Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1071011	05/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
West Chambers Medical Center	9825 Eagle Dr, Mont Belvieu, 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 05/29/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 surveyor's observations in the laboratory, review of manufacturer instructions. laboratory's policies/procedures and staff interview, the laboratory failed to document preparation date, concentration, lot number and expiration date on 6 of 6 pour-over vials (10mL each) of ACL Elite coagulation analyzer's reagents in use. Findings included: 1. Surveyor's observations on 05/29/2024 at 0905 hours in the laboratory revealed 6 vials of ACL Elite coagulation analyzer's reagents sitting on the countertop next to the instrument. The vials were as follows: 2 vials labeled as Clean A solution 2 vials labeled as Clean B solution 2 vials labeled as Factor Diluent The vials did not have documentation of open/pour-over/preparation date, concentration, lot number or expiration date. 2. Review of manufacturer instructions for use for the above reagents revealed Clean B solution preparation was described as: "Daily Preventive Maintenance ...Needle Cleaning Procedure 1. Prepare fresh 1L Cleaning Agent - Hypochloride (diluted 1:8)" 3. Review of laboratory's policies/procedures revealed there were no protocols in place defining requirements for secondary

	container labeling for the ACL Elite coagulation analyzer's reagents. 4. In an interview on 05/29/2024 at 1215 hours in the conference room, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.
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: A. Based on the review of the laboratory's maintenance log in 2023, the instrument maintenance records in 2023, and confirmed in interviews, the laboratory failed to perform for 2 of 2 scheduled 6-month maintenance on Vitros XT 3400 chemistry analyzer. The findings were: 1. Review of the laboratory's maintenance log in 2023 revealed failed to perform scheduled 6-month maintenance on Vitros XT 3400 chemistry analyzer (SN: 34500449). Perform Correction Factors (6 month) Perform System Filter (6 month) Perform Pad Reflectance Test (6 month) 2. Review of the instrument screen printout titled Periodic Maintenance-Activity List (V3. 7. 3) revealed the following, M 7. Perform Correction Factors (6 months) M 8. Replace System Filter (6 months) M 9. Perform Pad Reflectance Test (6 months) 3. Review of the maintenance records in 2023 from the Vitros XT 3400 chemistry analyzer reveled the following, Date: 01/26/2023 Status/Activities Remaining: M7 M8 M9 Date: 02/27 /2023 Status/Activities Remaining: M7 M8 M9 Date: 03/28/2023 Status/Activities Remaining: M7 M8 M9 Date: 04/25/2023 Status/Activities Remaining: M7 M8 M9 Date: 05/30/2023 Status/Activities Remaining: M7 M8 M9 Date: 06/30/2023 Status /Activities Remaining: M7 M8 M9 Date: 07/26/2023 Status/Activities Remaining: M7 M8 M9 Date: 08/30/2023 Status/Activities Remaining: M7 M8 M9 Date: 09/28/2023 Status/Activities Remaining: M7 M8 M9 Date: 10/27/2023 Status/Activities Remaining: M7 M8 M9 Date: 11/22/2023 Status/Activities Remaining: M7 M8 M9 Date: 12/26/2023 Status/Activities Remaining: M7 M8 M9 Therefore, it confirmed the laboratory failed to perform 2 of 2 scheduled 6-month maintenance on Vitros XT 3400 chemistry analyzer. 4. In an interview on 05/29/2024 at 1:30 pm in the conference room, the technical consultant #1 provided the annual volume of 2120 on Vitros XT 3400. 5. In an interview on 05/29/2024 at 2:04 pm in the conference room, the technical consultant #1 confirmed the above findings. 44698 B. Based on review of manufacturer's instructions, laboratory's instrument maintenance records and staff interview, the laboratory failed to document quarterly maintenance of the Cell-Dyn Emerald hematology analyzer for 5 of 5 required quarterly maintenance from January 2023 to April 2024. Findings included: 1. Review of manufacturer's instructions for use for the Cell-Dyn Emerald hematology analyzer (document 9140840D June 2010) revealed the following quarterly maintenance was required: "Quarterly Lubricate the Pistons In Line Filter Cleaning Barcode Reader Cleaning" 2. Review of the laboratory's instrument maintenance records for the Cell-Dyn Emerald hematology analyzer from January 2023 to April 2024 revealed there was no documentation of any quarterly maintenance for 5 required quarterly maintenance within that interval. 3. In an interview on 05/29/2024 at 1240 hours in the conference room, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, laboratory's policies /procedures, calibration records and staff interview, the laboratory failed to document performance of 2 of 3 required six-month Cell-Dyn Emerald hematology analyzer's Pre-calibration procedures from January 2023 to April 2024. Findings included: 1. Review of manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer (document 9140840D June 2010) revealed: "Calibration Complete the Pre-Calibration procedures and then verify calibration..." And, "Pre-Calibration Procedures ensure proper instrument performance and a successful calibration." 2. Review of laboratory's policy "Hematology Abbott Cell Dyn Emerald 22AL" (effective date 09/01/2021) revealed: "Calibration ...Calibration verification criteria include: ...- Every 6 months" There were no protocols in place defining pre-calibration procedure requirements for the Cell-Dyn Emerald hematology analyzer. 3. Review of laboratory's calibration records January 2023 to April 2024 revealed the Cell-Dyn Emerald's Pre-calibration procedures were documented on 02/20/2024. There was no documentation of the 2 required six-month pre-calibration procedures in 2023. 4. In an interview on 05/29/2024 at 1045 hours in the conference room, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.
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 manufacturer instructions for use, laboratory's policies /procedures, quality control (QC) records, calibration verification records and staff interview, the laboratory failed to document 2 of 3 required six-month Quidel Triage D-Dimer calibration verifications from January 2023 to May 2024. Findings included: 1. Review of manufacturer instructions for use for the Quidel Triage analyzer (document PN:26611en Rev. A 2018/03) revealed: "If appropriate, run CALIBRATION VERIFICATION SET as a Misc Test sample for each test panel type to be used." 2. Review of laboratory's policies/procedures revealed there were no protocols in place addressing calibration verification for the D-Dimer test on the Quidel Triage analyzer. 3. Review of laboratory's calibration and QC records revealed the laboratory used a Calibration Chip self-test and tested 2 levels of controls for the Quidel Triage D-Dimer test, therefore requiring calibration verification every 6 months. 4. Review of laboratory's calibration verification records from January 2023 to May 2024 for the Quidel Triage D-Dimer test revealed calibration verification was documented on 07/03/2023 and 05/24/2024. There was no documentation of calibration verification for the Quidel Triage D-Dimer test in January 2023 or January 2024. 5. In an interview on 05/29/2024 at 1310 hours in the conference room, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's policies/procedures, quality control (QC) records, submitted form CMS 116 and staff interview, the laboratory failed to document testing of required 2 levels of control material every 8 hours each day of patient testing for 1 of 1 Quidel Triage D-Dimer test performed by the laboratory from January 2023 to April 2024. Findings included: 1. Review of manufacturer instructions for use for the Quidel Triage D-Dimer (document PN: 26589en Rev. C 2020/05) revealed: "Users should follow government guidelines (for example, federal, state or local) and /or accreditation requirements for quality control." 2. Review of laboratory's policy for Quidel Triage D-Dimer's Individualized Quality Control Plan (IQCP), approved by laboratory director on 02/20/2023, revealed: Data gathering instructions (01/10/2023 to 02/11/2023): "Please run 2 levels of QCs daily on D-dimer for 30 days for IQCP. Record results on the form provided." And, D-Dimer IQCP: "QC Plan: ... 2. 2 levels of Liquid Controls run with each new lot/shipment, every 30 days and with each new untrained tester." 3. Review of the laboratory's IQCP risk assessment's QC records confirmed the laboratory performed liquid control testing once each day of the IQCP 30-day interval. 4. Review of

	submitted form CMS 116 revealed the laboratory's hours of operation were from 0700 to 2000 hours, Monday through Friday (13 hours of operation each day), therefore requiring a second QC run if patient testing exceeded the 8 hour QC limitation. 5. Review of Quidel Triage D-Dimer QC records from February 2023 to April 2024 revealed the laboratory performed QC with each new lot/shipment and every 30 days. There was no documentation of QC every 8 hours prior to patient testing. 6. In an interview on 05/29/2024 at 1315 hours in the conference room, the laboratory's Technical Consultant number 1 (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid