Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2149371	01/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Crockett Medical Center	1100 East Loop 304, Crockett, 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	An onsite survey conducted January 17th through January 19th 2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 a review of proficiency testing records and interview with facility personnel, the laboratory director failed to attest to the routine integration of proficiency testing samples into the patient workload using the laboratory's routine methods for one of three Chemistry Miscellaneous events in 2023, one of three Chemistry core events in 2023, and one of three Hematology/Coagulation events in 2022. The findings included: 1.Based on review of the American Proficiency Institute attestation sheets, the following instructions were provided: "SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation worksheet or this online attestation statement may be used. Electronic signatures must have evidence that only the authorized person can utilize the signature." The following attestation sheets were not signed by the laboratory director: 2023 - Chemistry Miscellaneous, 1st event 2023 - Chemistry Core - 3rd event 2022 - Hematology/Coagulation 3rd event 2. In an interview at 15:14 hours on 1/ 17/24, the laboratory's Administrative Supervisor confirmed the attestations had not been signed by the laboratory director.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with facility personnel, the laboratory failed to take corrective action for the one of one event in 2023 where the laboratory had unsatisfactory analyte performance for the analyte partial pressure of carbon dioxide (pCO2). The findings included: 1. Based on review of the American Proficiency Institute evaluation reports, the laboratory received the following scores: 3rd event 2023 pCO2 - 60% Scores less than 80 percent constitute unsatisfactory analyte performance. 2. In an interview at 15:14 hours on 1/17/24 in the break room, the laboratory administrative supervisor stated the former manager did not document any corrective action for this event.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, lot roll over studies, and interview with facility personnel, the laboratory failed to follow their own policy in establishing a mean of the normal patient range (MNPT) for one of one lot rollovers of RecombiPlasTin 2G reagent in 2023. The findings included: 1. Based on the laboratory policy "ACL Elite Coagulation Procedure", under Normal Range Study, the policy stated the following: "This study is to be run when changing lots of reagents for coagulation analysis. Normal patient range study is to be performed by running 20 specimens, both male and female and representative of the testing population. The normal range is used in calculating the INR and it is very important to choose the specimens carefully. Run this study over a period of a few days at different times to get an inter-day variation. " 2. Based on documentation from 4/19/2023, the laboratory's Technical Consultant at that time documented "The based upon test results of this assay and analyzer is accepted for patient testing. Due to having done a normal study less than 2 months ago and needing to change reagent we elected to do a patient correlation between old and new lots in order to demonstrate adequacy." 3. In an interview at 14:42 hours on 1/18/2024, Testing Person 5 as listed on the CMS-209 laboratory personnel report confirmed this lot of RecombiPlasTin 2 G was put into use around May 11-15th without a study to determine the mean of the normal patient range. The international normalized ratio (INR) is calculated by dividing the patient Protime value in seconds by the mean of the normal patient range and raising that value to the power of the International Sensitivity Index (ISI). 45469 II. Based on a review of laboratory policy, laboratory temperature documents, continuous monitoring temperature charts, and confirmed in an interview, the laboratory failed to

	follow its policy for the monthly documentation of alarm checks for the Follett refrigerator where blood products are kept, for two out of five months reviewed from August to December 2023. The findings included: 1. Review of the laboratory policy titled "Blood Bank Refrigerator Check" stated the following: "The monthly temperature check's (sic) may be done at the same time you change a weekly chart." Section "Procedure" outlined the following temperature check: "Check internal thermometer, LED reading, and chart should be in close agreement. document all temperature checks on the temperature log and directly on the temperature chart. Place 2 cups of water inside the blood bank refrigerator several hours before you intend to run the alarm checks, so that they are at the refrigerator temperature. For LOW temperature alarm check (set @ 1.5 C) a. Remove the temperature probe from the fluid inside the refrigerator and place it in the first cup which is already at the same temperature. b. Add a small amount of crushed ice to the cup and watch for dropping temp. (this way it will not drop too fast). this process will cause the pen on the chart to document a drop on the chart. This is appropriate and the action should be noted directly on the chart. c. The alarm should sound as the temperature reaches 1.5 C. For HIGH temperature alarm check (set @ 5.5 C) a. Remove the temperature pro from the cold test cup and place in the second cup. (this way it will not rise too fast). b. Add 5 - 10 ml of tap water to the cup and watch for increasing temperature. c. The alarm should sound as the temperature reaches 5.5 C. Notate this action next to the mark made by the pen on the chart." 2. Review of the laboratory temperature log titled "Blood Bank Temp Log Follett Fridge" included a section at the bottom of the form for documentation of the monthly alarm/temp check for the following: "Date - Lo Temp - Alarm Sound - Hi Temp - Alarm Sound - Acceptable? - Tech" A review of the blood bank temperature logs from August to December 2023 had the following two months where the monthly alarm and temperature check was not documented: November 2023 December 2023 3. In an interview on 1/18/2024 at 16:05, in the laboratory, testing personnel (TP) 3 confirmed that the laboratory failed to perform the monthly alarm and temperature check for November and December 2023. Key: C - Celsius
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the operator's manual for the ACL Elite coagulation analyzer, maintenance logs from 2023, and interview with facility personnel, the laboratory failed to document six of twelve weekly maintenance tasks, five of six bi-weekly maintenance tasks, and three of three monthly tasks between January to March 2023. The findings included: 1. Based on review of the operator's manual for the ACL Elite (Revision 7, November 2017), the following tasks are required maintenance: Weekly: Clean instrument external surfaces with damp cloth Verify needles position and clean Rinse/Waste reservoir Bi-weekly: Clean Rotor Holder and Optic Path Reboot the System Monthly: Clean air filter 2. Based on review of maintenance logs for January 2023, the weekly maintenance was not performed and documented for three of four weeks. The bi-weekly maintenance was not performed and documented for January 2023. The monthly maintenance was not performed and documented for January 2023. Based on review of maintenance logs for February 2023, the weekly

	maintenance was not performed and documented for two of four weeks. The bi-weekly maintenance was not performed and documented for February 2023. The monthly maintenance was not performed and documented for February 2023. Based on review of maintenance logs for March 2023, the weekly maintenance was not performed and documented for one of four weeks. The bi-weekly maintenance was not performed and documented for one of two events in March 2023. The monthly maintenance was not performed and documented for March 2023. 3. In an interview at 16:31 hours on 1/18/23 in front of the coagulation analyzer, Testing Person 3 as listed on the CMS-209 laboratory personnel report confirmed the laboratory did not have other records available that could demonstrate this maintenance was performed as required.
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 a review of laboratory policy, quality control (QC) instructions for use (IFU), QC records, and confirmed in an interview, the laboratory failed to have an accurate mechanism in place to detect immediate error for two of two levels of troponin QC, on the Beckman Coulter AU480 chemistry analyzer, since it was put into use 7/17/2023: The findings included: 1. A review of the laboratory policy titled "Chemistry Quality Control Procedure", stated the following: "4. Accept/Reject Criteria: Once results are obtained, the control results will be accepted, and the patients may be reported if the following criteria are met: 1. The run may be accepted if" 1. Controls read within +/- 2SD of the established mean. 2. Review of the Liquicheck Cardiac Troponins Control, Levels 1, 2, and 3, instructions for use, section "Assignment of Values" stated the following: "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." The corresponding data chart had the following information for the Liquicheck Cardiac Troponins Control, lot 89050, expiration 05/31/2024: Troponin I (pg/mL) QC Level: Mean [3SD range] QC Level I 89051: 16.8 [3.66 - 29.9] QC Level 3 89053: 5882 [4378 - 7386] Surveyor calculated a 2SD range for the above to be: QC Level I 89051: 16.8 [8.06 - 25.54] QC Level 3 89053: 5882 [4879.34 - 6884.66] 3. A review of the laboratory QC records only listed QC levels 1 and 3 in the testing of test acceptability which included the following 2SD range for the Liquicheck Cardiac Troponins Control, lot 89050, expiration 05/31/2024: Troponin I (pg/mL) QC Level: Mean [2SD range] QC Level I 89051: 16.8 [3.66 - 29.9] QC Level 3 89053: 5882 [4378 - 7386] 4. In an interview on 1/18/2024 at 14:45, in the laboratory, TP3 stated the laboratory staff did not realize that the stated ranges in the IFU were a 3SD range and that the laboratory used a 2SD criteria to determine acceptability.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, surveyor observations, and interview with facility personnel, the laboratory failed to have a system that twice a year evaluate the relationship between test results using the different methodologies, instruments, or test sites for two of two hematology analyzers, two of two Triage chemistry analyzers. The findings included: 1. Based on review of the laboratory policy "Bi-Annual Method Comparison - Draft", effective October 13, 2022, the policy stated: "The number of samples required for the comparison study will be 10 patients. These are to be ran a few at a time by all techs on all shifts for a total of 10 sample results. The samples will be run on one method and then the other method for a comparison of results. This must be done on the same patient sample for each method. The results will be compiled and given to the laboratory manager for data entry and statistical comparison of results. These results wil compare clinical allowable bias between both methods of testing. The paired Data calculator on Westgard.com is statistical tool that can be used for this comparison of values. After the data is put in, a report can be generated showing the comparison of the values." 2. Based on surveyor observations at 15:55 hours in the laboratory, the laboratory had two hematology analyzers, two Triage chemistry analyzers. 3. In an interview at 16:00 hours on 1/17/2024 in the break room, the Administrative Supervisor confirmed the laboratory had not performed comparison studies in 2023 to evaluate the relationship between different instruments and/or methodologies. This is a repeat deficiency cited on the initial certification inspection in October 2021.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory personnel competency assessments, and confirmed in interview, the laboratory failed to document competency assessments for two of six personnel performing moderate complexity testing in 2023. The findings included: 1. Review of the laboratory policy titled "Laboratory QA Plan", section "Annual Evaluation of Employee Competency" stated the following: "Annually the Laboratory Director is to review the competency assessments of all laboratory employees." 2. Review of laboratory testing personnel (TP) records for 2023 did not include and annual competency evaluation for the following two testing persons: TP2 TP6 3. In an interview on 1/17/2024 at 14:00 hours, in the breakroom, the laboratory administrative supervisor confirmed that the laboratory did not have record of the 2023 competency assessments for TP2 and TP6.