Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0976266	05/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
East Texas Border Health Clinic	1011 S William Street, Atlanta, 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 05/05/2022 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: Review of manufacturer's instructions, instrument printouts, and patient final reports and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for the handling of patient sample flags for four out of four random patients reviewed in March and April 2022 for the Sysmex XP-300 hematology analyzer. The findings include: 1. Review of the Sysmex Automated Hematology Analyzer XP-300 Instructions for Use, chapter 8 "Display and Output for Analysis Results" 8.3 "Histogram Flags" had the following statement for the meanings of signs displayed on the left of the analysis data: "Sign - Explanation [*] - Result is unreliable [AG] Flag Probable Sample Cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): 1) Check smear, ect." 2. Review of random patient instrument printouts and final patient results had the following patients with histogram flags resulted without corrective action: Sample ID /Date/Flag 158338 / 3/31/2022 / PLT AG* 159700 / 4/20/2022/ PLT AG* 159831 / 4 /21/2022 / PLT AG* 159880 / 4/22/2022 / PLT AG* 3. In an interview on 5/5/2022 at 11:00 hours, in the conference room, the laboratory director confirmed that the laboratory did not follow manufacturer's instructions for the handling of patient flags on the Sysmex XP-300 hematology analyzer.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview, the laboratory failed to remove supplies that had exceeded the expiration date indicated by the manufacturer for 220 blood collection tubes. The findings include: 1. In a tour of the laboratory on 5 /4/2022 at 1330 hours, the surveyor observed the following 220 blood collection tubes available for use that had exceeded the designated expiration date indicated by the manufacturer: 200 blue top buffered Sodium Citrate tubes, Lot 1195662, with an expiration date of 4/30/2022. 15 dark blue K2 EDTA tubes, lot 1014174, with an expiration date of 1/31/2022 5 dark blue K2 EDTA tubes, lot 1094898, with an expiration date of 4/30/2022 2. In an interview on 5/4/2022 at 13:35 hours, testing personnel 1 confirmed that the laboratory failed to remove expired supplies from the availability of use.
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 a review of quality control (QC) instructions for use, QC records, laboratory information system QC ranges, the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to establish the acceptance criteria for QC for two of two lots in use from November 2021 for the Sysmex XP-300 hematology analyzer. The findings include: 1. Review of the instructions for use for the Eightcheck-3WP X-TRA hematology controls for Sysmex, section "QC limits" stated: "Assay expected ranges Represent variation between analyzers. Meaningful statistical QC suggests that each laboratory established control limits based on the analyzer's nominal CV. Sysmex recommends as an option one of two methods: 1) established laboratory limits based on the lab historical CV or 2) enter the limits provided on the assay sheet provided with each lot of EIGHTCHEK 3-WP C-TRA." 2. Review of the reference ranges (RR) on the datasheets for the Sysmex Eightcheck 3WP X-TRA QC and the laboratory information systems (LIS) RR for the current and previous hematology QC lots in use: Sysmex Controls - Put in

	use 3/31/2022 Low Abnormal Control Lot 20260710 Parameter - Package insert RR vs Laboratory RR WBC - 2.7 -3.7 :: 2.7 - 3.7 RBC - 2.16 - 2.56 :: 2.14 - 2.54 HGB - 5.4 - 6.2 :: 5.4 - 6.2 HCT - 15.5 - 18.5 :: 15.5 - 18.5 MCV - 59.1 - 58.1 :: 59.1 - 85.1 MCH - 20.2 - 28.6 :: 20.2 -28.6 MCHC - 28.4 - 39.4 :: 28.4 - 39.4 PLT - 42 - 76 :: 42.0 - 76.0 Normal Control Lot 20260711 Parameter - Package insert RR :: Laboratory RR WBC - 6.3 - 7.7 :: 6.3 - 7.7 RBC - 4.16 - 4.68 :: 4.18 - 4.66 HGB - 12.1 - 13.7 :: 12.1 - 13.7 HCT - 33.3 - 38.1 :: 33.3 - 38.1 MCV - 70.4 - 91.4 :: 70.4 - 91.4 MCH - 25.4 - 32.8 :: 25.4 - 32.8 MCHC - 31.1 - 40.9 :: 31.1 -40.9 PLT - 196 - 270 :: 196 - 270 Sysmex Control put in use 11/8/2022 Abnormal Low Control Lot 13070710 Parameter - Package insert RR :: Laboratory RR WBC - 2.9 - 3.9 :: 3.0 - 3.8 RBC - 2.14 -2.54 :: 2.13 - 2.55 HGB - 5.8 -6.6 :: 5.9 - 5.6 HCT - 16.2 - 19.2 :: 16.1 -19.3 MCV 62.8 - 88.8 :: 62.8 - 88.8 MCH - 22.4 -30.8 :: 21.6 - 30.0 MCHC - 29.5 - 40.5 :: 29.5 - 40.5 PLT - 41 - 75 :: 41.0 - 75.0 Normal Control Lot 13070711 Parameter - Package insert RR :: Laboratory RR WBC - 6.3 - 7.7 :: 6.3 - 7.7 RBC - 4.11 - 4.63 :: 4.11 - 4.63 HGB - 12.2 - 13.8 :: 12.2 - 13.8 HCT - 33.2 - 38.0 :: 33.4 - 38.2 MCV - 71 - 92 :: 71 - 92 MCH - 26.0 - 33.4 :: 26 - 33.4 MCHC - 31.5 -41.3 :: 31.5 - 41.3 PLT - 190 -264 :: 190 - 264 High Abnormal Lot 13070712 Parameter - Package insert RR :: Laboratory RR WBC - 16.4 - 20 :: 16.4 - 20.0 RBC - 4.99 -5.51 :: 4.45 - 6.05 HGB - 15.7 - 17.5 :: 15.9 - 17.7 HCT - 42.0 - 49.2 :: 42.0 - 49.6 MCV - 75.5 - 98.1 :: 75.5 - 98.1 MCH - 28.4 -35. :: 28.4 - 35.0 MCHC - 31.0 - 41.5 :: 31.5 - 41.5 PLT - 481 - 607 :: 481 - 607 3. Review of the CMS-116 section VII "Non-Waived Testing" listed the annual test volumed for the specialty of hematology at 62,426. 4. In an interview on 5/4/2022 at 15:30 hours, in the conference room, the laboratory director confirmed there was no policy for the establishment of QC ranges for the Sysmex hematology analyzer.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results to the last acceptable QC for QC failures that could not be resolved with repeat testing for seven out of seven QC failures documented from January to March 2022. The findings include: 1. Review of laboratory quality control records from January to March 2022 had the following seven QC failures that could not be resolved with repeat testing: 1/26/2022: 3 QC Failures Control level - Analyte - Corrective Action Chem Control LVL2: AST - Recalibration Chem Control LVL3: Bili T - Recalibration 2/21/2022: 2 QC Failures Control level - Analyte - Corrective Action IA Control LVL3: Vitamin B12 - Recalibration IA Control LVL1: Vitamin B12 - Recalibration Bili 3/21/2022: 3 QC Failures Control level - Analyte - Corrective Action Chem Control LVL1: CO2 - Recalibration Chem Control LVL2: CO2 - Recalibration Chem Control LVL3: CO2 - Recalibration 2. Review of patient test results had the following 55 patients that were not evaluated to the last acceptable QC: 1/25/2022: 29 Patients tested with AST and T

	Bili results Patient #: 60380 9812 64845 84784 174337 12882 50966 53358 16990 67642 15190 31799 22290 39878 37223 32946 41943 14172 10188 49654 56232 21589 46071 23976 77322 50213 78164 15661 27267 2/18/2022: 3 Patients with Vitamin B12 results Patient ID: 11959 179923 54619 3/18/2022: 23 patients with CO2 results Patient ID: 24824 53881 51865 147443 178489 28214 24879 34445 13260 90384 75352 69783 49801 91065 144645 65860 194077 193196 83709 22366 190670 87047 74636 3. In an interview on 5/5/2022 at 10:30 hours, in the conference room, the laboratory director confirmed that the laboratory did not evaluate all patient test results to the last acceptable QC for QC failures that could not be resolved with repeat testing. Key: AST - Aspartate Aminotransferase Bili T - Bilirubin, Total CO2 - Carbon dioxide