Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483827	10/14/2021
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Review of manufacturer's instructions, patient final reports, personnel records and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Sofia SARS Antigen FIA , Sofia Flu+SARS Antigen FIA and the the GeneXpert Xpert Xpress SARS-COV-2/Flu/RSV test kits for testing patients as defined by the manufacturer under the Emergency Use Authorization (EUA). The findings included: 1. Review of the manufacturer's instructions for the Sofia SARS Antigen FIA found on page 19 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories must include with the test result reports, all authorized Fact Sheets." Further review found: " All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with authorized labeling." 2. Review of patient test records found the laboratory had tested 9081 patient specimens for SARS Covid providing no fact sheets with the final reports between December 2020 and the date of the inspection. 3. Review of personnel records found no documentation of training for eight of eight testing personnel. Interview of the General Supervisor conducted October 12, 2021 at 12:58 PM confirmed that the authorized Fact Sheets were not included with the patient test results for SARS COV-2 testing, and the laboratory failed to document training for eight of eight testing personnel.
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: Review of quality control records and interview of facility personnel found the laboratory failed to retain instrument printouts for Prothrombin time (Protime) and Activated Partial Thromboplastin time (APTT) tested on the ACL Elite coagulation analyzer between January 1, 2021 and July 29, 2021. The findings included: 1. Review of quality control records found the laboratory had printed and retained the monthly summary reports for Protime and APTT but did not retain individual printouts between January 1, 2021 and July 29, 2021. 2. Interview of the General Supervisor conducted on October 14, 2021 at 9:22 AM confirmed that the laboratory did not retain instrument printouts. She stated the printer was broken and results were transmitted directly into the Laboratory Information system (LIS) during this time.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observations, review of media quality control records, and verified in staff interview, it was revealed the laboratory failed to perform quality control procedures to ensure that each batch of blood culture media used for patient testing was able to support growth of organisms. The findings included : 1. Observations made during the tour of the facility found the laboratory was currently using blood culture media lots as follows: a. BacT Alert (anaerobic) FN Plus Lot # 0004100216 Expiration Date: 2022-03-17 3045727 12-09-2016 b. BacT Alert (pediatric) PF Plus Lot # 0004057068 Expiration Date: 2022-02-26 3045837 12-29-2016 c. BacT Alert (aerobic) FA Plus Lot #0004100216 Expiration Date: 2022-04-16 3045847 12-27-2016 2. The laboratory was asked to provide documentation of performing quality control testing for ability to support growth for each lot number of commercially prepared media it received or an IQCP study to modify the required frequency of controls. No documentation was provided. 3. Review of patient test records found the laboratory had tested 285 patients in 2021 for blood cultures without performing quality control procedures to ensure the media supports growth of microorganisms. 4. Interview with testing personnel conducted on October 13, 2021 at 9:45 AM confirmed the above findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

	(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Review of policies and procedures, refrigerator and freezer temperature records, observations and interview of facility personnel found the laboratory failed to to store fresh frozen plasma (for transfusion purposes) in a freezer with an audible alarm system that continuously monitors the product storage temperature. The findings included: 1. Review of policy BB-028 Quality Control of Refrigerator/Freezer Units (revised November 19, 2018) found on page 1: "Blood components, blood samples from patients and reagents for blood bank must be maintained with strict range of temperature, in order to ensure efficacy and avoid some potentially severe complications. For refrigerated storage, refrigerators must have a fan or be of the capacity and design to ensure stable, designated temperature is maintained throughout. The temperature of all areas of the Blood Bank refrigerator must be between 1 and 6C. The temperature of the Blood Bank plasma freezer must be at -18C or colder. There must be a system to continuously monitor the temperature of the Blood Bank refrigerator and freezer. There must be continuous surveillance of temperature. Standard recorders provide a continuous written record (temperature Chart). For circumstances when these recording devices fail to function, temperatures must be recorded at least every 4 hours. Temperature fluctuations that exceed the regulatory requirements must be explained in writing on the written record (i.e. door ajar, or alarm check). At the end of each 7 day cycle, the recording chart from the mechanical recording device should be changed, dated, and initialed by the individual changing the chart. The blood bank refrigerator and freezer is equipped with an alarm system. The alarm alerts personnel to take appropriate action before stored blood components reach undesirable temperatures. The alarm signals at the nursing station that has adequate personnel coverage 24 hours per day. The sound on this audible alarm can be heard by any personnel in adjacent hallways." 2. Review of refrigerator and freezer temperature recording charts for 2020 and 2021 found no documentation of continuous temperature monitoring (using temperature recording graphs) of the freezer used to store fresh frozen plasma after June 2, 2021. Temperature recording graphs were requested and a temperature log with daily recording of freezer temperatures was provided. 3. Observations made during the tour of the facility found the laboratory did not have a means to continuously monitor and record the temperature of the Jewett freezer (SN 1132819601210628 Model JPL 430A21) used to store fresh frozen plasma. Current Inventory of plasma stored in the freezer included: one unit O negative plasma one unit B positive plasma one unit B negative plasma two units A positive plasma one unit AB negative plasma three units O positive plasma. 4. Interview of the General Supervisor conducted October 12, 2021 at 4:23 PM confirmed the laboratory did not have a means to continuously monitor and record the temperature of the blood bank freezer used to store fresh frozen plasma. She stated that the previous freezer died June 2, 2021 and was replaced with the Jewett freezer on July 29, 2021. She states that she bought the temperature monitoring device for the freezer but the maintenance department said they can't attach it". She went on to say the laboratory measures the freezer temperature once each day and records it on the blood bank temperature and humidity logs.

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: Review of the verification records provided for the Sysmex XN 450 and 550 hematology analyzers found that the technical consultant failed to ensure that the reference range study met the manufacturer's specifications. The verification study had no documentation of review.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of policies and procedures, testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for three of eight testing personnel performing high complexity procedures. The findings included: 1. Review of the policy GL-021 LABORATORY PERSONNEL COMPETENCY ASSESSMENT POLICY (approved 10May19) found on page one under the heading POLICY: "1. Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. 2. Competency must be assessed a minimum of twice in the first year of employment for testing personnel and annually thereafter. Competence must also be assessed, prior to reporting results, whenever there are test methodology or instrumentation changes. Competency assessment can be done throughout the year the entire year coordinating it with routine practices and procedures to minimize impact on workload. 3. Competency will be documented in writing with additional supporting documentation when indicated. These records may be retained electronically or on paper. An annual Competency Assessment Summary Form must be completed for each person indicating the dates of assessment, procedure, method of assessment, identity of person assessing the competency, and dates of review. 4. Competency assessments will be performed by the Laboratory Director or Laboratory Supervisor/Manager who have documented competency and are proficient in the area assessed. Personnel performing the assessment must at a minimum meet the CLIA requirements of general supervisor, but need not be in a supervisory position." 2. Review of personnel files found: Testing person 4 (hired 03/04/2019) had no record of semiannual competency evaluations during 2021. Testing person 5 (hired 09/03/2019) had no record of semiannual competency evaluations during 2021. Testing person 7 (hired 07/29/2019) had no record of semiannual competency evaluations during 2021. 3. Interview of the general supervisor conducted October 12, 2021 at 10:38 AM confirmed that competency assessments would have to be retrieved from the Human Resources department if they were not in the laboratory files. Interview of personnel in the Human resources department conducted October 12, 2021 at 11:32 AM

	confirmed no additional competency assessment records were available for review for testing persons four, five and seven.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of policies and procedures, testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least annually for three of eight testing personnel performing high complexity procedures in 2020 and 2021. The findings included: 1. Review of the policy GL-021 LABORATORY PERSONNEL COMPETENCY ASSESSMENT POLICY (approved 10May19) found on page one under the heading POLICY: "1. Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. 2. Competency must be assessed a minimum of twice in the first year of employment for testing personnel and annually thereafter. Competence must also be assessed, prior to reporting results, whenever there are test methodology or instrumentation changes. Competency assessment can be done throughout the year the entire year coordinating it with routine practices and procedures to minimize impact on workload. 3. Competency will be documented in writing with additional supporting documentation when indicated. These records may be retained electronically or on paper. An annual Competency Assessment Summary Form must be completed for each person indicating the dates of assessment, procedure, method of assessment, identity of person assessing the competency, and dates of review. 4. Competency assessments will be performed by the Laboratory Director or Laboratory Supervisor/Manager who have documented competency and are proficient in the area assessed. Personnel performing the assessment must at a minimum meet the CLIA requirements of general supervisor, but need not be in a supervisory position." 2. Review of personnel files found: Testing person 1 (hire date September 26, 2018) had no documentation of competency assessment for 2020 or 2021. Testing person 3 (hire date December 10, 2018) had no documentation of competency assessment for 2020 or 2021. Testing person 6 (hire date 08/30/2015) had no documentation of competency assessment for 2020 or 2021. 3. Interview of the general supervisor conducted October 12, 2021 at 10:38 AM confirmed that competency assessments would have to be retrieved from the Human Resources department if they were not in the laboratory files. Interview of personnel in the Human resources department conducted October 12, 2021 at 11:32 AM confirmed no additional competency assessment records were available for review for testing persons one three and six.