Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2182395	03/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tdcj Montford Unit-Clinical Laboratory	8602 Peach St, Lubbock, 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 NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6056 - 42 C.F.R. 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview showed that the laboratory failed to self-grade results not scored by the proficiency testing agency in four of 15 events reviewed in 2022. Findings follow. A. Review of the College of American Pathologists (CAP) Evaluation results for Chemistry (C) proficiency testing records in A, B, and C testing events of 2022 showed the laboratory failed to self-grade results. The Evaluation for C-A (1), C-B (2), and C-C (3) 2022 events, showed ALP (Alkaline Phosphatase) was given a Result of "See Note [20]" for all 5 specimens in each event respectively, and the laboratory was given a false score of 100%. Review of the Participant Summary for that event under "Actions Laboratories Should Take when a PT Result is Not Graded" stated for Code 20 Exception Reason Code Description: "Response was not formally graded due to insufficient peer group data. Please see the participant summary for additional information." And, under Action Required stated, "Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that the laboratory performed a self-evaluation using the data presented in the participant summary and compared its results to a similar method, all method, all participant statistics, or data tables for groups of 3-9 laboratories, if provided. Perform

	and document the corrective action of any unacceptable results..." Review of the College of American Pathologists (CAP) Evaluation results for Clinical Microbiology (CM) proficiency testing records in B 2022 testing event showed the laboratory failed to self-grade results. The CM-B (4) 2022 event showed Urine Sediment ID for sample CMP-14 was given a Result of "See Note [27]", and the laboratory was given a false score of 100%. Review of the Participant Summary for that event under "Actions Laboratories Should Take when a PT Result is Not Graded" stated for Code 27 Exception Reason Code Description: "Lack of participant or referee consensus." And, under Action Required stated, "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." B. Documentation of self-evaluation was requested on March 14, 2023, at 1120 hours but not provided. C. Interview with the Technical Consultant, as listed on the CMS form 209, on March 14, 2023, at 1120 hours in the office confirmed the findings.
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 the manufacturer's instructions, TAT (Turn Around Time) reports, and interview, the laboratory failed to ensure specimens tested for Troponin I performed on the iSTAT were tested within 30 minutes of collection for two out of eight specimens tested from December 2022 to February 2023. Findings follow. A. Review of the iSTAT 1 System Procedure Manual, effective 03/01/2020, under Procedure Manual for the i-STAT System stated, "Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe. Test Sample collected without anticoagulant immediately. Test samples for ACT, lactate, and PT/INR immediately. Test samples for pH, PCO2, TCO2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For other cartridge tests, test sample within 30 minutes of collection." B. Review of the TAT report for 12/01/22 - 02/28/23 against the iSTAT instrument showed 2 out of 8 specimens exceeded 30 minutes from collection to tested for Troponin I: Accession # Collection Date & Time Testing Date & Time Elapsed Time 1. 223360112 12/02/22 @ 13:47 12/02/22 @ 14:55 1 hour 8 minutes 2. 230090079 01/09/23 @ 13:10 01/09 /23 @ 14:11 1 hour 1 minute C. Interview with the Technical Consultant, as listed on the CMS form 209, on March 15, 2023, at 1135 hours in the office confirmed the findings.
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 reference materials and interview, the laboratory failed to provide photomicrographs of sediment for performing microscopic urinalysis for two of two years reviewed. Findings follow. A. Photomicrographs for urine sediment were requested on March 14, 2023, at 1000 hours but not provided. B. Interview with the Technical Consultant, as listed on the CMS form 209, on March 14, 2023, at 1000 hours in the office acknowledged she used the internet to search for unknown sediment and did not have reference material in the laboratory.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of the pre-survey paperwork, personnel credentials, and interview the laboratory failed to employ personnel to provide clinical consultation for the laboratory for the moderately complex testing performed for 15 of 15 months reviewed (refer to D6057).
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the pre-survey paperwork, personnel credentials, and interview the laboratory failed to employ personnel to provide clinical consultation for the laboratory that met the qualifications of laboratory clinical consultant for the moderately complex testing performed for 15 out of 15 months reviewed. Findings follow: A. Review of the CMS form 209 Laboratory Personnel Report dated 3/14 /2023 showed the Laboratory Director also served as Clinical Consultant. B. Review of the Laboratory Director's educational credentials showed he had achieved a PhD in Microbiology, but was not board certified. C. Phone interview with the Laboratory Director on March 14, 2023, at 1150 hours in the office confirmed the findings.