Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483827	02/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Freestone Medical Center	125 Newman St, Fairfield, 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 February 21st and 22nd of 2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturers' instructions, laboratory maintenance records, and confirmed in interview, the laboratory failed to perform one of four quarterly maintenance tasks required in 2022 for the CA-660 coagulation analyzer. The findings include: 1. Review of the Sysmex Quick Reference Guide had the following maintenance to be performed quarterly: "- LED Calibration Refer to the LED page to perform an LED Calibration." 2. Review of the laboratory "Sysmex CA-600 Operator's Maintenance Checklist" for 2022 had documentation of quarterly maintenance being performed as follows: Perform LED Calibration: 3/25/2022 10/1 /2022 12/30/2022 3. In an interview on 2/21/2023 at 16:40, in the conference room, the technical consultant confirmed that the fourth quarterly maintenance had not been documented elsewhere for the LED calibration for 2022. II. Based on review of manufacturers' instructions, laboratory maintenance records, and confirmed in interview, the laboratory failed to perform three of four quarterly maintenance tasks required in 2022 for the CA-660 coagulation analyzer. The findings include: 1. Review of the Sysmex Quick Reference Guide had the following maintenance to be performed quarterly: "- Cleaning the rinse container 1. Turn OFF the instrument power. 2. Turn the cap of the rinse bottle counterclockwise to release the pressure from the bottle. Place cap on a clean paper towel. 3. Discard any remaining liquid in

	the rinse bottle. 4. Add 250-300 mL of 70% isopropyl alcohol to the rinse bottle. 5. Replace the cap on the rinse bottle to make sure it comes in contact with all surfaces, including the float switch. 7. Discard the alcohol and rinse the bottle well with distilled water." 2. Review of the laboratory "Sysmex CA-600 Operator's Maintenance Checklist" for 2022 had documentation of quarterly maintenance being performed as follows: Clean DI Water Rinse Bottle with Alcohol: 3/31/2022 3. In an interview on 2 /21/2023 at 16:40, in the conference room, the technical consultant confirmed that the remaining three quarterly maintenance had not been documented elsewhere for the DI Water Rinse Bottle for 2022.
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 laboratory policy, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to have documentation in place to monitor accuracy and precision over time for Prothrombin Time (PT) for five to five months from March to July 2022 on the Sysmex CA-660 coagulation analyzer use in patient coagulation testing. The findings include: 1. Review of the laboratory policy titled "C-003 Prothrombin time/INR", section "Quality Control" had the following statement: "Control results are entered into the RealTime QC software program for monthly analysis." 2. Surveyor queried the technical consultant (TC) for documentation of monthly quality control for PT, to monitor for accuracy and precision over time, from March to July 2022, and none was provided. The TC stated that the software program had deleted the documentation for the previous lot number of QC in use and that they had not printed hard copies since all review was performed in the software system. 3. In an interview on 2/21/2023 at 14:55 hours, the TC confirmed that the laboratory did not have documentation that accuracy and precision had been monitored for prothrombin time QC on the Sysmex CA-660 coagulation analyzer from March to July 2022.
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 with facility personnel, the laboratory failed to perform two levels of quality control each day of patient testing for 14 of 17 days of testing in September 2022 for the D-dimer assay performed on the Triage analyzer. The findings included: 1. Based on review of quality control records, the laboratory performed two levels of quality control for D-dimer on 9/6/2022. The "Triage QC & Maintenance Log" contained the following documentation: "Installed/Qc'd D-Dimer Lot#T13193N on Triage #1 L1-536, L-2 2,240 Triage #2 L1-508 L2-2130 9/6/2022" 2. Based on review of patient records, 19 patients were tested on 14 days in September that did not have documentation of two levels of quality control for the D-Dimer assay. Patient ID Date of Testing 1134751 09 /01/2022 1135030 09/05/2022 1135040 09/05/2022 1135413 09/08/2022 1135566 09 /10/2022 1135669 09/12/2022 1135704 09/12/2022 1135752 09/13/2022 1135862 09 /13/2022 1136172 09/17/2022 1136251 09/19/2022 1136624 09/22/2022 1136776 09 /24/2022 1136843 09/26/2022 1136883 09/26/2022 1136932 09/27/2022 1137166 09 /29/2022 1137313 09/30/2022 1137359 09/30/2022 3. In an interview at 15:00 hours on 2/21/2022 in the conference room, the Laboratory Manager confirmed two levels of quality control had not been performed each day of patient testing for the D-Dimer analyte on the Triage chemistry analyzers during September 2022.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Dimension chemistry analyzer operator's manual, quality control instructions for use, review of quality control records, and interview with facility personnel, the laboratory failed to accurately enter quality control acceptability criteria for three of three levels of quality control material used to assure the accuracy of twenty-six chemistry assays in February 2023. The findings included: 1. Based on review of the Dimension chemistry analyzer operator's manual (Dimension EXL with LM/EXL 200 System Operator's Guide), on page 4-27, the operator's manual stated the following: "Enter QC Ranges 1. Select FS: PROCESS CTRL > F4: QC RANGES. 2. Select the test key for the assay that will be edited. 3. Select the Lytes test key, then select F1: NEXT METHOD to see the K and Cl assays. 4. For each QC level, enter the QC range (low and high), expected mean, or expected SD as appropriate. The number of QC levels used determines how many days of QC data can be stored in the software for an assay." 2. Based on review of the BioRad Liquid Assayed Multiqual Premium quality control instructions for use (English * 2021-10 * 5871-00), under ASSIGNMENT OF VALUES, the instructions stated the

	following: "The mean values and corresponding plus/minus 3 SD ranges in the Assignment of Values Data charts (available separately) were derived from replicate analyses and are specific for this lot of product." 3. Based on review of the laboratory's quality control policy "POLICY NUMBER: CH-007 CONTROL RULES FOR REPORTING PATIENT DATA", under Purpose, the policy stated: "Quality control (QC) results are used to validate whether the instrument is operating within pre-defined specifications, inferring that patient test results are reliable. Once the test system is validated, patient results can then be used for diagnosis, prognosis, or treatment planning. Westgard Rules are multi-rule control procedures used to monitor clinical chemistry control values. The purpose of Westgard Rules are: 1. To detect errors 2. Monitor sensitivity to both random and systematic errors The Westgard Rules applied to control runs in the chemistry department are: 1. 1-2S - This is a warning rule only. If one control measurement exceeds the mean +/- 2 standard deviations, other controls in the run (within the run) and in previous runs should be evaluated before accepting the run and reporting the results. 2. 1-3.5s- rule indicates random error and may also indicate systematic error. The run is considered out of control when one control value exceeds the mean 3.5SD. This rule is applied within the run only. 3. R4s - reject when 1 control measurement in a group exceeds the mean plus 2s and another exceeds the mean minus 2s." 4. Based on a review of from February 1, 2023, the laboratory had set the Bio-Rad three standard deviation ranges in place of the acceptability criteria in the instrument software. Based on a random review of quality control records, the following Bio-Rad 3SD ranges had been entered into the laboratory's instrument acceptability criteria: Level 1 Analyte Lab Range Bio-Rad 3SD Sodium 114-124 114-124 Total Protein 3.9- 4.4 3.86-4.42 Phosphorus 1.8-2.3 1.78-2.32 Glucose 54-66 54.3-65.6 Urea Nitrogen 13-18 12.7-18 Level 2 Analyte Lab Range Bio-Rad 3SD Sodium 138-149 138-149 ALP 131-175 131-175 Glucose 115-133 115-133 Level 3 Analyte Lab Range Bio-Rad 3SD Sodium 154-166 154-166 Cholesterol 234-283 234-283 Chloride 116-129 116-129 AST 235-272 235-272 The outcome of using the Bio-Rad 3SD ranges as acceptability criteria for the assays would be the laboratory would not be able to apply quality control rules from the policy that were related to 2SD such as the 1-2S or R4 rules. 5. In an interview at 09: 59 hours on 2/22/2023 in the laboratory, the Laboratory Manager stated the night shift was responsible for updating the quality control ranges and they likely did not calculate the expected standard deviation based on the Bio-Rad assignment of values. Key: SD - Standard deviation QC - quality control K - potassium Cl- Chloride ALP - Alkaline Phosphatase AST - Aspartate Aminotransferase
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 instruments, assay instructions for use, and interview with facility personnel, the laboratory failed to evaluate and define the relationship between test results using different instruments or methodologies for the analyte CK-MB performed on both the Triage analyzer and the Dimension analyzer for two of two events in 2022. The findings included: 1. Based on review of laboratory

	instrumentation test menu documentation, the laboratory performed the same test using different methodolgies or instrumentation for the following: Complete Blood Counts - Sysmex XN-450 and XN-550 Siemens Dimension EXL 200 - two instruments performing routine chemistry tests including sodium, potassium, chloride Alere Triage - two instruments performing Cardiac Panels including Troponin I, Myoglobin, CK-MB CK-MB is performed on both the Dimension EXL platforms and the Alere Triage analyzers. 2. Based on review of the Triage Cardiac Panel instructions for use, under Principles of the Procedure, the instructions stated: "The Alere Triage Cardiac Panel is a single use fluorescence immunoassay device designed to determine the concentration of CK-MB, myoglobin and troponin I in EDTA anticoagulated whole blood or plasma specimens. The test procedure involves the addition of several drops of an EDTA anticoagulated whole blood or plasma specimen to the sample port on the Test Device. After addition of the specimen, the whole blood cells are separated from the plasma using a filter contained in the Test Device. The specimen reacts with fluorescent antibody conjugates and flows through the Test Device by capillary action. Complexes of each fluorescent antibody conjugate are captured on discrete zones specific for each analyte. The Test Device is inserted into the Alere Triage Meter (hereafter referred to as Meter). The Meter is programmed to perform the analysis after the specimen has reacted with the reagents within the Test Device. The analysis is based on the amount of fluorescence the Meter detects within a measurement zone on the Test Device. The concentration of the analyte(s) in the specimen is directly proportional to the fluorescence detected. The results are displayed on the Meter screen in approximately 20 minutes from the addition of specimen. All results are stored in the Meter memory to display or print when needed. If connected, the Meter can transmit results to the lab or hospital information system." Based on review of the Dimension EXL 200 LMMB (CK-MB) instructions for use, the instructions stated: Principles of Procedure: The LMMB method Is a one-step enzyme immunoassay based on the 'sandwich" principle. The sample Is incubated with chromium dioxide particles coated with monoclonal antibodies' specific for CKB subunit, and conjugate reagent (B-galactosidase labeled monoclonal antibodies' specific for CKMB isoenzyme).' A particle/CKMB/conjugate sandwich forms during the incubation period. Unbound conjugate is removed by magnetic separation and washing. The sandwich bound B-galactosidase is combined with a chromogenic substrate chlorophenol red B-d-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore (CPR). The concentration of CKMB present in the patient sample is directly proportional to the rate of color change due to formation of CPR measured at 577 nm. The amount of CKMB protein is measured immunologically, and the results are reported In mass units (ng/ml or ug/L). The Triage and Dimension platforms use different methodologies to measure the analyte CK-MB. Based on review of documentation and policy, the laboratory did not have a means to evaluate the relationship between multiple instruments performing the same test or across multiple methodologies. 3. In an interview at 09:30 hours on 2/22/2023 in the conference room, the Laboratory Manager stated that the laboratory would use proficiency samples to compare between analzyers but did not have a formal policy or evaluation of bias between methodologies such as CKMB performed on the Triage versus CKMB performed on the Dimension EXL 200 platforms.