

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0883999	(X3) Date Survey Completed 10/13/2020
Name of Provider or Supplier Texoma Urology Center	Street Address, City, State 5500 Kell West Blvd Suite 200, Wichita Falls, 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	<p>Entrance and exit conferences were held with laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The laboratory representatives 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. 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>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS)-209 form,</p>

American Proficiency Institute (API) Proficiency Testing (PT) records, and staff interview, the laboratory failed to test Chemistry/Endocrinology samples in the same manner as it tests patient specimens for 5 of 5 testing events in 2019 (Q1, Q2, and Q3) and 2020 (Q1 and Q2). Findings included: 1. Review of the CMS 209 form revealed 4 Testing Persons (TP #1 - TP#4) performing moderate complexity chemistry /endocrinology testing for Prostate Specific Antigen and Testosterone analytes. 2. Review of the API proficiency testing records from 2019 (Q1, Q2, and Q3) and 2020 (Q1 and Q2) revealed TP# 1 performed the proficiency testing for Prostate Specific Antigen and Testosterone analytes for 5 of 5 testing events. 3. In an interview on 10/13 /2020 at 1030 hours, Testing Person #1 was asked if all testing persons listed on the CMS-209 performed Prostate Specific Antigen and Testosterone patient testing. She stated that all testing persons listed performed these tests. TP #1 was asked if the API proficiency testing events were rotated among all testing persons. She confirmed that she was the only testing person that performed the API proficiency testing for 2019 and 2020. This confirmed the above findings.

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 direct observation, manufacturer's instructions, laboratory records and staff interview, the laboratory failed to ensure manufacturer's preanalytical specimen storage requirements for the Testosterone analyte tested on the Qualigen analyzer were followed. Findings included: 1. During a tour of the laboratory on 10/13/2020 at 1015 hours, two patient specimens (Patient 59325 and Patient 67638) were stored in the laboratory freezer for testosterone testing to be performed at a later date. Testing person #1 stated that specimens for testosterone were not tested every day. She further stated the laboratory waits until they have a few specimens before performing the test and the specimens are stored in the freezer until tested. 2. The manufacturer's instructions for the Qualigen FastPack testosterone test stated the following: "Specimen Collection/Preparationif not tested with 24 hours, the sample should be frozen at -20C or colder." 3. Review of the laboratory record titled "Environmental Logs" revealed an acceptable temperature range for the laboratory freezer of -20 or colder. A random review of the environmental logs from October 2019 and August 2020 revealed the following days when the temperature was above -20C: October 2019; 18 of 23 days when freezer temperature was out of acceptable limits. 10/1/2019; -17C 10/2/2019; -16C 10/3/2019; -16C 10/4/2019; -17C 10/8/2019; -19C 10/9/2019; -19C 10/10/2019; -19C 10/11/2019; -19C 10/14/2019; -19C 10/15/2019; -19C 10/17 /2019; -19C 10/18/2019; -19C 10/21/2019; -12C 10/23/2019; -19C 10/28/2019; -19C 10/29/2019; -19C 10/30/2019; -19C 10/31/2019; -19C August 2020; 16 of 21 days when freezer temperature was out of acceptable limits. 08/03/2020; -16C 08/04/2020; -14C 08/05/2020; -16C 08/11/2020; -19C 08/12/2020; -19C 08/13/2020; -19C 08/14 /2020; -19C 08/18/2020; -18C 08/19/2020; -18C 08/20/2020; -18C 08/24/2020; -18C 08/25/2020; -18C 08/26/2020; -18C 08/27/2020; -18C 08/28/2020; -18C 08/31/2020; -18C 4. Review of the laboratory record titled "Testosterone Levels" revealed the

following patient specimens were stored in the freezer when the temperature was above -20C: Patients specimens stored in freezer from 10/09/2019 and tested on 10/16/2019: Patient 40760 Patient 48058 Patient 60806 Patient 43966 Patient 19669 Patient 44734 Patient 67620 Patient 67620 Patient 23941 Patients specimens stored in freezer from 08/04/2020 and tested on 08/05/2020: Patient 60249 Patient 29060 Patient 32971 Patients specimens stored in freezer from 08/07/2020 and tested on 08/19/2020: Patient 69939 Patient 69913 Patient 32813 Patient 41686 Patient 63818 Patient 69949 Patient 65415 Patient 69891 5. In an interview on 10/13/2020 at 1030 hours, the laboratory director confirmed the findings that the freezer temperature was above the acceptable range of -20 C or colder.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and in staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in preanalytic systems. 1. Review of the laboratory record titled "Environmental Logs" revealed an acceptable temperature range for the laboratory freezer of -20 or colder. A random review of the environmental logs from October 2019 and August 2020 revealed the following days when the temperature was above -20C: October 2019; 18 of 23 days when freezer temperature was out of acceptable limits. 10/1/2019; -17C 10/2/2019; -16 C 10/3/2019; -16C 10/4/2019; -17C 10/8/2019; -19C 10/9/2019; -19C 10/10/2019; -19 C 10/11/2019; -19C 10/14/2019; -19C 10/15/2019; -19C 10/17/2019; -19C 10/18/2019; -19C 10/21/2019; -12C 10/23/2019; -19C 10/28/2019; -19C 10/29/2019; -19C 10/30/2019; -19C 10/31/2019; -19C August 2020; 16 of 21 days when freezer temperature was out of acceptable limits. 08/03/2020; -16C 08/04/2020; -14C 08/05/2020; -16C 08/11/2020; -19C 08/12/2020; -19C 08/13/2020; -19C 08/14/2020; -19C 08/18/2020; -18C 08/19/2020; -18C 08/20/2020; -18C 08/24/2020; -18C 08/25/2020; -18C 08/26/2020; -18C 08/27/2020; -18C 08/28/2020; -18C 08/31/2020; -18C 2. Review of the laboratory record titled "Testosterone Levels" revealed the following patient specimens were stored in the freezer when the temperature was above -20C: Patients specimens stored in freezer from 10/09/2019 and tested on 10/16/2019: Patient 40760 Patient 48058 Patient 60806 Patient 43966 Patient 19669 Patient 44734 Patient 67620 Patient 67620 Patient 23941 Patients specimens stored in freezer from 08/04/2020 and tested on 08/05/2020: Patient 60249 Patient 29060 Patient 32971 Patients specimens stored in freezer from 08/07/2020 and tested on 08/19/2020: Patient 69939 Patient 69913 Patient 32813 Patient 41686 Patient 63818 Patient 69949 Patient 65415 Patient 69891 3. In an interview on 10/13/2020 at 1030 hours, the laboratory director and office manager were asked to provide a policy or procedure to document corrective actions performed for the unacceptable freezer temperatures. No documentation was provided. The laboratory did not establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in preanalytic systems.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, Qualigen manufacturer's instructions, personnel records, and staff interview, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 1 of 4 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form revealed 4 Testing Persons (TP #1 - TP#4) performing moderate complexity testing. 2. The manufacturer's instructions for the Qualigen FastPack (65000160 Rev. 006 07/13) chemistry analyzer stated, "Personnel Evaluation Checklists: Instructions: 1. Complete the checklist at the time of installation and training. 2. Repeat evaluations 6 months after initial installation. 3. Complete the checklist annually thereafter." 3. Review of the laboratory's personnel records revealed TP#4 was hired 12/03/2018 and was trained to perform testing on the Qualigen FastPack System on 01/03/2019. Further review of the laboratory personnel records revealed the next competency assessment was performed 01/04/2020. 4. In an interview on 10/13/2020 at 1030 hours, the office manager was asked to provide documentation of another competency assessment for TP# 4 during the first year of patient testing. No documentation was provided. This confirmed the above findings.