Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507284	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Childress Regional Medical Center	Highway 83 North, Childress, 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 the corQC Test System manufacturer instructions, and interview of facility personnel, the the laboratory failed to follow the manufacturer's instructions for recording the reagent lot number and expiration dates used for immunohematology testing when testing daily Quality Control (QC) each day of patient testing in 2022. The findings included: 1. Review of the corQC Test System manufacturer instructions found on page 1 under the heading Test Method: "Record the lot number and expiration date of each reagent and observations on the corQC log sheet." 2. Review of Immunohematology records for 2022 found the laboratory recorded quality control results on the blood bank transfusion logs without documenting lot numbers and expiration dates instead of using the corQC log sheet. 3. In interview of the general supervisor conducted October 12 at 9:54 AM confirmed that testing personnel did not follow the manufacturer instructions for using the corQC Test System.
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: I. Observations, patient test records and interview of facility personnel, the laboratory failed to verify the performance specifications of the erythrocyte sedimentation rate using the Alcor miniiSED erythrocyte sedimentation analyzer prior to testing 375 patient specimens. The findings included: 1. Observations made during the inspection found the laboratory was using the miniiSED erythrocyte sedimentation analyzer (serial number 1677) to test patient specimens for sedimentation rates. 2. Review of patient test records found the laboratory had tested 375 patient specimens using the Alcor miniiSED erythrocyte sedimentation analyzer since the installation of the analyzer on May 1, 2022. 3. During interview of the General Supervisor conducted October 12, 2022 at 10:00 AM, she stated she may not have printed the verification study and put it in the book. She went on to say that the laboratory "did the work according to the manufacturer's written protocol". Verification studies for the Alcor miniiSED erythrocyte sedimentation analyzer were not included in the notebook provided under the verification tab. They were requested twice more at 1:22 PM and 5: 30 PM.
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 quality control records, patient test records, and interview with facility personnel, the laboratory failed to ensure that testing personnel had a means of identifying immediate errors in quality control results for Prothrombin Time. The findings included: 1. Based on review of the Prothrombin Time Levy Jennings graphs from the CPSI Laboratory information Systems and the ACL TOP 350 for September 2022 the following quality control values were outside of the laboratory's acceptable limits on September 18, 2022. CPSI Quality control records defined an acceptable Range for Hemosil Normal Control of 11.0 to 13.0 seconds. 14:07 - 10.5 seconds with control not repeated 22:09 - 10.6 seconds with control not repeated ACL TOP 350 control records defined an acceptable range for Hemosil Normal Control 1 of 11.6 to 13.2 seconds 06:03 - 11.3 seconds with control not repeated 14:07 - 10.5 seconds with control not repeated 22:09 - 10.6 seconds with control not repeated 2. Based on review of the patient worklist for September 18, 2022, the laboratory reported 3 patient specimens when Prothromin Normal Control 1 was low and outside of acceptable limits. patient 10386630 reported at 06:31 patient 10386634 reported at 13: 19 patient 10386657 reported at 21:18 3. In interview conducted on October 12, 2022

	at 8:43 AM the General Supervisor confirmed that patient results were released without acceptable quality control results. She stated the testing personnel should have verified the results were acceptable through CPSI and they should be repeating quality control levels that fail before patient results were reported.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records, patient test records, and interview with facility personnel, the laboratory failed to ensure that the results of Prothrombin Time quality control materials were acceptable prior to reporting patient test results for one of thirty days in September 2022, when 3 patient results were tested and reported without two levels of acceptable quality control. The findings included: 1. Based on review of the Prothrombin Time Levy Jennings graphs from the CPSI Laboratory information Systems and the ACL TOP 350 for September 2022 the following quality control values were outside of the laboratory's acceptable limits on September 18, 2022. CPSI Quality control records defined an acceptable Range for Hemosil Normal Control of 11.0 to 13.0 seconds. 14:07 - 10.5 seconds with control not repeated 22:09 - 10.6 seconds with control not repeated ACL TOP 350 control records defined an acceptable range for Hemosil Normal Control 1 of 11.6 to 13.2 seconds 06:03 - 11.3 seconds with control not repeated 14:07 - 10.5 seconds with control not repeated 22: 09 - 10.6 seconds with control not repeated 2. Based on review of the patient worklist for September 18, 2022, the laboratory reported 3 patient specimens when Prothromin Normal Control 1 was low and outside of acceptable limits. patient 10386630 reported at 06:31 patient 10386634 reported at 13:19 patient 10386657 reported at 21:18 3. In interview conducted on October 12, 2022 at 8:43 AM the General Supervisor confirmed that patient results were released without acceptable quality control results. She stated the testing personnel should have verified the results were acceptable through CPSI and they should be repeating quality control levels that fail before patient results were reported.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Review of quality control records, patient test records and interview of facility personnel, the laboratory director failed to ensure the quality control program was

	maintained to ensure patient samples were not tested for Prothrombin Time without two levels of acceptable quality control tested every 8 hours of patient testing. (See D 5441 and D 5481)
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review of the CMS report 209 Laboratory Personnel Report, personnel files and interview of facility personnel found the laboratory director failed to specify in writing, the responsibilities and duties for 12 of 12 testing personnel involved in non-waived testing. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory designated 12 testing personnel, t10 performing high complexity testing and two performing moderate complexity testing. 2. Review of personnel files found no written delegation of duties for testing personnel defining the procedures they were authorized to perform. 3. In interview of the general supervisor conducted October 11, 2022 at 9:34 AM she confirmed that he did not designate in writing the duties and responsibilities of each testing person involved in non-waived testing.