Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0976266	12/15/2023
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 12/15/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to ensure that patient remedial action was taken for three of three unsatisfactory analyte test performances for the Chemistry 2022 3rd event. The findings included: 1. A review of the laboratory policy titled "Proficiency Testing Policy for Genesis PrimeCare" stated the following: "For all PT specimen failure of 60% or below, corrective action is necessary to resolve the failure. A patient specimen look-back will be required on all failures of 60% or below." 2. Review of the laboratory PT "Performance Evaluation" for the 2022 Chemistry - Core - 3rd Event had the following analyte failures: HCG - 60% Bilirubin, Total - 60% Magnesium - 20% 3. A review of the laboratory documents titled "Performance Review and Corrective Action Documentation" for the above failures did not include remedial action. 4. In an interview on 12/14/2023 at 11:50, in the conference room, the laboratory director (LD) confirmed that the laboratory failed to perform remedial action for the above failures in the 2022 Chemistry Core 3rd PT event. HCG: human chorionic ghonadotropin

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of chemistry calibration and calibration verification records, laboratory policy, and confirmed in interview, the laboratory failed to perform calibration verification every six months for six of eleven chemistry analytes, that had less than three calibration points on the Abbott Architect C4100, for records reviewed in 2022 and January to November 2023. The findings included: 1. Review of laboratory calibration and calibration verification records for 2022 and January to November 2023 had the following six analytes with a single blank (water) calibrator: Alanine Aminotransferase (ALT) Creatine Kinase (CK) Lactate Dehydrogenase (LDH) Alkaline Phosphatase (ALP) Asparate Aminotransferase (AST) Amylase (AMY) On 12/15/2023 at 10:00 hours, in the conference room, the surveyor queried for the calibration verification records for the above analytes, for the period reviewed, and none was provided. 2. Review of laboratory policy did not include a calibration verification procedure to include the number, type, and concentrations of the materials, as well as acceptable limits for calibration verification, and criteria for reagent calibration verification needs. 3. In an interview on 12/15/2023 at 10:10 hours, the (LD) stated that the laboratory did not perform calibration verification on the above chemistry analytes on the Abbott Architect C4100.
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 a review of laboratory policy, quality control (QC) records, patient test

	results, and confirmed in interview, the laboratory failed to ensure QC on the Sysmex XP 300 was acceptable before reporting complete blood count (CBC) for 21 of 21 patients tested on days where the QC was out of acceptable limits for records reviewed from July to September 2023. The findings included: 1. Review of the laboratory policy titled "Complete Blood Count (CBC) on the Sysmex XP-300 Automated Hematology Analyzer", section VI "Quality Control" stated the following: "G. Corrective Action for Out of Range QC Results Two of three controls must be within range on all analytes prior to any patient testing. If controls fail, notify the Laboratory Supervisor or Director for assistance." 2. Review of QC records for July through September 2023 had the following six days where QC was outside of the laboratory's acceptability criteria, two of three controls must be within range, on the Sysmex XP300: July 2023: 7/25/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - HCT - 36.2 % - [31.2 - 36.0] - Outside 2SD High - HCT - 50.9 % - [43.5 - 50.7] - Outside 2SD The following five patients had CBC testing resulted on 7/25/2023 when QC was out of acceptable limits: Patient # 85364 Patient # 16667 Patient # 37877 Patient # 49425 Patient # 51250 7/26/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - HCT - 36.1 % - [31.2 - 36.0] - Outside 2SD High - HCT - 51.1 % - [43.5 - 50.7] - Outside 2SD The following two patients with CBC testing resulted on 7/26/2023 when QC was out of acceptable limits: Patient # 216985 Patient # 10670 August 2023: 8/10/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - WBC - 8.2 x 10^3k/uL - [6.7- 8.1] - Outside 2SD Low - WBC - 4.1 x 10^3k/uL - [3.0 - 4.0] - Outside 2SD The following five patients with CBC testing resulted on 8/10/2023 when QC was out of acceptable limits: Patient # 193233 Patient # 61817 Patient # 76263 Patient # 19219 Patient # 192838 8/11/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - GRAN# - 5.0 x 10^3k/uL - [3.6 - 4.8] - Outside 2SD High - GRAN# - 10.3 x 10^3k /uL - [8.2 - 10.2] - Outside 2SD The following four patients with CBC testing resulted on 8/11/2023 when QC was out of acceptable limits: Patient # 169431 Patient # 25040 Patient # 42748 Patient # 214343 8/21/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - MID# - 1.2 x 10^3k/uL - [0.7 - 1.1] - Outside 2SD High - MID# - 3.7 x 10^3k/uL - [2.6 - 3.6] - Outside 2SD The following patient had CBC testing resulted on 8/21/2023 when QC was out of acceptable limits: Patient # 53677 September 2023: 9/21/2023 QC Level - Analyte - Result - [Expected Range] - Flag Normal - GRAN# - 4.9 x 10^3k/uL - [3.6 - 4.8] - Outside 2SD High - GRAN# - 10.3 x 10^3k/uL - [8.2 - 10.2] - Outside 2SD The following four patients had CBC testing resulted on 9/21/2023 when QC was out of acceptable limits: Patient # 53410 Patient # 150413 Patient # 50313 Patient # 40140 3. In an interview on 12/14/2023 at 14:40 hours, in the conference room, the laboratory director confirmed that quality control was outside of acceptable limits on the Sysmex XP300 for the above days and that patients had been resulted. KEY: HCT - hematocrit WBC - White blood cell GRAN# - absolute granulocyte MID# - WBC's not classified as lymphocytes or granulocytes
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of laboratory documents, laboratory policy,

	and confirmed in interview the laboratory failed to identify and correct the twice annual comparison of test results between the Abbott Emerald and Sysmex XP300 hematology analyzers for two of four comparisons reviewed from 2022 to January to November 2023. The findings included: 1. In a tour of the laboratories on 12/14/2023 at 10:20 hours had the following two hematology analyzers in use for hematology testing: Abbott Emerald, located in the main laboratory. Sysmex 300 XP, located in the 'Stat Lab' 2. Review of the laboratory documents titled "6 Month Correlations CBC" for 2022 and 2023 had the following acceptability criteria for the instrument test results comparison: "Acceptable Results: >/= 0.95" Review of the comparisons included the following two evaluations that did not meet the acceptability criteria for white blood cell (WBC) comparison: October 10, 2022: WBC - 0.9315356 October 6, 2023: WBC - 0.9452699 3. In an interview on 12/14/2023 at 13:24, in the conference room, the laboratory director (LD) confirmed that the WBC comparisons did not meet the laboratory acceptability criteria, and that the laboratory failed to identify and correct the failure. II. Based on review of laboratory policy, laboratory quality control (QC) records, patient test results, and confirmed in interview, the laboratory failed to have a mechanism in place to identify and correct quality control issues on the Sysmex XP 300 hematology analyzer to ensure acceptable QC before reporting complete blood count (CBC)'s for 21 of 21 patients on days where the QC was out of the laboratory's acceptability criteria for records reviewed from July to September 2023. Refer to D5481. III. Based on a review of chemistry calibration and calibration verification records, laboratory policy, and confirmed in interview, the laboratory failed have a mechanism in place to identify and correct calibration verification failures on the Abbot Architect C4100 for six of eleven chemistry analytes, that had less than three calibration points, for records reviewed in 2022 and January to November 2023. Refer to D5439.