Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2044214	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Low Testosterone Men's Clinic	5604 Colleyville Blvd Suite H, Colleyville, 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 at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 45 CFR 493.1250 Analytic Systems 493.1403 Moderate Complexity Laboratory Director 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's (API) Chemistry - Miscellaneous proficiency testing records from 2016, 2017 and 2018 and staff interview, it was revealed the laboratory failed to ensure that each testing person participated in proficiency testing. Findings included: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/15/2019) revealed the laboratory identified three testing persons for the Qualigen Fast Pack chemistry analyzer. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records

	from 2016 (Chemistry Miscellaneous Event 2 and 3), 2017 (Chemistry Miscellaneous Event 1 and 2) and 2018 (Chemistry Miscellaneous Event 1) revealed testing person number 3 performed the testing for each event. The laboratory failed to ensure that each testing person participated in proficiency testing. 3. In an interview on 01/15 /2019 at 1045 hours in the breakroom, testing person number 2 stated he was unaware of the requirement that all testing personnel needed to participate in proficiency testing. This confirmed the findings.
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 review of the laboratory's American Proficiency Institute (API) Proficiency Testing (API) Chemistry - Miscellaneous proficiency testing records from 2016, 2017 and 2018 and confirmed in staff interview, the laboratory failed to maintain all PT records for 1 of 7 chemistry testing events. Findings included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (Chemistry Miscellaneous Event 2 and 3), 2017 (Chemistry Miscellaneous Event 1 and 2) and 2018 (Chemistry Miscellaneous Event 1 and 2) revealed the following records were not maintained for the API 2018 Chemistry Miscellaneous Event 2: a. API Chemistry Miscellaneous 2018 Event 2 did not include proficiency testing report forms for testing samples IA-04, IA-05, and IA-06 for prostate specific antigen (PSA) and testosterone on the Qualigen analyzer. b. API Chemistry Miscellaneous 2018 Event 2 did not include attestation statement for testing samples IA-04, IA-05, and IA-06 for prostate specific antigen (PSA) and testosterone on the Qualigen analyzer. 2. The above findings were confirmed by testing person number 2 in an interview on 01 /15/2019 at 1045 hours in the breakroom.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute's (API) Chemistry - Miscellaneous proficiency testing records from 2016, 2017 and 2018 and staff interview, it was revealed the laboratory failed to have documentation of laboratory director review for 2 of 6 proficiency testing events. Findings included: 1. Review of the laboratory policy "Tab 4" titled "The Laboratory

	Director Responsibilities" stated, "All aspects of proficiency testing (PT) are properly followed and PT results are reviewed. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (Chemistry Miscellaneous Event 2 and 3), 2017 (Chemistry Miscellaneous Event 1 and 2) and 2018 (Chemistry Miscellaneous Event 1 and 2) revealed the laboratory director failed to review the following proficiency testing records: a. 2018 Chemistry Miscellaneous 1st Event Review by testing person number 3 b. 2018 Chemistry Miscellaneous 2st Event Review by testing person number 2 3. The laboratory was asked to provide documentation of laboratory director review of the results or documentation of the delegation of this responsibility to the testing personnel. No documentation was provided. 4. The above findings were confirmed by testing person number 2 in an interview on 01/15/2019 at 1045 hours in the breakroom.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory quality control records, facility communications, laboratory records and staff interview, the laboratory failed to meet the requirements for the analytic systems, as evidenced by: 1. The laboratory failed to have documentation of the open date and the revised expiration date for the PSA and Testosterone control material. (Refer to D5415) 2. The laboratory failed to perform preventive maintenance on the StatSpin Express 4 High Speed Horizontal Centrifuge. This is a repeat deficiency. (Refer to D5429) 3. The laboratory failed to have documentation of a mechanism to monitor quality control results over time to detect shifts and trends. (Refer to D5441)
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the Qualigen Fast Pack control material for Prostate Specific Antigen (PSA) and Testosterone, direct observation and staff interview, it was revealed that the laboratory failed to have documentation of the open date and the revised expiration date for the PSA and Testosterone control material. Findings included: 1. The Qualigen Fast Pack Control package insert (Rev 001 02/13) stated, "After opening, controls are stable for 120 days when stored and handled as directed." 2. Observed in the laboratory refrigerator on 01/15/2018 at 1200 hours was one box of

	Qualigen Fast Pack control material containing the following: a. One vial of Level 1 Control Lot number 1801022-5/Expiration Date 2019-05-17 b. One vial of Level 2 Control Lot number 1801022-5/Expiration Date 2019-05-17 3. The laboratory was asked to provide documentation of when the box was opened or when it would expire. The laboratory failed to provide documentation of the open date or the revised expiration date for the Qualigen Fast Pack control material. 4. An interview with testing person number 2 in the laboratory on 01/15/2019 at 1200 hours revealed the controls observed in the refrigerator were in use and that he was unaware of when the control material was opened or that the manufacturer stated it should be used within 120 days. This confirmed the above findings.
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 on manufacturer's instructions, facility communications, laboratory records and staff interview, the laboratory failed to perform preventive maintenance on the StatSpin Express 4 High Speed Horizontal Centrifuge. Findings included: 1. The manufacturer's instructions for the StatSpin Express 4 High Speed Horizontal Centrifuge in the section titled "Checking the Rotor Speed" stated, "The rated speeds (5%) can be checked with a stroboscope or photoelectric tachometer." 2. Review of an email (07/21/2016) from testing person number 1 to the CLIA surveyor who conducted the previous recertification survey (07/14/2016) stated, "I just purchased a photoelectric tachometer so that we can perform maintenance and check rotor speed yearly ... ...We will do yearly maintenance on our centrifuges and make sure to document those assessments." 3. Review of laboratory records for 2016, 2017, and 2018 revealed the laboratory failed to ensure documentation of yearly rotor speed checks on the StatSpin Express 4 High Speed Horizontal Centrifuge. The laboratory was asked to provide documentation. No documentation was provided. 4. The above findings were confirmed by testing person number 2 in an interview on 01/15/2019 at 1200 hours in the breakroom NOTE: THIS IS A REPEAT DEFIENCY FROM SURVEY PERFORMED 07/14/2016.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for PSA and Testosterone testing, and staff interview, it was revealed the laboratory failed to have documentation of a mechanism to monitor quality control results over time to detect shifts and trends. The findings were: 1. A review of the laboratory's quality control records for PSA and testosterone performed on the Qualigen Fast Pack endocrinology analyzer from 2017 and 2018 revealed the laboratory failed to have a mechanism to monitor quality control results over time to detect shifts and trends. 2. The laboratory was asked to provide documentation of monitoring the controls (Levy-Jennings charts, peer group analysis, etc) over time. No documentation was provided. 3. An interview with testing person number 2 on 01/15/2018 at 1046 hours in the breakroom revealed the laboratory assessed quality control acceptability on a daily basis by determining if controls were in the acceptable range. No evaluation of the controls over time was done to identify any
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory records, and laboratory proficiency testing, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure manufacturer's instructions were followed for preventive maintenance on the StatSpin Express 4 High Speed Horizontal Centrifuge. (Refer to D6007) 2. The laboratory director failed to document his review for 2 of 6 proficiency testing events. (Refer to D6018)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review on manufacturer's instructions, facility communications, and laboratory records, the laboratory director failed to ensure manufacturer's instructions were followed for preventive maintenance on the StatSpin Express 4 High Speed Horizontal Centrifuge. (Refer to D5429)
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute's (API) Chemistry - Miscellaneous proficiency testing records from 2016, 2017 and 2018 and staff interview, it was revealed the laboratory director failed to document his review for 2 of 6 proficiency testing events. (Refer to D5211)