Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0976266	09/09/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records from 2019 to 2021 and confirmed in interview, the laboratory failed to test proficiency testing materials the same number of times as patient samples for CBC (complete blood count) on the Cell-Dyn Emerald hematology analyzer for three of eight PT events reviewed. Findings were: 1. Review of the laboratory policy Proficiency Testing Policy revealed "PT specimens are to be treated the same as patient samples. The lab should document all steps taken in PT performance." 2. A review of the CELL-DYN Emerald Operators Manual (9140848E-June 2010) Section 3: Instrument Alarms, Operational Alerts and Measurand Data Flags revealed that: "An asterisk (*) for count invalidation or (s) suspect measurand

	flags are displayed with corresponding results." "These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be suspect due to interference substances or the inability of the instrument to measure a particular measurand due to sample abnormality." "s" (Suspect Measurand Flags) flags may indicate the presence of myelocytes, lymphoblasts, basophils, eosinophils or myelocytes. Differential "s" flag L2 May indicate the presence of myelocytes, lymphoblasts, or basophils. Differential "s" flag L5 Large-size cells present. Count Invalidation Flags (*) WBC and Differential "*" flag L5 Large-size cells present The actions indicated by the manufacturer for "s" flags was "check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." For "*" flags the actions indicated by the manufacturer was "check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." 3. Review of the CBC instrument printout from the 2019 - 2021 API Hematology PT events revealed three of eight events that the laboratory had flags for the following PT specimens with no documentation of the rerun result per the laboratory policy. 2020-2nd event specimen flag Hem-06 L5 Hem-07 L5 Hem-08 L5 Hem-09 L5 Hem-10 L5 2020-3rd event specimen flag Hem-11 L5 Hem-12 L2, L5 Hem-13 L5 Hem-14 L5 Hem-15 L5 2021-2nd event specimen flag Hem -06 L5 Hem-07 L5 Hem-08 L5 Hem-09 L5 Hem-10 L5 4. An interview with the laboratory director and testing person #1 on 9/9/21 at 1340 hours in the conference room confirmed the above findings.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of laboratory records, American Proficiency Institute (API) proficiency testing records from 2019 to 2021 and confirmed in interview, the laboratory failed to test all proficiency samples in the same manner as it tests patient specimens by personnel who routinely performed the testing in the laboratory for 13 of 15 test events reviewed . Findings were: 1. Review of the CMS209 revealed five testing personnel performing nonwaived hematology and chemistry (TP#1 to TP#5). 2. Review of the API test records from 2019 to 2021 proficiency testing events revealed that for 13 of 15 events only testing person #1 who performed the proficiency testing. By not involving all testing personnel who normally test patient specimens in the testing of proficiency testing samples, the facility failed to treat proficiency samples in the same manner as patient samples. 2019 API hematology 1st event: TP#1 2019 API hematology 3rd event: TP#1 2019 API chemistry 1st event: TP#1 2019 API chemistry 2nd event: TP#1 2019 API chemistry 3rd event: TP#1 2020 API hematology 1st event: TP#1 2020 API hematology 2nd event: TP#1 2020 API chemistry 1st event: TP#1 2020 API chemistry 2nd event: TP#1 2021 API hematology 1st event: TP#1 2021 API hematology 2nd event: TP#1 2021 API chemistry 1st event: TP#1 2021 API chemistry 1st event: TP#1 3. An interview with testing person #1 on 9/9/21 at 1310 hours in the conference room confirmed the above findings. She acknowledged that all testing persons should perform the PT. key: CMS - Center for Medicare and Medicaid Services

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 the surveyor's direct observation, a review of the QC package insert, and confirmed in an interview revealed the laboratory failed to indicate the opened dates and expiration dates on three of three QC materials for CBC on Sysmex XP-300 hematology analyzer. The findings were: 1. Direct observation of the surveyor's revealed the QC materials, EIGHTCHECK-3WPX-TRA Hematology control ((Ref: 140-3004-0) had no documentation of the opened dates or revised expiration on three tubes of Sysmex EIGHTCHECK-3WPX-TRA Hematology QCs (Ref: 140-3004-0) EIGHTCHECK-3WPX-TRA Hematology control Level I: Lot: 12230710 Exp. 2021 /11/17 Level II: Lot: 12230711 Exp. 2021/11/17 Level III: Lot: 12230712 Exp. 2021 /11/17 2. Review of the Sysmex EIGHTCHECK-3WPX-TRA Hematology control package insert (350493-6, Date of issue or revision: 03/2021, Rev.19) under Storage and shelf life after first opening revealed "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C after being re-capped." 3. An interview with the lab manager on 9/9/21 at 10:38 am in the walk-in Clinic lab confirmed the above findings. Key: QC=Quality Control CBC=Complete Blood Count
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of Sysmex XP-300 Instruction for use, review of the laboratory's maintenance records, patient records, and confirmed in an interview revealed the laboratory failed to document the required maintenance procedures for three of thirty-five weekly maintenance from Jan to Aug, 2021. The findings were: 1. Review of Sysmex XP-300 Instruction for use (Code No: AU553517, Date of Last Revision: November 2017, Software Version: 00-14 and onwards) under Chapter 12 Cleaning and Maintenance revealed "To ensure proper functioning of the instrument, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below, and record the results in the Maintenance checklist." Weekly Clean SRV tray 2. Random review of the laboratory's maintenance records revealed the laboratory had no documentation of performing the required weekly maintenance procedures on Sysmex XP-300 (SN# B5888) for three of thirty-five weekly maintenance from Jan to Aug, 2021. Weekly: 5/9/21-5/15/21 5/30/21-6/5/21 8 /22/21-8/28/21 3. Random review of patient records from 1/1/21-8/31/21 revealed the following eight patient testing without required weekly maintenance procedures performed on Sysmex XP-300. 5/12/21 Accession#: 135577 5/12/21 Accession#:

	135581 5/12/21 Accession#: 135610 6/2/21 Accession#: 136805 6/2/21 Accession#: 136762 6/2/21 Accession#: 136794 8/27/21 Accession#: 141881 8/27/21 Accession#: 141893 4. An interview with laboratory manager on 9/9/21 at 11:15 am in the walk-in Clinic breakroom confirmed the above findings.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, the laboratory's records from 5/1/21 to 9/9/21, patient records, and confirmed in an interview revealed the laboratory failed to document a quality control after a change in reagents on the Sysmex XP-300 hematology analyzer for one of ten days reviewed. The findings were: 1. Review of the laboratory's Quality Control Assessment policy revealed under Hematology, "3. It is also important to check the QC in the following situations: a. change in reagent lot number..." 2. Random review of the 5/1/21 to 9/9/21 Reagent Replacement log revealed no documentation of the quality control run after the following reagent change on the Sysmex XP-300 (SN#B5888) hematology analyzer for one of ten days reviewed. 5/12/21 Stromatolyser-WH Lot: Y0006 Exp: 11/12/21 3. Review of the patient test records for the above dates revealed the laboratory performed three patient testing after the reagent change above with no documentation of the quality control run. 5/12/21 Accession#: 135610 5/12/21 Accession#: 135577 5/12/21 Accession#: 135581 4. An interview with the lab manager on 9/9/21 at 9:30 am in the walk-in Clinic lab confirmed a quality control was not run after a change of reagent on the Sysmex XP-300. Key: QC=Quality Control
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 the QC package insert, the laboratory's QC records for the

	Sysmex XP-300 from 5/28/21 to 9/9/21, patients records from 5/28/21 to 9/9/21, and confirmed in an interview revealed the laboratory failed to verify new lot numbers of external QCs for CBC testing on the Sysmex XP-300 hematology analyzer before putting them in use for nine of nine lot numbers reviewed. The findings were: 1. Review of the EIGHTCHECK-3WPX-TRA package insert revealed under Performance Characteristics and Limitations "Sysmex recommends that each laboratory uses the targets and limits provided on the assay sheet included with each lot of EIGHTCHECK-3WPX-TRA, or establish laboratory specific targets and limits." 2. Review of the laboratory's QC records for Sysmex XP-300 (SN# B5888) hematology analyzer from 5/1/21 to 9/9/21 revealed no documentation of the laboratory verifying the following nine external QC materials lot numbers: EIGHTCHECK-3WPX-TRA Hematology control XP-series Started on 8/27/21 Level I: Lot: 12230710 Exp. 2021/11/17 Level II: Lot: 12230711 Exp. 2021/11/17 Level III: Lot: 12230712 Exp. 2021/11/17 Started on 6/9/21 Level I: Lot: 1139070 Exp. 2021/08 /25 Level II: Lot: 1139071 Exp. 2021/08/25 Level III: Lot: 1139072 Exp. 2021/08/25 Started on 5/28/21 Level I: Lot: 10550710 Exp. 2021/06/02 Level II: Lot: 10550711 Exp. 2021/06/02 Level III: Lot: 10550712 Exp. 2021/06/02 3. Random review of patient records from 5/28/21 to 9/9/21 revealed the laboratory performed the following five patient CBC testing. 6/2/21 Accession#: 136762 6/2/21 Accession#: 136794 6/2/21 Accession#: 136805 8/27/21 Accession#: 141881 8/27/21 Accession#: 141893 4. An interview with the lab director and the lab manager on 9/9/21 at 4:50 pm in the conference room confirmed Sysmex XP-300 (SN# B5888) did not verify new lot of QC materials before putting in use. Key: QC=Quality Control CBC=Complete blood count .
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of the QC package insert, the laboratory's policy, the laboratory's temperature log from 1/1/21 to 8/31/21, patient results, and confirmed in an interview revealed the laboratory failed to document corrective actions when the refrigerator temperature readings were outside the acceptable range listed on the temperature log for one of ten days reviewed. The findings were: 1. Direct observation of the surveyor revealed the refrigerator #1 (SN# VS50876410) in walk-in Clinic Lab stored three tubes of Sysmex EIGHTCHECK-3WPX-TRA Hematology QCs (Ref: 140-3004-0). EIGHTCHECK-3WPX-TRA Hematology control Level I: Lot: 12230710 Exp. 2021/11/17 Level II: Lot: 12230711 Exp. 2021/11/17 Level III: Lot: 12230712 Exp. 2021/11/17 2. Review of the Sysmex EIGHTCHECK-3WPX-TRA Hematology control package insert (350493-6, Date of issue or revision: 03/2021, Rev.19) under Storage and shelf life after first opening revealed "Opened and recapped vials and vials whose caps have been pierced will

	retain stability for 14 days if stored at 2-8C after being re-capped." 3. Review of the laboratory's policy revealed no policy was established for corrective actions when the temperature was out of limit. 4. Review of the temperature log revealed the temperature limit for the refrigerator #1 (SN# VS50876410) in walk-in Clinic Lab was 2-8C. 5. Random review of the temperature log from 1/1/31 to 8/31/21 revealed one of ten days reviewed temperatures were out of 2-8C limit without corrective actions. 8/27/21 1.6C 4. Review of patient test records for the above date revealed the laboratory performed the following three patients. 8/27/21 Accession#: 136794 8/27 /21 Accession#: 141881 8/27/21 Accession#: 141893 5. An interview with the lab manager on 9/9/21 at 11:37 a.m. in the walk-in Clinic lab confirmed the above findings. Key: QC=Quality Control
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 the laboratory policy, review of the patient and quality test records from 03/2020, 12/2020, and 07/2021, and confirmed in interview, the laboratory failed to document corrective actions when quality control was outside of the acceptable ranges for three of ten analytes (bHCG, Vitamin B12, BUN) on five of twenty days reviewed. Findings included: 1. Review of the laboratory policy Quality Control Guidelines for Acceptability under Documentation of Corrective Action revealed "all violations must be documented. Enter comments on the Levy-Jennings Printout. Ensure that the repeat value is shown on the Levey Jennings. Document all corrective action taken on the Levey Jennings." 2. Random review of quality control records from 03/2020, 12/2020, and 07/2021 revealed no documentation of the corrective action for five of twenty days reviewed with quality control failures. 7/02 /21: bHCG control lot 32908190 7/02/21, 7/06/21: Vitamin B12 control 32908190 7/1 /21; 7/7/21; BUN control lot 45870 3. Random sampling of patients tested for the above dates included the following eight patients. 7/02/21: bHCG Patient #31129 7/02 /21: Vitamin B12 Patient ID #51778; Patient ID#11603 7/06/21: Vitamin B12 Patient ID #13161 7/01/21: BUN Patient ID #170380; Patient ID #34783 7/07/21: BUN Patient ID #34400; Patient ID #34285 4. An interview with testing person #1 on 9/9 /21 at 1635 hours in the laboratory confirmed the above findings.