Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2083648	**(X3) Date Survey Completed** 03/20/2024
Name of Provider or Supplier Houston Fertility Institute Mc Women's Laboratory	**Street Address, City, State** 7900 Fannin Street Suite 2700, Houston, TX	
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**
D0000	Based on an announced validation inspection completed on 3/20/24, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of one of one policy that reflects the laboratory's procedures for performing quality control (QC) testing on the Roche Cobas e411 analyzer. Findings include: 1. A review of the laboratory's policy

	titled 'QC Procedures for Hormone Assay' (Effective date: 2011) revealed the following: "- Run three levels of QC before running patient's sample." 2. A review of the laboratory's records revealed the laboratory runs only 2 levels of QC material every 24 hours. 3. In an interview on 3/20/24 at 11:00 am in the conference room, after review of the records, the laboratory supervisor confirmed the policy needed to be updated.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, personnel files, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment on one of two testing personnel in 2022 for testing on the Roche Cobas e411 analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 2 testing personnel performing moderate complexity testing on the Roche Cobas e411 analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing a competency assessment for testing person #1 in 2022. 3. In an interview on 3/20/24 at 10:30 am in the conference room, after review of the records, the laboratory supervisor confirmed the above findings.