Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0499286	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Frio Regional Hospital	200 South Ih 35, Pearsall, 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
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: Based on review of laboratory policy, review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to resolve flags on patient results prior to their release to the healthcare provider. The findings were: 1. Review of laboratory policy, "Laboratory Procedure Blood Smear Preparation and Manual Differential" approved by the laboratory director on September 22, 2016 under, "Testing Procedure" it stated, "1. Flags are present on the automated differential report. For the primary hematology analyzer, the Abbott Ruby, flags are addressed in Section 3 of the Operator's Manual, 30-27 through 3-40. Please refer to the Ruby Operator's Manual for detailed descriptions for the differential flags, and 2. Smear review is indicated by an automated note on the instrument report." 2. Review of the manufacturer's instructions for the Abbott Cell-Dyn Ruby (9140547C, December 2008) under "Principles of Operation" it stated, "RBC MORPH: 1. Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria. 2. If NRBC or RRBCs are suspected to be present, run the specimen in the CBC+RBC test section." 3. Random review of patient results from January 2019 revealed the following patient results that were flagged with "RBC MORPH" and no stained smear was reviewed as required by the manufacturer: Specimen # 41231 Date: January 1, 2019 Flag: RBC MORPH Specimen # 41234 Date: January 1, 2019 Flag: RBC MORPH Specimen # 41581 Date: January 2, 2019 Flag: RBC MORPH Specimen # 41612 Date: January 2, 2019 Flag: RBC MORPH Specimen # 41621 Date: January 2,

	2019 Flag: RBC MORPH Specimen # 41624 Date: January 2, 2019 Flag: RBC MORPH 4. An interview with testing personnel one (as listed on Form CMS-209) on January 14, 2019 at 16:30 hours in the laboratory confirmed the findings. He confirmed the laboratory did not review stained smears for the CBC flag "RBC MORPH." Key: NRBC - nucleated red blood cell PLT - platelet CMS - Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the temperature of the environment where supplies were located. The findings were: 1. Surveyor observation made on January 15, 2019 of stored supplies located in the Emergency Department revealed the following: a. BD Sodium citrate tubes (Lot B180734): quantity of 99 b. Vaccuette Serum tubes (Lot 8183825): quantity of 100 c. Vaccuette EDTA tubes (Lot 1807E6): quantity of 95 d. Vaccuette Lithium Heparin tubes (Lot B1809385): quantity of 92 e. Copan Specimen Transport System for Aerobes and Anaerobes (Lot 180349400): quantity of 7 2. Review of manufacturer's instructions for BD tubes located on package labeling for vacutainer tubes stated the storage requirement was, "4-25 degrees Celsius." 3. Review of the manufacturer's instructions for Vacccuette tubes located on the package labeling for vacutainer tubes stated the storage requirement was, "4-25 degrees Celsius." 4. Review of manufacturer's instructions for Copan swabs located on package labeling stated the storage requirement was, "5-25 degrees Celsius." 5. Interview with the Director of Emergency Department and Trauma Services on January 15, 2019 at 15:05 hours confirmed the findings. She confirmed that the temperature of the environment where the supplies are located is not documented. Key: EDTA - ethylenediamenetetraacetic acid BD - Becton Dickinson
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to label reagents stored in the laboratory. The findings were: 1.

	Surveyor observation on January 14, 2019 at 17:30 hours in the laboratory refrigerator revealed a yellow liquid in a vial with a blue cap. The vial was not labeled with any information. 2. An interview with testing personnel two (as listed on Form CMS-209) on January 14, 2019 at 17:30 hours confirmed the findings. He revealed the vial was filled with analyzer cleaner used for the hematology instrument. He agreed the vial was not labeled. Key: CMS - Centers for Medicare and Medicaid Services
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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: Based on review of manufacturer's instructions, review of validation records, and confirmed in interview of facility, the laboratory failed to perform verification studies on pediatric patients on the ACL Elite coagulation analyzer. The findings were: 1. Review of the manufacturer's instructions for the ACL Elite coagulation analyzer (Rev B, April 2014) under, "Specimen Collection and Preparation" it stated, "Donors should span the adult range. Pediatric ranges should be established separately." 2. Review of verification records revealed the laboratory did not perform a patient normal range study for pediatric ranges. 3. Random review of patient results from September 2018 to December 2018 revealed a PT w/INR and PTT was performed and resulted on the following pediatric patient: Order # 32576 Date: 11-26-2018 Result: PT w/INR = 12.3 seconds, INR = 1.0 Order # 32577 Date: 11-26-2018 Result: PTT = 33.4 4. Interview of the technical consultant in the laboratory on January 15, 2019 at 09:00 hours confirmed the findings. Key: PT - prothrombin time INR - International Normalized Ratio PTT - partial thrombin time
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to perform a positive and negative control each day of testing for Clostridium Difficile Toxin (CDT). The findings were: 1. Based on review of laboratory policy, "CDIFF Immunocard Toxins A & B" under, "External QC" stated, "External QC Frequency: The external controls should be run: with every kit opened, for each day of patient testing, when training new personnel on

	test kit use." 2. Review of the manufacturer's instructions for Imunocard Toxins A & B (Ref. 712050) under, "Quality Control" it stated, "This test should be performed per applicable local, state, or federal regulations or accrediting agencies." 3. Review of patient results from November and December 2018 revealed the following patients were performed on days that quality control was not performed: Order # 299006 Date: November 8, 2018 Result: Negative Order # 33298 Date: November 29, 2018 Result: Negative Order # 33392 Date: November 29, 2018 Result: Negative Order # 33568 Date: November 30, 2019 Result: Negative Order # 34127 Date: December 2, 2018 Result: Negative 4. An interview with the technical consultant on January 14, 2019 at 15:30 hours in the office confirmed the findings.