

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2182395	(X3) Date Survey Completed 12/01/2021
Name of Provider or Supplier Tdcj Montford Unit-Clinical Laboratory	Street Address, City, State 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
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 proficiency testing records and interview, the laboratory failed to test proficiency testing samples in the same manner as it tested patient specimens for four out of four events for the manual differential and three out of three events for the microscopic urinalysis. Findings follow. A. Review of the College of American Pathologists (CAP) proficiency testing records from the B and C events from 2020, and the A, B, and C events from 2021 showed the C event from 2021 for the Blood Cell Identification (manual differential) and the B event from 2020 for the Clinical Microscopy (microscopic urinalysis) had three sticky notes (one for each testing person) with answers attached to the photomicrographs. B. Interview with the technical consultant on November 17, 2021 at 1430 in the laboratory confirmed everyone (3 testing personnel) participated in answering the photomicrographs and they rotated whose answer would be reported, and confirmed they have been performing the proficiency testing in this manner for each of the testing events.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

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:

I. Based on review of the manufacturer's instructions, Mean Normal Prothrombin Time (MNPT) study, interview, and email, the laboratory failed to perform the MNPT study and establishment of the reference range using 120 patient samples for Prothrombin (PT) and Activated Partial Thromboplastin Time (APTT) tested on the Siemens CA-620. Findings follow. A. Review of the Siemens Healthcare Diagnostics Sysmex CA-600 System Installation Package, Rev 2.1 02/06/2018: 1. V. Reference Interval, Verification of Reference Interval, Siemens Coagulation Procedures stated, "A reference interval is the interval between and including two reference limits. Reference intervals vary from laboratory to laboratory depending on the population, the technique, and reagent lot. Reference intervals for each assay should be established by each institution and verified whenever one or more of the assay /analyzer variables are changed. For more information on establishing reference intervals see CLSI document EP28-A3c, How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline. Your laboratory is responsible to develop internal policies and procedures for verification of performance specifications, in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable. Requirements: Donors must be from a healthy population (no known Pathological condition; no pre-surgical or hospitalized patients) Donors should not take any medications, including aspirin Donors should span the adult age range Testing should be performed over a period of several days and by different people, if possible to allow for day to day variation Samples should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing The test results from the donors should be analyzed statistically. Software that performs this calculation can be used. NOTE: Reference intervals are typically defined with a +/- 2SD. Values falling outside this range may or may not be normal and should be further evaluated. Statistically a certain percentage of these patients will be normal. However, by defining the reference range in this manner, patients who are abnormal will be less likely to go undetected. See CLSI document EP28-A3c. Calculation of Geometric Mean for PT INR 1. The MNPT for INR calculation should be the geometric mean. For data pool with a Gaussian distribution the mean and geometric mean will be essentially the same. With equal mean/median values will be similar. A skewed data pool is most likely the result of improper specimen type and additional samples may be required... 2. Use of the geometric mean is often preferred because it is less affected by outliers in the normal plasma samples or errors associated with possible non-randomness. 3. From this data, set a reference interval of the (Geometric mean - 2SD) to (Geometric mean + 2SD). Refer to the Instrument Operator's Manual for the procedure of entering the reagent lot specific ISI values and PT Geomean to allow INR calculation." 2. XIV. Lot Roll Over Procedures, Hemostasis Laboratory, Reagent Lot Roll-Over Studies, CA-600 series stated, "I. Verification of Reference Range If a lab has previously established a reference interval (using 120 samples) for its population, it may verify that reference interval." B. Review of the laboratory's MNPT

study performed at installation showed 21 samples were used in the study. The laboratory's established reference interval for PT using 21 samples was 9.4 - 11.2, and APTT using 21 samples was 22.6 - 29.7. C. Interview with the technical consultant on November 17, 2021 at 1500 hours in the laboratory confirmed they did not perform a MNPT study with 120 samples, they performed a study using 21 samples performed by the representative. D. Email from the technical consultant on 11/19/2021 reported PT testing began 05/12/2020 and PT testing volume to survey date was 2,607. Email from the technical consultant on 12/01/2021 reported APPT testing began 05/12/2020 and PT testing volume to survey date was 363. NOTE: The MNPT is used to calculate the INR and to establish the normal reference range. II. Based on review of the validation studies, patient testing records, and interview, the laboratory failed to verify the reference ranges for three of three cardiac markers, CKMB (Creatinine Kinase MB), Troponin I and BNP (B-type Natriuretic Peptide), performed using the Abbott i-STAT. Findings follow. A. Review of the laboratory's i-STAT verification of performance specifications titled i-STAT System Verification performed for: 1. CKMB May 12-13, 2019, 2. Troponin I May 13-14, 2020, 3. BNP May 20-21, 2020, did not include the verification of the normal range. B. Interview with the technical consultant on November 17, 2021 at 1635 hours in the laboratory confirmed they used the manufacturer's reference ranges, and the verification of the normal range was not performed. C. A query on the LIS showed an annual test volume of six for CKMB, 51 for Troponin I, and 16 for BNP. KEY LIS = Laboratory Information System

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, references cited, records of platelet poor study, and interview, the laboratory failed to perform platelet poor plasma studies every six months for one of three events reviewed using the Siemens CA-620 for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT). Findings follow. A. Review of the Siemens Healthcare Diagnostics Sysmex CA-600 System Installation Package, Rev 2.1 02/06/2018, XIV. Lot Roll Over Procedures, Hemostasis Laboratory, Reagent Lot Roll-Over Studies, CA-600 series stated, "I. Verification of Reference Range If a lab has previously established a reference interval (using 120 samples) for its population, it may verify that reference interval. A lab may verify a reference interval by collecting a minimum of 20 samples (10 male and 10 female representing reference population). A. 20 Normal Individuals 10 Males; 10 females representing reference population. 20 is the minimum requirement for a statistically valid study. Fresh samples preferred but frozen platelet poor plasma may be used if prepared and thawed per CLSI Guidelines. Note medication history. After review of data, history may be used for excluding aberrant results." B. Review of the CLSI H21-A5 stated at section 6.132 Other specimens stated, "it is imperative that the speed and duration are tested to determine the optimum conditions for platelet-poor plasma. The reliability of the centrifugation procedure, to ensure plasma platelet counts are within acceptable limits, should be validated every six months or after modification of the centrifuge." C. The Siemens CA-620 was validated on 04/21/2020 and a platelet poor plasma study was performed

04/21/2020. The next platelet poor plasma study was performed on 06/15/2021, 13 months and 25 days later. An additional six-month platelet poor plasma study was requested but not provided. D. Interview with the technical consultant on November 17, 2021 at 1615 hours in the laboratory confirmed the platelet poor plasma study was not performed every six months.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the calibration verification, patient testing records, and interview, the laboratory failed to perform calibration verification every six months for three of three cardiac markers, CKMB (Creatinine Kinase MB), Troponin I and BNP (B-type Natriuretic Peptide), performed using the Abbott i-STAT for three out of four events for the duration of 18 months reviewed. Findings follow. A. Review of the calibration verifications performed for CKMB, Troponin I, and BNP showed one calibration verification performed at installation in May 2020. Additional calibration verifications were requested but not provided. B. Interview with the technical consultant on November 18, 2021 at 0950 hours in the laboratory confirmed only one calibration verification had been performed at installation, and no other calibration verifications had been performed. C. A query on the LIS showed an annual test volume of six for CKMB, 51 for Troponin I, and 16 for BNP. KEY LIS = Laboratory Information System

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records, patient testing records, and interview, the laboratory failed to perform quality control everyday of patient testing or perform an IQCP (Individualized Quality Control Plan) study for three of three cardiac markers, CKMB (Creatinine Kinase MB), Troponin I and BNP (B-type Natriuretic Peptide), performed using the Abbott i-STAT for 14 out of 18 months reviewed. Findings follow. A. Review of quality control records from 10/01/2020 - 11/17/2021 for CKMB, Troponin I, and BNP showed the laboratory performed quality control once per month. Review of the quality control records showed controls were performed on the following dates: 10/01/2020 11/02/2020 12/01/2020 01/05/2021 02/01/2021 03/01/2021 03/12/2021 04/01/2021 05/03/2021 06/01/2021 07/01/2021 08/02/2021 09/01/2021 10/01/2021 10/25/2021 11/02/2021 B. Interview with the technical consultant on November 17, 2021 at 1215 hours in the laboratory acknowledged they thought the cardiac markers on the i-STAT were waived. Interview with testing personnel # 2, as listed on the CMS form 209, on November 17, 2021 at 1700 hours confirmed they were performing quality control on the i-STAT monthly and had not performed an IQCP study. C. A query on the LIS showed an annual test volume of six for CKMB, 51 for Troponin I, and 16 for BNP. KEY LIS = Laboratory Information System

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of the patient test report, validation studies, laboratory's policies and procedures, and interview, the laboratory failed to provide the established reference ranges on the Complete Blood Count (CBC) test report performed on the Beckman Coulter DXH600 for one of one test reports reviewed. Findings follow. A. Based on the test report sample ID 213210047 tested on 11/17/2021 showed the following reference ranges on the CBC test report: WBC 1.3 - 24.9 K/uL RBC 2.45 - 5.64 M/uL HGB 6.2 - 17.9 g/dL HCT 19.3 - 52.1 % MCV 72 - 107 fL MCH 25.6 - 32.2 pg MCHC 32.2 - 35.5 g/dL RDW 12.8 - 30.1 % PLT 22 - 685 K/uL MPV 6.9 - 11.3 fL NE% 47.4 - 86.2 % LY% 5.7 - 40. % MO% 3.6 - 16.1 % EO% 0.1 - 4.7 % BA% 0.2 - 1.4 % NE# 1.6 - 6.1 K/uL LY# 1.2 - 3.7 K/uL MO# 0.2 - 0.9 K/uL EO# 0.0 - 0.5 K/uL BA# 0.0 - 0.1 K/uL B. Review of the Method Comparison performed at installation, printed 03/19/2020, showed the following statistical summary: Result Range WBC 1.3 - 24.9 RBC 2.45 - 5.64 HGB 6.2 - 17.9 HCT 19.3 - 52.1 MCV 72 - 107 MCH 25.6 - 32.2 MCHC 32.2 - 35.5 RDW 12.8 - 30.1 PLT 22 - 685 MPV 6.9 - 11.3 NE% 47.4 - 86.2 LY% 5.7 - 40. MO% 3.6 - 16.1 EO% 0.1 - 4.7 BA% 0.2 - 1.4 C. Review of the laboratory's procedure titled UniCel DxH 600 Coulter Cellular Analysis System, effective 03/01/2020, starting on page 32 under Reference Ranges stated, "A study conducted to assess the Reference Ranges for the DxH 600. Whole-blood samples were collected from 50 male patients at Montford TDCJ Unit. Our reference lab, UMC, provided their normal ranges and for the sake of uniformity for our providers we compared our results with UMC's results. Our Reference range was within CLIA acceptable +/-20% for CV. Montford Unit Laboratory will utilize UMC reference range as our own. WBC 4.23 - 9.07 K/uL RBC 4.63 - 6.08 M/uL HGB 13.7

- 17.5 g/dL HCT 40.1 - 51.0 % MCV 79.0 - 92.2 fL MCH 25.7 - 32.2 pg MCHC 32.3 - 36.5 g/dL RDW 11.6 - 14.4 % PLT 163 - 337 K/uL MPV 9.4 - 12.4 fL NE% 34.0 - 71.1 % LY% 19.3 - 53.1 % MO% 4.7 - 12.5 % EO% 0.7 - 7.0 % BA% 0.1 - 1.2 % NE# 1.56 - 6.13 K/uL LY# 1.18 - 3.74 K/uL MO# 0.24 - 0.86 K/uL EO# 0.04 - 0.54 K/uL BA# 0.01 - 0.08 K/uL" D. Interview with the technical consultant on November 18, 2021 at 1010 hours in the laboratory confirmed he had mistakenly used the method comparison statistical result range as the normal reference range in the LIS. Patient testing began 03/23/2020 and they had an annual test volume of 17089. KEY: WBC (White Blood Cell) RBC (Red Blood Cell) HGB (Hemoglobin) HCT (Hematocrit) MCV (Mean Corpuscular Volume) MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) RDW (Red cell Distribution Width) PLT (Platelets) MPV (Mean Platelet Volume) NE% (percent Neutrophils) LY% (percent Lymphocytes) MO% (percent Monocytes) EO% (percent Eosinophils) BA% (percent Basophils) NE# (absolute Neutrophils) LY# (absolute Lymphocytes) MO# (absolute Monocytes) EO# (absolute Eosinophils) BA# (absolute Basophils) LIS (Laboratory Information System)

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, Mean Normal Prothrombin Time (MNPT) study, validation studies, patient testing records, interview, and email, the technical consultant failed to complete the verification of performance specifications when: 1. The laboratory failed to perform the MNPT study and establishment of the reference range using 120 patient samples for Prothrombin (PT) and Activated Partial Thromboplastin Time (APTT) tested on the Siemens CA-620 (see D5421 I). 2. The laboratory failed to verify the reference ranges for three of three cardiac markers, CKMB (Creatinine Kinase MB), Troponin I and BNP (B-type Natriuretic Peptide), performed using the Abbott i-STAT (see D5421 II).

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on review of quality control records, patient testing records, and interview, the technical consultant failed to establish a quality control program appropriate for the testing performed using the i-STAT for the moderately complex cardiac markers (refer to D5447).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 manufacturer's instructions, Mean Normal Prothrombin Time (MNPT) study, validation studies, patient testing records, interview, and email, the Laboratory Director failed to ensure the verification of performance specifications were complete when: 1. The laboratory failed to perform the MNPT study and establishment of the reference range using 120 patient samples for Prothrombin (PT) and Activated Partial Thromboplastin Time (APTT) tested on the Siemens CA-620 (see D5421 I). 2. The laboratory failed to verify the reference ranges for three of three cardiac markers, CKMB (Creatinine Kinase MB), Troponin I and BNP (B-type Natriuretic Peptide), performed using the Abbott i-STAT (see D5421 II).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of quality control records, patient testing records, and interview, the Laboratory Director failed to ensure an appropriate quality control program was established for the testing performed using the i-STAT for the moderately complex cardiac markers (refer to D5447).