Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161122	08/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Houston Male Health Clinic Pllc	6625 Spring Stuebner Rd #205, Spring, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
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 a review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2022 and staff interview, it was revealed that the laboratory failed to retain analyzer print outs for one testing event in 2022. Findings include: 1. A review of the laboratory's API proficiency testing records from 2022 revealed the laboratory failed to retain the analyzer print outs for the two samples tested (IA-01 and IA-02) for the 2022 Chemistry - Core- 1st Event. 2. An interview with laboratory director on 8/23/22 at 1:20 p.m. in the consultation room, after review of the records, confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the FastPack IP System Quality Assurance Manual, surveyor observation, a review of patient test records, and staff interview, it was revealed that the laboratory failed to follow its policy 8 of 8 times by not including the patient's first and last name on the blood specimen tubes for Testosterone testing. Findings include: 1. A review of the FastPack IP System Quality Assurance Manual (65000160 REV. 007 06/15) revealed the following: "Label all vacuum tubes with at least the patient's name and your initials as well as the time and date the specimen is drawn." 2. Surveyor observation of the laboratory on 8/23/22 at 1:45. p.m., when looking through the specimen storage rack, revealed a note taped to the rack that read: "First & Last Name". 3. Further review of the specimen storage rack revealed the following 8 blood specimen tubes that were labeled with only the patient's first or last name: - Olson - Todd - Henry - Leo - Gonzalez - Whitney - Ugge - Cox 4. A review of the test records for August 23, 2022 revealed the 8 above listed patient's samples were used to test for Testosterone on the FastPack IP System analyzers. 5. An interview with the laboratory director on 8/23/22 at 1:45 p.m. in the consultation room, after review of the records, confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by:

	Based on a review of the FastPack IP System Quality Assurance Manual, the laboratory's calibration verification records from 2020, 2021, and 2022, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification procedures at least every 6 months in 2021 and 2022 for Testosterone testing on the two Qualigen FastPack IP system analyzers. Findings include: 1. A review of the FastPack IP System Quality Assurance Manual (65000160 Rev. 007 06/15) revealed the following: "Testosterone: Every 6 months, verify calibration of the FastPack IP System using the FastPack Testo Method Verification Kit to verify that calibration is accurate to the limits of the reportable range specified by Qualigen, Inc." 2. A review of the calibration verification records for the two Qualigen FastPack IP Systems revealed the following dates when Testosterone was verified and the elapsed time between calibration verification testing: a) Analyzer Serial Number 1195 12/16/20 10/7/21 Elapsed time between calibration verifications: 9 months, 22 days 5/17/22 Elapsed time between calibration verifications: 7 months, 11 days b) Analyzer Serial Number 1173 12/16/20 10/7/21 Elapsed time between calibration verifications: 9 months, 22 days 5/17/22 Elapsed time between calibration verifications: 7 months, 11 days 3. An interview with the laboratory director on 8/23/22 at 1:30 p.m. in the consultation room, after review of the records, confirmed the above findings.