Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0680299	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tdcj-Id-B1l-Attn Adm Lab Services	1391 Fm 1328, Tennessee Colony, 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 found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
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 CMS 209, review of the laboratory's College of American Pathologists' (CAP) proficiency testing records from 2022, and 2023, and staff interview, the laboratory failed to ensure 8 of 9 testing personnel participated in proficiency testing. The findings included: 1. A review of the laboratory's CMS 209 form for the Beto facility determined the laboratory identified 9 personnel who performed testing. 2. A review of the laboratory's College of American Pathologists' proficiency testing records from 2022 and 2023 determined the testing was performed by testing personnel number 1 for 12 of 12 events. They were: 2022 AQI - A 2022 AQI - B 2022 AQI - C 2022 PCARM- A 2022 PCARM - B 2022 PCARM - C 2023 AQI - A 2023 AQI - B 2023 AQI - C 2023 PCARM - A 2023 PCARM - B 2023 PCARM - C 3. The laboratory was asked to provide documentation of the other 8 testing personnel performing proficiency testing. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/14 /2024 at 0950 hours in the conference room.
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 the laboratory's College of American Pathologists' (CAP) proficiency testing records from 2022 and 2023, and staff interview, the laboratory failed to have documentation of the laboratory director signing 11 of 12 attestations and of testing personnel signing 7 of 12. The findings included: 1. A review of the laboratory's College of American Pathologists' proficiency testing records from 2022 and 2023 determined the laboratory failed to have documentation of the laboratory director signing the following attestation statements: 2022 AQI - A 2022 AQI - B 2022 AQI - C 2022 PCARM- A 2022 PCARM - B 2023 AQI - A 2023 AQI - B 2023 AQI - C 2023 PCARM - A 2023 PCARM - B 2023 PCARM - C Note: The attestations were signed by the Registered Nurse at each location, however this had not been delegated. 2. A review of the laboratory's College of American Pathologists' proficiency testing records from 2022 and 2023 determined the laboratory failed to have documentation of testing personnel signing the following attestation statements: 2022 AQI - C 2022 PCARM - B 2023 AQI - A 2023 AQI - C 2023 PCARM - A 2023 PCARM - B 2023 PCARM - C 3. The laboratory was asked to provide documentation of the required signatures. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/14/2024 at 0945 hours in the conference room.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2023, review of the laboratory's calibration verification records from 2022 and 2023, and staff interview, the laboratory failed to retain 15 of 15 package inserts to ensure the correct acceptable ranges were used. The findings included: 1. A review of the laboratory's quality control records for the iSTAT EG6+ cartridge from 2023 identified the following lots were used: a) Level 1 301154 301157 b) Level 3 321154 321161 321154 2. A review of the laboratory's quality control records for the iSTAT troponin cartridge from 2023 identified the following lots were used: a) Level 1 011160 011164 b) Level 3 031155 031164 3. A review of the laboratory's calibration verification records for the iSTAT EG6+ cartridge from 2022 and 2023 identified the following master lots were used: 20245 21256 23011 4. A review of the laboratory's calibration verification records for the iSTAT troponin cartridge from 2022 and 2023 identified the following master lots were used: 200153 210348 220262 5. The laboratory was asked to provide the package inserts to ensure the acceptable ranges used were the ones provided by the manufacturer. No package inserts were available. 6. The laboratory director confirmed the findings in an interview conducted on 05/14/2024 at 1400 hours in the conference room.
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 manufacturer's instructions for the Abbott iSTAT analyzer, review of patient test records from September 2023, and staff interview, the laboratory failed to ensure 2 of 12 samples were tested with the timeframe defined by the manufacturer. The findings included: 1. A review of the manufacturer's instructions for the Abbott iSTAT analyzer (Art. 714258-00V, Rev. Date: 18-Oct-2021) under the section titled "Testing Timing" determined: "Within 30 minutes after collection Samples collected with anticoagulant for the measurement of sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, beta hCG and BNP." 2. A sampling of patient test records from September 2023 identified 2 of 15 patient samples which were tested for troponin more than 30 minutes after collection. They were: a) Patient: 2459769 Date: 9/12/2023 Collection: 9/12/2023 13: 23 Test time: 9/12/2023 14:05 Elapsed time: 32 minutes b) Patient: 2394020 Date: 9 /22/2023 Collection: 9/22/2023 00:15 hours Test time: 9/22/2023 00:46 hours Elapsed time: 31 minutes 3. The laboratory director confirmed the findings in an interview conducted on 05/14/2024 at 1445 hours in the conference room.
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 patient test records and staff interview, the laboratory's quality assurance program failed to identify that incorrect collection times were documented on 3 of 6 results for the Abbott iSTAT analyzer. The findings included: 1. A sampling of patient test records from September 2023 and October 2023 for Abbott iSTAT EG6+ testing identified the following 3 of 6 patients when the collection time for the sample was documented as being after the sample was tested. They were: a) Patient: 2099272 Collection: 9/13/2024 23:20 Test time: 9/13/2024 23:13 b) Patient: 2022332 Collection: 9/16/2024 11:32 Test time: 9/16/2024 11:22 c) Patient: 02459341918 Collection: 10/06/2024 23:21 Test time: 10/06/2024 23:08 2. The laboratory was asked to explain how the collection times were documented after the samples were tested. No explanation was provided. 3. The laboratory director confirmed the findings in an interview conducted on 05/14/2023 at 1445 hours in the conference room.
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: Based on review of the laboratory's equipment, review of the laboratory's test menu, and staff interview, the laboratory failed to have documentation of performing verification studies on 6 of 6 iSTAT analyzers. The findings were: 1. A review of the laboratory's equipment determined between 2022 and 2023 the laboratory received 6 new Abbott iSTAT analyzers. They were: Serial number: 242797 Serial number: 339328 Serial number: 242797 Serial number: 318389 Serial number: 318497 Serial number: 420219 2. A review of the laboratory's test menu determined the following tests were performed on each of the analyzers: a) EG6+ cartridge Sodium Potassium pH PO2 PCO2 Hematocrit b) Troponin cartridge Troponin 3. The laboratory was asked to provide documentation of verification studies on each of the analyzers. No documentation was provided. 4. An interview with the laboratory director on 05/14 /2024 at 1215 hours in the conference room confirmed the findings.
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 from 2023, review of the laboratory's test menu, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time to detect possible shifts and trends for 9 of 9 tests. The findings included: 1. A review of the laboratory's quality control records for the iSTAT EG6+ cartridge from 2023 identified the following lots were used: a) Level 1 301154 301157 b) Level 3 321154 321161 321154 2. A review of the laboratory's quality control records for the iSTAT troponin cartridge from 2023 identified the following lots were used: a) Level 1 011160 011164 b) Level 3 031155 031164 3. A review of the laboratory's test menu identified the following test were performed: a) EG6+ cartridge Sodium Potassium pH PO2 PCO2 Hematocrit b) Troponin cartridge Troponin 4. The laboratory was asked to provide documentation of monitoring quality control values over time to detect any

	possible shifts or trends. No documentation was provided. 5. The laboratory director confirmed the findings in an interview conducted on 05/14/2024 at 1235 hours in the conference room.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's equipment, review of the laboratory's records and staff interview, the laboratory director failed to ensure verification studies were performed on 9 of 9 Abbott iSTAT analyzers (refer to D5421).
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS 209 of the McConnell unit, review of the laboratory's personnel records and staff interview, the technical consultant failed to have documentation of performing 14 of 14 annual competencies in 2023. The findings included: 1. A review of the CMS 209 of the McConnell determined the facility identified 14 testing personnel. 2. A review of the laboratory's personnel records for McConnell personnel determined the facility failed to have annual competencies for 14 of 14 testing personnel for 2023. 3. The laboratory was asked to provide documentation of the technical consultant performing the required competency assessments. No documentation was provided. 4. An interview with Director of Nursing on 05/14/2024 at 1330 hours in the conference room confirmed the findings after his review of the records.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by:

	Based on review of the laboratory's records and staff interview, the laboratory failed to have documentation of education to qualify 8 of 127 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209s, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 8 of 127 testing personnel. The findings were: 1. A review of the laboratory's submitted CMS 209s determined the laboratory identified 127 testing personnel. 2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education for 8 of the 127 testing personnel. They were: Beto testing personnel number 6 - Associate's degree but doesn't state what in Jester testing personnel number 9 - Associate's degree but doesn't state what in Polunsky testing personnel number 1 - Associate program without graduation date Polunsky testing personnel number 14 - Bachelor of Science in Nursing program without graduation date Polunsky testing personnel number 15 - high school transcripts without graduation date Terrell testing personnel number 6 - Bachelor's degree from the Philippines - no foreign credentialing Young testing personnel number 6 - Associate's degree but doesn't state what in Young testing personnel number 12 - no education records 3. The laboratory was asked to provide documentation of education for the identified personnel. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/14/2024 at 1230 hours in the conference room.