Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161122	12/08/2020
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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 42141
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing policy, laboratory's proficiency testing records from 2019 and 2020, and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same number of times as patient samples for 1 of 5 test events. The findings were: 1. Review of the laboratory's policy, "Proficiency Testing Policies" under "Proficiency Testing Procedures" stated "Follow your normal routine: Test PT samples in the same manner as you would patient sample. In other words, test PT samples with the regular patient workload using a staff member who routinely performs FastPack IP system testing. Do not repeat PT sample testing testing unless you would repeat a patient test in the same situation ." 2. Review of the laboratory's American Proficiency Institute proficiency testing records from 2019 (2nd and 3rd event to 2020 (1st, 2nd and 3 rd events) revealed 2 proficiency specimens were repeated, unlike a patient specimen, for 1 of of 5 events. 2020 3rd event IA - 11 tested 08/27/2020 by TP #2 repeated 08/31/2020 by TP #3 IA- 12 tested 08/27/2020 by TP #2 repeated 08/31/2020 by TP #3 3. An interview with the technical consultant 12/08/2020 at 1053 hours in the office confirmed the findings.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control records from 2019 - 2020, and confirmed in interview of facility personnel, the laboratory failed to retain the manufacturer's package insert for 2 of 3 quality control lots for the Qualigen analyzer. The findings were: 1. Review of the laboratory's quality control records for the Qualigen FastPack Testo from January 2018 to December 2020 revealed no documentation of the package insert of the control card for the following lot numbers: Control 1 Control 2 Lot Number 1809006 exp 01/31/2020 1809007 exp 01/31/2020 1904008 exp 02/18 /2020 1904009 exp 02/18/2020 2. An interview with the testing person #1 (as listed on CMS form 209) 12/082020 in the office at 1345 hours confirmed the findings. She was unaware she needed to keep them. Key CMS - Centers for Medicaid and Medicare Services
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, lack of laboratory policy and staff interview, it was revealed the laboratory failed to establish a policy and document competency assessments for 2 of 2 technical consultants. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory identified two technical consultants TC#1 and TC#2. 2. A review of the personnel records from 2019 - 2020 for the technical consultants revealed the records did not contain documentation of a competency assessment. 3. A review of the the laboratory SOPs revealed there was no policy for a competency assessment for technical consultants. 4. An interview with the staff facility on 12/08/2020 at 1415 hours in the office revealed no competency assessment was performed for 2 of 2 technical consultants. Key: SOP- Standard operating practice
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 laboratory environmental records from June 2019 to December 2019 and confirmed in interview of facility personnel, the laboratory failed to document temperatures and humidity on days of patient testing. The findings were: 1. Review of the manufacturer's instructions for FastPack IP system revealed the operating temperature is 15 - 32 degrees celsius and humidity is 10 - 80 percent. 2. Review of laboratory environmental records from June 2019 to December 2019 revealed the laboratory failed to document temperatures and humidity for 4 of 184 days of patient testing. Date Tested 08/23/2019 10/04/2019 10 /24/2019 12/02/2019 3. Review of patient test records for the above dates revealed the laboratory performed patient testing for testosterone. Date Tested Patient ID 08/23 /2019 11208 08/23/2019 11305 08/23/2019 11296 08/23/2019 11287 08/23/2019 11177 10/04/2019 7551 10/04/2019 11305 10/04/2019 10455 10/04/2019 11886 10/04 /2019 11843 10/04/2019 11878 10/04/2019 11849 10/04/2019 5188 10/04/2019 11882 10/04/2019 11601 10/04/2019 3036 10/24/2019 12105 10/24/2019 11764 10/24 /2019 120909 10/24/2019 12100 10/24/2019 12082 12/02/2019 11601 12/02/2109 12014 12/02/2019 12105 4. Interview with testing person #3 (as listed on the CMS form 209) on 12/08/2020 at 1145 hours in the laboratory, she said "If it isn't written on the log, they forgot to do it".
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of manufacturers instructions, review of laboratory's verification records for the Qualigen FastPack IP system analyzer, and staff interview, it was revealed the laboratory failed to have documentation of complete verification studies for 1 of 1 test (testosterone) on the Qualigen FastPack IP system prior to performing patient testing. The findings were: 1. Review of the manufacturer's instruction titled "Testosterone Calibration Verification Records" under "Method Validation" states " Prior to using the FastPack IP System to test patients, you must validate the assays your facility plans on using in order to demonstrate that the instrument meets the manufacturer's specifications for accuracy, precision and reportable range. Each laboratory director must decide upon the appropriateness of the manufacturer's normal values for the laboratory's patient population." 2. Random review of patient records from 2019-2020 revealed documentation of a normal reference range of 350 ng/dL to 1000 ng/dL. 3. Review of the laboratory records revealed no documentation of the laboratory verifying the above normal reference range. 4. An interview with Technical consultant on 12/08/2020 at 15:30 hours in the office confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, laboratory environmental records, and confirmed in interview it was revealed that the laboratory failed to establish the frequency and document the maintenance on the FastPack IP system. The findings were: 1. Review of manufacturer's instruction for the FastPack IP system under "Cleaning the FastPack IP System" states " The FastPack IP System analyzer is completely self enclosed, and only requires periodic cleaning to remove excess sample. Use a damp cloth to wipe down the entire exterior and interior compartment of the analyzer. Do not use solvents to wipe down the exterior of the analyzer." 2. Review of laboratory environmental records from May 2019 to December 2020, revealed there is no documentation of the laboratory performing the above maintenance. 3. Review of the laboratory policies revealed no documentation of a policy establishing the frequency of the required maintenance. 4. Review of the CMS116 revealed the laboratory performed 1300 annual endocrinology tests. 5. An interview with the facility personnel on 12/08/2020 at 1415 hours in the office confirmed the 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 review of manufacturer's instructions, review of the laboratory's calibration verification records for the Qualigen FastPack IP analyzer for 2019 and 2020, and

	staff interview, it was revealed the laboratory failed to have documentation of performing calibration verifications for Testosterone testing every 6 months. The findings were: 1. A review of the manutfacturer's instructions titled "Testosterone" states "Verify Reportable Ranges (Calibration Verification) every 6 monhts". 2. A review of the laboratory's calibration verification records for the Qualigen FastPack IP analyzer for Testosterone revealed calibration verification were not documented every 6 months. Calibration verification were performed on the following dates: May 15, 2019 December 16, 2019 (7 months later) July 08, 2020 (7 months later) 3. An interview with the technical consultant on December 08, 2020 at 1300 hours after he review of the records confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's Individualized Quality Control Plan (IQCP) for the Qualigen FastPack Testosterone testing, laboratory quality control records, patient records and staff interview revealed the laboratory failed to have documentation of performing a complete IQCP for external quality control (QC) testing prior to modifying the frequency of quality control testing for 1 of 1 test (testosterone). The findings were: 1. A review of the laboratory's quality control records for the FastPack Testo from May 15, 2019 to December 8, 2020 revealed external quality control testing was performed weekly. 2. Review of laboratory policy titled "Individualized Quality Control Plan (IQCP)" states "CLIA requires a minimum QC frequency of 2 levels of controls each day of patient testing. As an alternative, your facility may customize its QC plan by implementing and IQCP. IQCP may reduce the QC frequency to a weekly schedule if IQCP Risk Assessment determines that risk levels are manageable". 3. The laboratory was asked to provide documentation of performing an IQCP study to include: Risk Assessment (RA); Quality Control Plan (QCP); and Quality Assessment (QA) to modify the required frequency of controls to every week. No documentation was provided. 4. An interview with the technical consultant on 12/08/2020 at 1315 in the office revealed they did not perform a complete IQCP study and were not performing quality control each day of patient testing. This confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of manufacturers instructions, review of laboratory's quality control and patient records from May 2019 to December 2020, and confirmed in interview of facility personnel, the laboratory failed to ensure at least two levels of quality control (QC) were documented prior to testing patients for testosterone for 22 of 27 days reviewed. The findings were: 1. Review of the manufacture instructions titled "Qualigen FastPack IP Testo Immunoassay" under "Quality Control" states "Quality materials simulates real specimens and are essential for monitoring the system performance of assays. Good Laboratory Practices include the use of control specimens to ensure that all reagents and protocols perform properly. Users should follow the appropriate federal, state and local guidelines concerning the running of external controls." 2. Review of laboratory policy titled "Individualized Quality Control Plan (IQCP)" states "CLIA requires a minimum QC frequency of 2 levels of controls each day of patient testing. As an alternative, your facility may customize its QC plan by implementing and IQCP. IQCP may reduce the QC frequency to a weekly schedule if IQCP Risk Assessment determines that risk levels are manageable". The laboratory did not have a complete IQCP to reduce QC testing weekly. (cross refer to D5445) 3. Random review of patient and quality control records from May 2019 to December 2020 revealed 85 patient samples were performed with no documentation of quality control for 22 of 27days of testing. (see patient alias list) 4. Interview with the technical consultant on 12/08/2020 at 13:15 hours in the office confirmed the findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of facility personnel, the laboratory failed to document twice annually comparison of 2 of 2 analyzers performing testosterone on the Qualigen FastPack analyzers. The findings were: 1. Review of the laboratory records revealed the laboratory has 2 Qualigen FastPack IP analyzers (System ID 1173 and 1195) that perform testosterone testing. 2. Review of the laboratory records from 2019 and 2020 revealed no comparison of tests between the above instruments for Testosterone. 3. An interview with testing person #3 (as listed on CMS form 209) on 12/08/20 at 1530 hours in the office stated "I look at the results and eyeball them to see if they are okay [same]". She was unaware that the laboratory needed a policy and/or acceptance criteria when performing twice annual comparison. This confirms the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. The quality assessment program failed to identify the laboratory did not documentation when temperatures and humidity were not recorded. (refer to D5413) 2. The quality assessment program failed to identify the laboratory did not document and verify normal reportable ranges for their patient population. (refer to D5421) 3. The quality assessment program failed to identify the laboratory did not document routine maintenance of the Qualigen FastPack IP system. (refer to D5433) 4. The quality assessment program failed to identify the laboratory failed to perform Calibration verification every 6 months. (refer to D5439) 5. The quality assessment program failed to identify the laboratory did not have a written IQCP for quality controls. (refer to D5445) 6. The quality assessment program failed to identify the laboratory did not perform 2 level QC on each day of patient testing. (refer to D5447) 7. The quality assessment program failed to identify the laboratory perform instrument comparison testing for the 2 Qualigen FastPack IP systems. (D5775) Key QC - Quality Control IQCP -Individualized Quality Control Plan
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of records, verification studies and procedures, the laboratory director failed to ensure verification studies used were complete for the FastPack testosterone immunoassay prior to patient testing. (Refer to D5421)
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, and confirmed

	in interview, the laboratory director failed to ensure the laboratory established a quality control program appropriate for the testing performed. Refer to D5445, D5447
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 test menu, review of the laboratory's submitted Form CMS-209 and confirmed in interview of facility personnel, the laboratory director failed to specify in writing the responsibilities and duties for the technical consultant. The findings included: 1. Review of the laboratory's test menu revealed the laboratory performed moderate complexity testing. 2. Review of the laboratory's Form CMS-209 revealed the laboratory identified two technical consultant. 3. Review of the laboratory's personnel records for the technical consultant revealed a job description was not available for review for the technical consultant that specified in writing each of his responsibilities and duties. 4. The laboratory was asked to provide documentation of the missing job description for the technical consultant. No documentation was provided. 5. An interview with the facility staff on 12/08/2020 at 1500 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services