

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2106191	<b>(X3) Date Survey Completed</b>  02/05/2020
<b>Name of Provider or Supplier</b>  Modern Male T Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 D6063 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute's proficiency testing records from 2018 and 2019 and staff interview, it was revealed the laboratory failed to have documentation of successfully performing a second accuracy assessment for the unregulated analyte Testosterone in 2019. Findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 revealed the laboratory participated in the following events to assess accuracy for Testosterone testing using the Qualigen FastPack IP System: 2019 Chemistry - Miscellaneous - 1st Event 2019 Chemistry - Miscellaneous - 2nd Event 2. Further review of the 2019 Chemistry - Miscellaneous - 2nd Event from October 2019 revealed the laboratory failed to perform successfully for Testosterone. The laboratory</p>

	<p>scored Unacceptable for all three Testosterone samples (IA-06, IA-07, IA-08) sent for the 2nd Event, resulting in a score of 0%. 3. An interview with the certified medical assistant on 2/5/20 at 10:00 a.m. in the back room, after review of the records, confirmed the above findings.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance Assessment records and staff interview, it was revealed the laboratory's quality assessment plan failed to assess and correct problems identified in general laboratory systems. Findings include: 1. The laboratory's Quality Assurance Assessment plan failed to ensure two successful accuracy assessments were performed for Testosterone in 2019 (refer to D5217).</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Instructions for Use for the Beckman Coulter StatSpin Express 2 centrifuge and staff interview, it was revealed the laboratory failed to have documentation of performing 2 of 2 required maintenance procedures in 2018 and 2019 on the Beckman Coulter StatSpin Express 2 centrifuge used for spinning patient blood samples prior to testing. Findings include: 1. A review of the Instructions for Use (document number: 55-003910-001FD, September 2018) for the Beckman Coulter StatSpin Express 2 centrifuge revealed the following two required maintenance procedures under the Chapter 4 Maintenance section : "Beckman Coulter recommends that instrument operators perform periodic inspections and preventative maintenance on all devices. a) Cleaning The Express 2 is supplied with disposable bowl liner to simplify routine cleaning. Additional bowl liners are available. (Product No. DL01). The liner should be replaced monthly or whenever a spill occurs. Clean the outside surfaces and the control panel with a water-dampened cloth and mild detergent. Clean the inner surface or bowl, with a mild detergent and if necessary, a disinfectant, wiping with an cloth dampened with 70% alcohol or 10% bleach solution. b) Inspecting the Rotor Speed The rated speeds can be inspected with a stroboscope or photoelectric tachometer. " 2. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 1/31/2020) on 2/5 /20 at 11:30 a.m. in the back room, confirmed that the maintenance procedures have not been done on the centrifuge.</p>
<p><b>D5435</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on surveyor observation, a review of the Instructions for Use for the Beckman Coulter StatSpin Express 2 centrifuge, and staff interview, it was revealed the laboratory failed to have documentation of a function check protocol (monitoring the speed and time of the centrifuge and defining the frequency of the function checks) of the Beckman Coulter StatSpin Express 2 centrifuge in 2018 and 2019. Findings include: 1. At 10:30 a.m. on 2/5/2020 in the laboratory, the surveyor observed the following centrifuge used for spinning patient blood samples prior to testing: Beckman Coulter StatSpin Express 2 Centrifuge Model: M501-22 Serial Number: 1145M50108408 2. A review of the Instructions for Use (document number: 55-003910-001FD, September 2018) for the StatSpin Express 2 Centrifuge revealed the following: "Beckman Coulter recommends that instrument operators perform periodic inspections and preventative maintenance on all devices. Maintenance: Inspecting the Rotor Speed The rated speeds can be inspected with a stroboscope or photoelectric tachometer. If the StatSpin Express 2 fails to achieve an operating speed of 8,500 rpm +5% in the 120s and 180s settings, contact Beckman Coulter Customer Support." 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 1/31/2020) on 2/5/20 at 11:30 a.m. in the back room, confirmed that the centrifuge had never had a rotor speed inspection. This confirmed the above findings.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on a review of the laboratory's personnel records and staff interview it was revealed the laboratory failed to ensure testing personnel were qualified. Findings include: 1. The laboratory failed to have documentation of education for 1 of 12 testing personnel to qualify them to perform moderate complexity testing (refer to D6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a

chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education for 1 of 12 testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 1/31/2020) revealed 12 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 1 of 12 testing personnel. The testing person missing the documentation of education: Testing Person #7 (as indicated on the CMS 209 form) 3. The laboratory was asked to provide the documentation of education. No documentation was provided. 4. An interview with the certified medical assistant on 2/5/20 at 11:00 a.m. in the back room, after review of the records, confirmed the above findings.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed that 3 of 12 testing personnel failed to have documentation of training on the Qualigen FastPack IP System prior to performing patient testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/31/2020) revealed the laboratory identified 12 testing personnel who performed moderate complexity testing on the Qualigen FastPack IP System. 2. A review of the laboratory's personnel records revealed that the following testing personnel, as indicated on the CMS 209 form, did not have documentation of training on the Qualigen FastPack IP System prior to performing patient testing: Testing Person #7 Testing Person #11 Testing Person #12 3. An interview with certified medical assistant on 2/5/20 at 11:00 a.m. in the back room, after review of the records, confirmed the above findings.