Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482673	02/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Clinic Of Longview	707 Hollybrook, Longview, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, surveyor observation, patient test records, and confirmed in interview, the laboratory failed to handle patients according to laboratory policy for six of six patients submitted for complete blood counts (CBC's) testing on the Sysmex XN-2000 hematology analyzer. The findings include: 1. Review of the laboratory policy titled "XN-2000 Hematology Analyzer", section II "Specimen requirements, subsection F had the following statement: "Do not place CBC and Diff samples on a mechanical rocker. Constant rocking may alter white cell membranes, resulting in false interpretive messages." 2. Surveyor observation on 2/16/2022 at 0943 hours had the following six patients for CBC testing placed on a mechanical rocker next to the XN-2000 Hematology analyzer: 3201419 3201467 3201491 3200532 3200565 3201490 3. In an interview on 2/16/2023 at 09:43 hours, in the laboratory, testing person (TP) 2 confirmed that it was the laboratory practice to place CBC on the mechanical rocker before testing on the XN-2000 Hematology Analyzer.
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 review of the manufacturer's calibrator instructions for use, reagent test lists for the two Architect Chemistry Analyzers, and interview of facility personnel, the laboratory failed to perform calibration verification procedures for 17 analytes tested on both Architect Chemistry analyzer at least every 6 months in 2022. The findings included: 1. Based on review of the manufacturer's package inserts for calibrators found: a. The Multiconstituent Calibrator (2 calibrators -Cal 1 and Cal 2) is intended for use in the calibration of the Albumin, Calcium, Cholesterol, Creatinine, Glucose, Iron, Lactic Acid, Magnesium, Phosphorous, Total Protein, Triglyceride, Urea Nitrogen, and Uric Acid assays. b. The ICT Serum Calibrator (2 calibrators Cal L and Cal H) is intended for use in calibration of the Sodium, Potassium, and Chloride assays. 2. Review of the reagent test lists for the two Architects (SN 36220 and SN 36120) found the 17 analytes calibrated with two calibrators were routinely tested on both analyzers. 3. Interview of testing person 4 on the CMS Report 209 Laboratory Personnel Report conducted February 15, 2023 at 12:22 PM in the laboratory confirmed she had not performed calibration verification procedures at least once every 6 months for analytes calibrated with less than 3 calibrators.
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 review of laboratory policy and confirmed in interview, the laboratory failed to have a policy in place for the Sysmex XN-2000 Hematology analyzer that specified

	the number, type, and frequency of control materials used in determining acceptability for patient testing since the analyzer was implemented for use in October 2022. The findings include: 1. Review of the laboratory policy titled "XN-2000 Hematology Analyzer", approved by the laboratory director (LD) on 11/7/2022, section "V. Quality Control", subsection "C. Frequency of Control use and review" had the following statement and incomplete template: "Complete this section with your laboratory's policy for commercial control analysis and review frequency." "XN CHECK control levels: _____ will be run on 1st shift. XN CHECK Control levels: _____ will be run on 2nd shift. XN CHECK Control levels: _____ will be run on 3nd shift. The supervisor reviews commercial and X-barM charts every _____. The supervisor reviews the QC reports at the following intervals: - Insight IQAP every _____." Surveyor queried if a completed policy had been in place for testing personnel and none was provided. 2. In an interview on 2/15/2023 at 14:15 hours, in the conference room, the technical supervisor (TS) 1 confirmed that the laboratory policy for the Sysmex XN-2000 Hematology analyzer was missing the number, type, and frequency of quality control used in determining acceptability.
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 review of laboratory documents, surveyor observation, laboratory quality control records, patient test results, and confirmed in interview, the laboratory failed to ensure that QC was acceptable before reporting patient test results for one of one patients tested with the Vitek 2 ANC cards, used in the identification of anaerobic bacteria, in a record reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory document titled "Quality Control Frequency Cheat Sheet" listed the QC frequency for the Vitek 2 ANC identification cards as every new lot or shipment. Surveyor queried for the laboratory protocol when Vitek QC failed to meet the expected results, testing person (TP) 2 stated they will rerun the QC for the organisms that failed to achieve the expected results. 2. In a tour of the microbiology department on 2/16/2023 at 14:30 hours, the surveyor noted one box of Vitek 2 ANC cards, lot number 2242019503, had a received date of 2/8/2022. A review of QC documents for the Vitek ANC identification, lot number 2242019503, card had the following unacceptable QC performed on 2/16/2022: Organism: Clostridium perfringens 13124 Biochemical: Actual, Expected dMAL: - , + MTE: -, + SAC: -, + Organism: Clostridium septicum 12464 Biochemical: Actual, Expected OPS: -, + Surveyor queried for documentation that the above organisms were rerun to ensure that the Vitek ANC Identification card met the expected results, and no documentation was provided. 3. Review of patient results had the following patient-reported tested with the Vitek 2 ANC identification card when the quality control for the Vitek 2 ANC did not meet expected results: Patient ID: 518430, resulted on 2/6/2023 4. In an interview on 2/16/2023 at 1430, in microbiology, TP2 confirmed that the QC for the Vitek 2 ANC identification card had not been within the laboratory's acceptable limits before testing patients.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

	(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of laboratory documents and confirmed in interview, the laboratory failed to resolve identified problems caught by quality assurance (QA) for coagulation quality control (QC) accuracy and precision comparisons with laboratory peer groups for four of four months reviewed by the technical consultant (TC) for the ACL Elite coag analyzer. The findings include: 1. Review of QC records and corrective action forms for July through October 2022 had the following exception summary with the peer review data: July 2022: HemosIL Routine Control Level 1: PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 3: : PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 1: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 3: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." A review of the Corrective action form for July 2022 stated the following from the technical consultant (TC) 3 , signed 8/18/2022: "Will follow up next month. Precision check." August 2022: HemosIL Routine Control Level 1: PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 1: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 3: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." A review of the Corrective action form for August 2022 stated the following from TC 3, signed 12/09/2022: "Precision in question ... Will check next month." September 2022: HemosIL Routine Control Level 1: PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 3: : PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 1: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 3: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." A review of the Corrective action form for September 2022 stated the following from TC 3 , signed 12/09/2022: "Mean values are close to peer values. Precision is still an issue. Need to have service look at instrument." October 2022: HemosIL Routine Control Level 3: : PT-RecombiPlasTin: "Your Lab's Two SD range is wider than the Group's Three SD Range." HemosIL Routine Control Level 1: APPT-Synth: "Your Lab's Two SD range is wider than the Group's Three SD Range." A review of the monthly report face sheet for October 2022 had the following note: "Reviewed/Acceptable 12/9/2022" Signed by TC3. In an interview, TC3 stated they recognized the issue and couldn't pinpoint the cause of the occurrences but continued with patient testing. 3. In an interview on 2/16/2023 at 11:45 hours, in the breakroom, TC3 confirmed that the issue had been identified but the laboratory failed to investigate for a resolution of the issue when it was identified.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the technical consultant failed to assess and document the competency for one of three testing personnel at least semi-annually in the first year of testing patient specimens for Chemistry and Hematology procedures. The findings included: 1. Review of the CMS report 209 found the laboratory documented three of nine testing personnel performing moderately complex procedures. 2. Review of personnel files found no documentation of semi-annual competency assessment for testing person 6 (hire date 05/08/2022) listed on the CMS Report 209 for 2022. 3. Interview of the Technical Consultant conducted February 15, 2023 at 11:37 AM confirmed their was no semi-annual competency assessment for testing person 6 available for review.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the technical consultant failed to assess and document the competency for one of three testing personnel performing moderately complex testing in Chemistry for 2022. The findings included: 1. Review of the CMS report 209 found the laboratory documented three of nine testing personnel performing moderately complex procedures. 2. Review of personnel files found no documentation of competency assessment for testing person 4 listed on the CMS Report 209 for 2022. Documentation was requested and the form provided was signed by testing person 6, with the name of testing person 4 covered with liquid paper correction fluid. 3. Interview of the Technical Consultant conducted February 15, 2023 at 11:37 AM confirmed their was no 2022 competency assessment for testing person 4 available for review.