

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2106191	(X3) Date Survey Completed 02/06/2018
Name of Provider or Supplier Modern Male T Clinic	Street Address, City, State 1801 Durham # 4, 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	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.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records from 2016 and 2017 and confirmed in interview, the laboratory failed to test all proficiency samples in the same manner as it tests patient specimens by personnel who routinely performed the testing in the laboratory. Findings were: 1. A review of 2016 and 2017 proficiency testing events revealed that for 4 of 4 events (2016 1st and 2nd event in chemistry and 2017 1st and 2nd events in Chemistry) were tested by the same testing person, testing person #1. The facility listed 3 testing persons on the CMS209 involved in testing patient specimens. 2. An interview with the testing person #1 on 02/06/18 at 0940 hours in the laboratory confirmed the above findings. key: CMS - Center for Medicare and Medicaid Services</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the</p>

current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory Individualized Quality Control Plan (IQCP) and confirmed in interview, the laboratory failed to ensure that all laboratory quality control plan was approved, signed and dated by the laboratory director before use for the Qualigen FastPack Testosterone and FastPack PSA. Findings were: 1. Review of the IQCP for the Qualigen FastPack Testosterone and FastPack PSA Risk Assessment checklist revealed no documentation of the lab director approval signature and date prior to use. 2. An interview with the testing person # 1 on 02/06/18 at 0930 hours in the laboratory confirmed the above findings.

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 the laboratory policy and test records and confirmed in interview, the laboratory failed to perform a complete verification study for Testosterone and total PSA on the Qualigen Fastpack IP System analyzer. (normal patient study) Findings were: 1. Review of the laboratory policy Method Validation (65000160 Rev. 007, 06/15) revealed "each laboratory should determine their own reference range appropriate for their population." 2. Review of the verification study for Testosterone and total PSA performed on 11/2015 revealed no documentation of a normal patient study. 3. An interview with the testing person #1 on 02/06/18 at 0930 hours in the laboratory confirmed the above findings. He was unaware the normal range study was needed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions and confirmed in interview, the laboratory failed to perform the manufacturer required maintenance for the Qualigen FastPack IP System analyzer. Findings were: 1. Review of the Qualigen FastPack IP System analyzer procedure manual (65000159 Rev.008 06/17) revealed under Cleaning the FastPack IP System "that 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.

	<p>Do not use solvents to wipe down the exterior of the analyzer." 2. Review of the Daily Environment Log from January 2016 to January 2018 revealed no documentation of the above maintenance. 3. An interview with the testing person #1 02/06/18 at 1025 hours in the laboratory confirmed the above findings. He was unaware he needed to perform maintenance. .</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions and confirmed in interview, the laboratory failed to establish the frequency of the required periodic maintenance for the Qualigen FastPack IP System analyzer. Findings were: 1. Review of the Qualigen FastPack IP System analyzer procedure manual (65000159 Rev.008 06/17) revealed under Cleaning the FastPack IP System "that 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. The laboratory was asked for documentation that stated how often periodic cleaning should be performed. No documentation was provided. 3. An interview with the testing person #1 02/06/18 at 1025 hours in the laboratory confirmed the above findings.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory quality assurance policy and checklists, and confirmed in interview, the laboratory quality assurance assessment program failed to identify and correct problems in analytic systems. Findings were: 1. The laboratory failed to perform a complete a normal patient verification study for Testosterone and total PSA on the Qualigen Fastpack IP System analyzer. (refer to D5421) 2. The laboratory failed to perform the manufacturer required maintenance for the Qualigen FastPack IP System analyzer. (Refer to D5429)</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p>

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 the laboratory policy and test records and confirmed in interview, the laboratory director failed to ensure the laboratory performed a complete verification study for Testosterone and total PSA on the Qualigen Fastpack IP System analyzer. (refer to D5421)

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency test records and interview, the laboratory director failed to ensure proficiency samples were tested in the same manner it tested patient specimens. (Refer to D2007)