

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2165939	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Texan Procedure Center Llc	Street Address, City, State 7924 Gateway East Blvd Suite # 150-J, El Paso, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1411 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts(AAB) proficiency testing results from 2021 and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results returned as 'not graded' by the proficiency testing agency. The findings included: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing results from the Nonchemistry Q3 2021 testing event revealed the proficiency testing agency used the (?) code next to results which were not graded because of a lack of participant consensus." The laboratory failed to evaluate results for specimen 11 which was coded with (?) next to the result of 81 submitted by the laboratory. The Expected results for Specimen 11 as provided by the proficiency testing agency was 203-301. 3. Review of the laboratory's own proficiency testing results review found "NA" next to the Probable Cause for Failure. There was no documentation of evaluation of the results coded with exceptions. 4. An interview with testing person one listed on the Form-209 Laboratory Personnel Report conducted March 16, 2022 at 10:23 AM confirmed that the laboratory did not evaluate the results not graded by the proficiency testing agency due to nonconsensus.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Review of Laboratory records and interview of facility personnel found the laboratory failed to verify the accuracy, precision, reportable ranges and verify the reference ranges were appropriate for the patients when using the Abbott iSTAT CG8+ Cartridge and the iSTAT Kaolin Activated Clotting Time Cartridge before testing patient specimens. The findings included: 1. Review of laboratory records found no verification studies performed for the Abbott iSTAT CG8+ cartridge or the iSTAT Kaolin Activated Clotting Time Cartridge. 2. Review of patient test records found the laboratory had tested 4 patient specimens using the iSTAT Kaolin Activated Clotting Time Cartridge between August 12, 2021 and February 10, 2022 without verifying the performance of the manufacturers specifications. No patient specimens were tested using the Abbott iSTAT CG8+ cartridge. 3. Interview of Testing Person on on the Form 209- Laboratory Personnel Report conducted March 16, 2022 at 10:48 AM. She stated that "the Laboratory Director thought that because the calibration of the iSTAT was automatically done, the validation was not required."

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to have a technical consultant to provide oversight of laboratory services that met the minimum education and experience requirements. (see D 6034)

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of

podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Review of Form- 209 Laboratory Personal Report, the Technical Consultant Job Description, personnel records and interview of facility personnel the laboratory failed to have a technical consultant that met the minimum education and experience to provide technical consultation for the specialties of Hematology and Chemistry. The findings included: 1. Review of the Form- 209 Laboratory Personal Report found the laboratory designated one individual as the Technical Consultant. 2. Review of the laboratory's CLIA Technical Consultant Job Description found on page 1 under the heading Minimum Education Requirements: "The laboratory must have a technical consultant qualified by education and either training or experience to provide technical consultation for each of the specialties tested in the laboratory. The qualifications include: Be a doctor of medicine or osteopathy in the state in which the laboratory is located and be certified in anatomic, clinical pathology, or both by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications that are equivalent. OR Be a doctor of medicine, osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the state in which the laboratory is located, and have at least one year of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible." 3. Review of the personnel records for the individual designated as the Technical Consultant found he did not have previous experience or training in the specialties of Hematology or Chemistry that would qualify him as the Technical Consultant. 4. Interview of Testing person one listed on the Form- 209 Laboratory Personal Report conducted March 16, 2022 at 9:23 AM confirmed that the laboratory director did not have at least one year of experience direction and or supervising a laboratory performing moderate complexity testing in Hematology and Chemistry.