the Rh test; c. Step-by-step procedures for performing the patient test, expected results, interpretation of patient results and corrective actions the lab must take if the patient auto control fails to react as expected; d. Pertinent literature references; e. Procedures for entering the test results onto intermediate test records and transcribing those result into the patient chart; and f. Procedures for staff to follow when either the daily external (positive/negative) controls or auto controls for either patient or control reagents do not react as expected or are unable to be tested.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab test records did not ensure the patient test records were documented in an accurate and reliable manner. Findings: 1. The lab staff records the patient Rh test result in a log, and that result is transcribed into an electronic chart; 2. The log is a chart with multiple rows and columns, the first column is to record the patient identification and the following columns are used to document lab results (all defined in the log header); 3. The first row on the log is not to be used to document patient results as preprinted examples of test results are recorded in the first row of each page in the log, the log does not indicate that the first row must not be used for recording patient test results; 4. On June 24, 2017 a sticker used to identify "PATIENT A" was placed in the first column of the first row of the log for this date, and it appeared as if the typed examples for recording patient results were the observed results for this patient, when in fact they were not; 5. The lab did not record that the result of the auto control, the control used to check for unexpected agglutination (false positive) test results, met the labs criteria for acceptability for both patient and daily external quality control testing or if appropriate did not met the labs criteria for acceptability; and 5. This was confirmed with lab staff during interview at noon on the day of survey.