Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2130674	07/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
National Low T Clinic	3118 Alcoa Hwy, Knoxville, TN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: ========== Based on review of Proficiency Testing (PT) reports for 2018 and 2019, attestation sheets which lacked testing personnel and director signatures and upon interview with the Nurse Practitioner, determined the testing personnel and laboratory director failed to sign attestation sheets. The findings include: 1. Review of PT reports for 2018 and 2019. 2. Review of attestation sheets revealed lack of testing personnel and director signatures for the first event of 2018 and lack of director signature for the second event of 2018 and the first event of 2019. 3. Interview at approximately 3:00 p.m. July 16, 2019 with the Nurse Practitioner confirmed the PT attestation sheets for 2018 and 2019 lacked testing personnel and director signatures as stated. ==========
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: ========== Based on review of Qualigen Fast Pack Operator's Manual used as the procedure manual for Testosterone testing, lack of director's approval of manual, lack of normal values for Testosterone, lack of laboratory's system for reporting results and lack of course of action if test system becomes inoperable and upon interview with Nurse Practitioner, determined the laboratory failed to have a complete and approved procedure manual for Testosterone testing 7/16/19. The findings include: 1. Review of Qualigen Fast Pack Operator's Manual for performing Testosterone used as procedure manual. 2. Lack of Laboratory Director's signature and date for approval as procedure manual. 3. Lack of defined normal values for Testosterone. 4. Lack of system for reporting results. 5. Lack of course of action if test system becomes inoperable. 6. Interview at approximately 3:00 p.m. July 16, 2019 with Nurse Practitioner confirmed the laboratory failed to have a complete and approved procedure manual for Testosterone testing and reporting 7/16 /19. ==========
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: ========== Based on observation of Testosterone test packs in refrigerator 7/16/19 at approximately 10:15 a.m., review of Operator's Manual for Qualigen IP Fast Pack System and interview with the Nurse Practioner, determined the laboratory failed to follow manufacturer's instructions regarding storage of Testosterone test packs. The findings include: 1. Observed 2 Testosterone test packs in refrigerator 7/16/19 at approximately 10:15 a.m. lying in a prone position. 2. Review of Qualigen IP Fast Pack System states test packs are to be stored sitting in an upright position. 3. Interview at approximately 3:00 p.m. 7/16/19 with Nurse Practioner confirmed 2 Testosterone test packs were not stored according to manufacturer's instructions. ==========
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 the IQCP (Individualized Quality Control Procedure) which states Quality Control (QC) is to be performed weekly for Testosterone testing, review of Quality Control from 1/10/18 to 2/27/19 showing lack of QC documentation weekly and upon interview with the Nurse Practitioner, determined the laboratory failed to follow their IQCP for performing QC weekly. The findings include: 1. Review of the IQCP states to perform Quality Controls weekly for Testosterone testing. 2. Review of Quality Control results from 1/10/18 to 2/27/10 showed the following dates QC was performed: 1/10/18 and 1/24/18 (2 weeks between QC) 2 patients tested between QC. 9/27/18 and 10/10/18 (13 days between QC) 1 patient tested between QC. 10/30/18 and 11/13/18 (2 weeks between QC) 9 patients tested between QC. 11/27/18 and 12/10 /18 (13 days between QC) 4 patients tested between QC. 2/13/19 and 2/27/19 (2 weeks between QC) 9 patients tested between QC. 3. Interview at approximately 3:00 p.m. July 16, 2019 with the Nurse Practitioner confirmed the Laboratory failed to follow their IQCP for performing Testosterone QC weekly with patient testing. ==========
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: ========== Based on review of four patient reports from November 2018 to July 2019, lack of Facility name on reports and upon interview with the Nurse Practitioner, determined the laboratory failed to ensure name of facility was on patient test report. The findings include: 1. Review of four patient reports for 11/5/18, 1/7/19, 4/15/19 and 7/12/19. 2. Lack of Facility name on four of the four reports. 3. Interview at approximately 3:00 p.m. July 16, 2019 with the Nurse Practitioner confirmed patient reports do not contain the facility name. ==========
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: ========== Based on review of four patient reports from November 2018 to July 2019, lack of reference range for Testosterone results on reports and upon interview with the Nurse Practitioner, determined the laboratory failed to ensure reference range for Testosterone was on patient test reports. The findings include: 1. Review of four patient reports for 11/5/18, 1/7/19, 4 /15/19 and 7/12/19. 2. Lack of Testosterone reference range on four of the four reports. 3. Interview at approximately 3:00 p.m. July 16, 2019 with the Nurse Practitioner confirmed patient reports do not contain reference ranges for Testosterone results. ==========
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 Proficiency Testing (PT) results for 2018 and 2019 for Testosterone, lack of director and testing personnel review of PT results and upon interview with the Nurse Practitioner, determined the Laboratory Director failed to ensure Proficiency Testing reports were reviewed. The findings include: 1. Review of PT results for 2018 and 2019 for Testosterone testing. 2. Lack of director and testing personnel review of PT results for all events. 3. Interview at approximately 3:00 p.m. July 16, 2019 with Nurse Practitioner confirmed the Laboratory Director failed to ensure review of Proficiency Testing results for 2018 and 2019. ==========