Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128419	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Total Men's Primary Care-Congress	823 Congress Ave, Suite # 125, Austin, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records, laboratory policy, and interview with facility personnel, the laboratory failed to evaluated the performance of the testosterone assay on 1 of 1 event in 2018. The findings included: 1. Based on review of the American Proficiency Institute (API) performance summary for Chemistry - 2nd event, the laboratory received a score of 100 percent for the analyte testosterone. Based on review of the Comparative Evaluation, API reported a code of "Not Graded 3" under Performance for testosterone specimens IA-04, IA-05, and IA-06. A note below the comparative summary states: "3 - See Data Summary" 2. Based on review of the API performance evaluation page, the laboratory director reviewed the proficiency testing results on 11/25/2018. The laboratory did NOT document the evaluation of the specimens IA-04, IA-05, and IA-06 in the context of the API data summary. 3. Based on review of the laboratory's policy "Proficiency Testing", under Analysis of Results, the policy states the following: "The Lab Director will also review the results of PT and a summary will be emailed to the testing personnel in the PT group. Corrective Actions: In the event of a failure, No patient samples can be ran until a repeat PT testing has passed." The laboratory must have a mechanism for routine review of its proficiency testing results that are evaluated by its PT providers. This includes a review of its actual PT results against the PT provider's participant summary results for the particular PT event and when any of the following occur: *The PT program assigned an artificial score of 100% (e.g., results not evaluated or

	scored); 4. In an interview at 10:16 a.m. hours on 1/22/2019 in the laboratory, the Regional Director stated the laboratory was unaware of the requirement to evaluate ungraded analytes.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the NanoEnTek FREND Testosterone instructions for use, laboratory policy, review of patient records, and interview with facility personnel, the laboratory failed to ensure 5 of 5 randomly reviewed specimens were collected in the appropriate anticoagulated blood collection tubes between August 8, 2018 and November 29, 2018. The findings included: 1. Based on review of the NanoEnTek FREND Testosterone instructions for use (NESPI-FRTEAP-002EN(V.0.0)), under Specimen Collection and handling, the document states the following: "Human serum or plasma (K3 EDTA and lithium heparin) samples are acceptable for use with FREND Testosterone cartridges." And; "For plasma (K3 EDTA and lithium heparin), invert the sample plus/minus five times immediately after collection to mix with anticoagulant." 2. Based on review of the laboratory's procedure "4. FREND Testo Testing:", (approved by the Laboratory Director as V3 on 10/01/2018), under "SPECIMEN COLLECTION AND HANDLING", the document states the following: "Human serum and plasma (EDTA and Lithium-heparin) samples are suitable for use with FREND Testosterone cartridges." The laboratory policy did not differentiate between K2 EDTA and K3 EDTA anticoagulant filled tubes. 3. Based on surveyor observations at 10:23 hours on 1/22/2019 in the storage room, the surveyor observed the following Becton Dickinson purple top tubes stored in the storage room: K2 EDTA 7.2 mg Blood Collection tubes 4 milliliter 13 by 75 millimeters Lot: 8215703 Expiration: 2019-12-31 In an interview at 10:29 hours on 1/22/2019 in the laboratory, when asked what specimen was used for FREND testosterone patient testing, the Regional Manager stated the laboratory used EDTA plasma from purple top tubes. When the surveyor asked if the laboratory was aware the NanoEnTek package insert required K3 EDTA, the Regional Manager stated the laboratory was not aware of the requirement to use K3 EDTA and had been using K2 EDTA for patient testing. 4. Based on a random review of patient records, the following 5 of 5 patients were tested in August 2018 and November 2018 with K2 EDTA plasma, and not the K3 EDTA plasma required by the manufacturer: Date: 8/8/2018 Patient ID: 3 19 1979 Testosterone: 182.9 ng/dL Date: 8/16/2018 Patient ID: 09 01 1980 Testosterone: 410.6 ng/dL Date: 11/05/2018 Patient ID: 05 23 1986 Testosterone: 267.4 ng/dL Date: 11/07/2018 Patient ID: 06 23 1983 Testosterone: 126.2 ng/dL Date: 1129/2018 Patient ID: 08 23 1981 Testosterone: 115.0 ng/dL