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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0976266 | (X3) Date Survey Completed 02/18/2026 |
| Name of Provider or Supplier East Texas Border Health Clinic | Street Address, City, State 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 |
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| D0000 | The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on February 18, 2026. Standard level deficiencies cited. |
| D5441 | <p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control lot roll over records, quality control instructions for use, quality control records, daily quality control records, patient test results, and confirmed in interview, the laboratory failed to have a mechanism in place to detect immediate errors for quality control reviewed in May 2025 and January 2026. The findings included: 1. Review of the laboratory policy titled "Parallel Testing and Reagent Lot Validation- Guidelines", section "CBC Controls" stated the following: "The mean for the new control and standard deviation for the new lot of the controls will be approved by the Laboratory Director or Designee before the new control is used." 2. Review of the laboratory Lot Roll over records for QC in May 2025 and January 2026 included the following established QC mean and 2SD: May 2025 QC Lot number 5097, exp 06/20/2025, signed by the laboratory director and put in use on 4/25/2025, the following means and 2SD were</p> |

established: QC Level 1 - Low Analyte: Established Mean, 2SD, [LL - UL] WBC: 3.4, 0.2, [3.2 - 3.6] RBC: 2.47, 0.25, [2.22 - 2.72] HGB: 8.9, 0.2, [8.7 - 9.1] HCT: 23, 1, [22 - 24] PLT: 75, 5, [70 - 80] QC Level 2 - Normal Analyte: Established Mean, 2SD, [LL - UL] WBC: 7.2, 0.2, [7 - 7.4] RBC: 4.23, 0.21, [4.02 - 4.44] HGB: 13.8, 0.2, [13.6 - 14] HCT: 36.9, 1, [35.9 - 37.9] PLT: 229, 10, [219 - 239] QC Level 3 - High Analyte: Established Mean, 2SD, [LL - UL] WBC: 15.9, 0.4, [15.5 - 16.3] RBC: 6.22, 0.07, [6.15 - 6.29] HGB: 18.8, 0.2, [18.6 - 19] HCT: 44.5, 0.6, [43.9 - 45.1] PLT: 529, 15, [514 - 544] January 2026: QC Lot number 5321, exp 01/30/2026, signed by the laboratory director and put in use on 12/01/2025, the following means and 2SD were established: QC Level 1 - Low Analyte: Established Mean, 2SD, [LL - UL] WBC: 3.5, 0.2, [3.3 - 3.7] RBC: 2.51, 0.25, [2.26 - 2.76] HGB: 8.9, 0.2, [8.7 - 9.1] HCT: 23.7, 1, [22.7 - 24.7] PLTL: 81, 5, [76 - 86] QC Level 2 - Normal Analyte: Established Mean, 2SD, [LL - UL] WBC: 6.9, 0.2, [6.7 - 7.1] RBC: 4.24, 0.21, [4.03 - 4.45] HGB: 13.6, 0.2, [13.4 - 13.8] HCT: 36, 1, [35 - 37] PLT: 212, 10, [202 - 222] QC Level 3 - High Analyte: Established Mean, 2SD, [LL - UL] WBC: 15.8, 0.4, [15.4 - 16.2] RBC: 6.22, 0.07, [6.15 - 6.29] HGB: 18.3, 0.2, [18.1 - 18.5] HCT: 46.9, 0.6, [46.3 - 47.5] PLT: 516, 15, [501 - 531] Review of the QC records for May 2025 and January 2026 did not include the established QC mean and 2SD acceptability that was established in the lot rollover. Surveyor asked where the laboratory obtained the acceptability, the Laboratory Director stated the acceptability came from the CBC Cell-DYN 22 instructions for use acceptability. 3. Review of the laboratory "Cell-DYN 22 Plus Control" instructions for use, section "Performance Characteristics" included the following information: "The recovery ranges are intended to reflect inter-laboratory and inter instrument variability; thus, they are wider than the +/- 2SD QC range for one instrument ..." 4. Review of laboratory hematology lot roll over records for May 2025 and January 2026, and daily quality control records, included the following 36 days where quality control was outside of the established QC range: May 2025: Review of daily QC records included the following 20 days in May 2025 where QC was outside of the established acceptability range: Date 05/02/2025 QC L3 - HIGH HCT 48.7, [43.9 - 45.1] QC L1 - LOW PLT 82, [70 - 80] A total number of 11 patients had CBC testing performed on 05/02/2025 to include the following 5: 232523, 232556, 232549, 232550, 232531. 05/05/2025 QC L3 - HIGH RBC 6.3, [6.15 - 6.29] HCT 49.5, [43.9 - 45.1] PLT 509, QC L2 - NORMAL WBC 6.9, [7 - 7.4] PLT 214, [219 - 239] QC L1 - LOW PLT 68, [70 - 80] A total number of 33 patients had CBC testing performed on 05/05/2025 to include the following 5: 232606, 232650, 232601, 232605, 232622. 05/06/2025 QC L2 - NORMAL PLT 242, [219 - 239] QC L3 - HIGH HCT 48.7, [43.9 - 45.1] A total number of 25 patients had CBC testing performed on 05/06/2025 to include the following 5: 232720, 232692, 232684, 232708, 232703. 05/07/2025 QC L2 - NORMAL WBC 6.8, [7 - 7.4] QC L3 - HIGH RBC 6.31, [6.15 - 6.29] HCT 49.7, [43.9 - 45.1] A total number of 22 patients had CBC testing performed on 05/07/2025 to include the following 5: 232754, 232765, 232776, 232784, 232753. 05/08/2025 QC L3 - HIGH RBC 6.09, [6.15 - 6.29] HCT 48, [43.9 - 45.1] A total number of 38 patients had CBC testing performed on 05/08/2025 to include the following 5: 232857, 232872, 232828, 232860, 232805. 05/09/2025 QC L3 - HIGH HCT 49, [43.9 - 45.1] A total number of 19 patients had CBC testing performed on 05/09/2025 to include the following 5: 232922, 232929, 232910, 232938, 232931. 05/12/2025 QC L3 - HIGH WBC 15.4, [15.5 - 16.3] QC L2 - NORMAL WBC 6.9, [7 - 7.4] QC L1 - LOW PLT 67, [70 - 80] A total number of 38 patients had CBC testing performed on 05/12/2025 to include the following 5: 232996, 233003, 232971, 232983, 232979. 05/13/2025 QC L3 - HIGH RBC 6.1, [6.15 - 6.29] HCT 48.2, [43.9 - 45.1] QC L2 - NORMAL WBC 6.9, [7 - 7.4] A total number of 25 patients had CBC testing performed on 05/13/2025 to include the following 5: 233058, 233068, 233090, 233174, 233105. 05/14/2025 QC L2 -

NORMAL PLT 243, [219 - 239] QC L3 - HIGH RBC 6.1, [6.15 - 6.29] HCT 48.3, [43.9 - 45.1] QC L1 - LOW PLT 82, [70 - 80] A total number of 31 patients had CBC testing performed on 05/14/2025 to include the following 5: 233209, 233239, 233257, 233213, 233195. 05/15/2025 QC L2 - NORMAL HGB 13.5, [13.6 - 14] QC L3 - HIGH HCT 48.8, [43.9 - 45.1] A total number of 8 patients had CBC testing performed on 05/15/2025 to include the following 5: 233315, 233279, 233281, 233310, 233286. 05/16/2025 QC L3 - HIGH HCT 49.4, [43.9 - 45.1] QC L1 - LOW HCT 24.3, [22 - 24] A total number of 20 patients had CBC testing performed on 05/16/2025 to include the following 5: 233387, 233382, 233380, 233347, 233389. 05/19/2025 QC L2 - NORMAL WBC 6.9, [7 - 7.4] PLT 216, [219 - 239] QC L3 - HIGH HCT 49.1, [43.9 - 45.1] A total number of 38 patients had CBC testing performed on 05/19/2025 to include the following 5: 233425, 233467, 233509, 233472, 233513. 05/20/2025 QC L3 - HIGH WBC 15.4, [15.5 - 16.3] RBC 6.04, [6.15 - 6.29] HGB 18.5, [18.6 - 19] HCT 47.5, [43.9 - 45.1] QC L1 - LOW PLT 82, [70 - 80] A total number of 45 patients had CBC testing performed on 05/20/2025 to include the following 5: 233584, 233554, 233567, 233558, 233533. 05/21/2025 QC L2 - NORMAL WC 6.9, [7 - 7.4] PLT 240, [219 - 239] A total number of 11 patients had CBC testing performed on 05/21/2025 to include the following 5: 233627, 233633, 233636, 233629, 233666. 05/22/2025 QC L3 - HIGH HGB 18.5, [18.6 - 19] HCT 49, [43.9 - 45.1] QC L2 - NORMAL PLT 240, [219 - 239] QC L1 - LOW PLT 83, [70 - 80] A total number of 23 patients had CBC testing performed on 05/22/2025 to include the following 5: 233717, 233680, 233716, 233715, 233695. 05/23/2025 QC L3 - HIGH HCT 49, [43.9 - 45.1] QC L2 - NORMAL PLT 243, [219 - 239] QC L1 - LOW HCT 24.4, [22 - 24] PLT 83, [70 - 80] A total number of 16 patients had CBC testing performed on 05/23/2025 to include the following 5: 233765, 233791, 233764, 233762, 233790. 05/27/2025 QC L1 - LOW PLT 81, [70 - 80] A total number of 14 patients had CBC testing performed on 05/27/2025 to include the following 5: 233831, 233811, 233817, 233835, 233820. 05/28/2025 QC L3 - HIGH HCT 49, [43.9 - 45.1] QC L1 - LOW PLT 90, [70 - 80] A total number of 30 patients had CBC testing performed on 05/28/2025 to include the following 5: 233915, 233888, 233894, 233874, 233879. 05/29/2025 QC L2 - NORMAL HGB 13.5, [13.6 - 14] PLT 218, [219 - 239] QC L1 - LOW HCT 24.4, [22 - 24] PLT 87, [70 - 80] QC L3 - HIGH RBC 6.35, [6.15 - 6.29] HCT 49.8, [43.9 - 45.1] A total number of 10 patients had CBC testing performed on 05/29/2025 to include the following 5: 233962, 233952, 233946, 233944, 233942. 05/30/2025 QC L1 - LOW HCT 24.2, [22 - 24] QC L3 - HIGH HGB 18.5, [18.6 - 19] HCT 48.7, [43.9 - 45.1] A total number of 19 patients had CBC testing performed on 05/30/2025 to include the following 5: 234027, 234017, 233995, 233989, 234004. January 2026: Review of daily QC records included the following 16 days in January 2026 where QC was outside of the established acceptability range: Date 01/05/2026 QC L3 - HIGH Analyte: Value [Acceptable range] RBC 6.14, [6.15 - 6.29] HGB 18, [18.1 - 18.5] A total number of 13 patients had CBC testing performed on 01/05/2026 to include the following 5: 246093, 246098, 246099, 246106, 246108. 01/06/2026 QC L2 - NORMAL HCT 37.3, [35 - 37] QC L3 - HIGH RBC 6.11, [6.15 - 6.29] HGB 18, [18.1 - 18.5] A total number of 13 patients had CBC testing performed on 01/06/2026 to include the following 5: 246147, 246148, 246149, 246151, 246153. 01/08/2026 QC L3 - HIGH WBC 16.3, [15.4 - 16.2] HCT 47.9, [35 - 37] QC L2 - NORMAL PLT 233, [202 - 222] QC L1 - LOW PLT 87, [76 - 86] A total number of 17 patients had CBC testing performed on 01/08/2026 to include the following 5: 246284, 246286, 246287, 246289, 246295. 01/09/2026 QC L3 - HIGH WBC 16.5, [15.4 - 16.2] PLT 532, [501 - 531] A total number of 20 patients had CBC testing performed on 01/09/2026 to include the following 5: 246364, 246371, 246373, 246374, 246377. 01/12/2026 QC L3 - HIGH WBC 16.4, [15.4 - 16.2] RBC 6.33, [6.15 - 6.29] HCT 48, [46.3 - 47.5]

QC L2 - NORMAL HCT 37.1, [35 - 37] PLT 225, [202 - 222] A total number of 31 patients had CBC testing performed on 01/12/2026 to include the following 5: 246452, 246454, 246455, 246461, 246463. 01/13/2026 QC L3 - HIGH HCT 47.8, [46.3 - 47.5] QC L1 - LOW PLT 68, [76 - 86] A total number of 38 patients had CBC testing performed on 01/13/2026 to include the following 5: 246544, 246545, 246547, 246554, 246555. 01/14/2026 QC L3 - HIGH PLT 500, [501 - 531] A total number of 23 patients had CBC testing performed on 01/14/2026 to include the following 5: 246636, 246637, 246642, 246650, 246653. 01/16/2026 QC L3 - HIGH HCT 48, [46.3 - 47.5] QC L1 - LOW PLT 70, [76 - 86] QC L3 - HIGH RBC 6.37, [6.15 - 6.29] HCT 48.9, [46.3 - 47.5] PLT 545, [501 - 531] QC L2 - NORMAL HCT 37.2, [35 - 37] PLT 244, [202 - 222] A total number of 30 patients had CBC testing performed on 01/16 /2026 to include the following 5: 246797, 246798, 246800, 246807, 246808. 01/19 /2026 QC L3 - HIGH WBC 16.3, [15.4 - 16.2] RBC 6.6, [6.15 - 6.29] HGB 19, [18.1 - 18.5] HCT 50.8, [46.3 - 47.5] PLT 540, [501 - 531] QCL2 HGB 13.9, [13.4 - 13.8] HCT 37.8, [35 - 37] PLT 229, [202 - 222] QC L1 - LOW Hct 25.5, [22.7 - 24.7] A total number of 28 patients had CBC testing performed on 01/19/2026 to include the following 5: 246888, 246890, 246891, 246892, 246893. 01/20/2026 QC L3 - HIGH RBC 6.57, [6.15 - 6.29] HGB 18.6, [18.1 - 18.5] HCT 50.5, [46.3 - 47.5] PLT 571, [501 - 531] A total number of 33 patients had CBC testing performed on 01/20/2026 to include the following 5: 246985, 246993, 246994, 246996, 246997. 01/21/2026 QC L3 - HIGH RBC 6.41, [6.15 - 6.29] HGB 18.6, [18.1 - 18.5] HCT 49.7, [46.3 - 47.5] PLT 552, [501 - 531] QC L1 - LOW PLT 87, [76 - 86] QC L2 - NORMAL HCT 37.8, [35 - 37] PLT 225, [202 - 222] A total number of 24 patients had CBC testing performed on 01/21/2026 to include the following 5: 247085, 247088, 247089, 247092, 247093. 01/22/2026 QC L2 - NORMAL HGB 13.9, [13.4 - 13.8] HCT 38, [35 - 37] PLT 237, [202 - 222] QC L1 - LOW HCT 25.4, [22.7 - 24.7] QC L3 - HIGH RBC 6.33, [6.15 - 6.29] HCT 49, [46.3 - 47.5] PLT 568, [501 - 531] A total number of 16 patients had CBC testing performed on 01/22/2026 to include the following 5: 247154, 247158, 247163, 247164, 247166. 01/23/2026 QC L3 - HIGH RBC 6.38, [6.15 - 6.29] HCT 49.3, [46.3 - 47.5] PLT 573, [501 - 531] QC L2 - NORMAL RBC 4.48, [4.03 - 4.45] HCT 38.6, [35 - 37] PLT 235, [202 - 222] A total number of 21 patients had CBC testing performed on 01/23/2026 to include the following 5: 247230, 247233, 247236, 247239, 247249. 01/28/2026 QC L3 - HIGH HGB 19, [18.1 - 18.5] HCT 50.5, [46.3 - 47.5] PLT 558, [501 - 531] QC L2 - NORMAL WBC 6.6, [6.7 - 7.1] PLT 231, [202 - 222] QC L1 - LOW WBC 3.2 QC L3 - HIGH RERUN HGB 18.6, [18.1 - 18.5] HCT 48.7, [46.3 - 47.5] PLT 550, [501 - 531] QC L2 - NORMAL RERUN HGB 13.9, [13.4 - 13.8] HCT 37.5, [35 - 37] PLT 228, [202 - 222] A total number of 13 patients had CBC testing performed on 01/28/2026 to include the following 5: 247302, 247309, 247314, 247316, 247317. 01/29/2026 QC L1 - LOW PLT 88, [76 - 86] QC L2 - NORMAL HGB 13.9, [13.4 - 13.8] HCT 38.2, [35 - 37] QC L3 - HIGH RBC 6.35, [6.15 - 6.29] HCT 49.3, [46.3 - 47.5] PLT 582, [501 - 531] A total number of 26 patients had CBC testing performed on 01/29/2026 to include the following 5: 247360, 247367, 247369, 247370, 247373. 01/30/2026 QC L1 - LOW HCT 34.9, [22.7 - 24.7] PLT 89 QC L2 - NORMAL HGB 13.9, [13.4 - 13.8] HCT 381, [35 - 37] PLT 237, [202 - 222] QC L3 - HIGH RBC 6.47, [6.15 - 6.29] HCT 49.8, [46.3 - 47.5] PLT 570, [501 - 531] A total number of 22 patients had CBC testing performed on 01/30/2026 to include the following 5: 247464, 247465, 247467, 247469, 247470. 5. In an interview on 2/18/2026 at 10:00 hours, in the conference room, the laboratory director confirmed the acceptability criteria for CBC controls on the CELL-DYN Emerald 22 AL, to detect immediate error, had not been in place for May 2025 and January 2026.