Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659938	02/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Electra Memorial Hospital	1207 S Bailey, Electra, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation and confirmed in interview, the laboratory failed to ensure one of one reagent stored in a secondary container was labeled with identification, concentration, poured dates, and expiration dates. Findings included: 1. During a tour of the hematology area in laboratory on 02/04/2025 at 12:24 p.m., the surveyor observed the following reagent in the refrigerator: 1 glass vial (secondary container) labeled "CACL" The laboratory failed to label the secondary container with identification (lot numbers), concentration, poured dates, and expiration dates. 2. During the exit interview on 02/04/2025 at 3:50 p.m., the Technical Consultant-1 confirmed the above findings. II. Based on review of the manufacturer's instructions, direct observation, and confirmed in interview, the laboratory failed to have documentation of the correct open date and revised expiration date/time for the in-use Dade Ci-Trol Coagulation Control for two of two bottles of quality control. Findings included: 1. Review of the Dade Ci-Trol Coagulation Control Level 1 and Level 3 quality control package inserts stated: "Stability 2-8 C: reconstituted, 16 hours" 2. During a tour of the laboratory on 02/04/2025 at 12:24 p.m., the following Dade Ci-Trol Coagulation Controls were observed to be stored in the reagent refrigerator with an open date of 02/05/2025 [sic], expiration date 02/06/25 [sic] and no revised

	expiration time: 1 reconstituted bottle of Dade Ci-Trol Coagulation Control Level 1 lot# 564891, manufacturer expiration date 10/15/2026 1 reconstituted bottle of Dade Ci-Trol Coagulation Control Level 3 lot# 556587B, manufacturer expiration date 10 /10/2026 The laboratory failed to ensure the documentation of a correct open date and revised expiration date/time for in use quality control reagents. 3. During the exit interview on 02/04/2025 at 3:50 p.m., the Technical Consultant-1 confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 surveyor observation, review of laboratory policy, staff interview, i-Stat analyzer quality control (QC) records, patient final reports and confirmed in interview, the laboratory failed to document quality control results prior to patient testing for five of ten reviewed patients tested in 2024. Findings Included: 1. During a tour of the facility on 02/03/2024 at 01:20 PM, the surveyor observed one i-Stat analyzer performing patient blood gas analysis (Serial Number: 410077). 2. Review of laboratory policy, "i-Stat CG4+" (Reviewed by the Laboratory Director on 06/2024) revealed the following: " ...Quality Control A. Frequency of Quality Control and Review ...5. Three levels of external quality controls (TriControls levels 1, 2, & 3) are performed daily of patient testing, with each new lot of test cartridges, monthly, when results are in doubt, and/or when training new operators. One level must be performed with each patient. NOTE: Every time a patient specimen is tested a level of external quality control must be performed. Three levels of external quality controls must be performed every calendar day of patient testing." 3. During an interview with the lead respiratory therapist on 02/04/2025 at 09:15 AM in the facility conference room, the lead therapist stated all three levels of QC were performed on the i-Stat analyzer prior to any patient testing, on every single patient specimen received for blood gas testing. 4. Random review of i-Stat analyzer QC records in 2024, revealed the following times QC was performed: a. 01/15/2024 i-Stat Controls Performed: Level 1 Performed at: 15:04 Level 2 Performed at: 15:09 Level 3 Performed at: 15:16 b. 02/01/2024 Level 1 Performed at: 19:29 Level 2 Performed at: 19:35 Level 3 Performed at: 19:41 c. 03/20 /2024 Level 1 Performed at: 15:31 Level 2 Performed at: 15:35 Level 3 Performed at: 15:40 d. 07/18/2024 Level 1 Performed at: 10:18 Level 2 Performed at: 10:23 Level 3 Performed at: 10:28 e. 12/25/2024 Level 1 Performed at: 18:30 Level 2 Performed at: 18:35 Level 3 Performed at: 18:41 5. Review of patient final reports on the above dates revealed the following: a. 01/15/2024 Patient 1: See Patient Alias List 1 Performed at: 12:09 (Two hours and fifty-five minutes prior to the laboratory processing QC material.) b. 02/01/2024 Patient 2 Performed at: 19:24 (Five minutes prior to the laboratory processing QC material.) c. 03/20/2024 Patient 3 Performed at: 15:19 (Twelve minutes prior to the laboratory processing QC material.) d. 07/18/2024 Patient 5 Performed at: 10:01 (Seventeen minutes prior to the laboratory processing QC material.) e. 12/25/2024 Patient 5 Performed on: 18:11 (Nineteen minutes prior to the laboratory processing QC material.) The laboratory was asked to provide further documentation of QC analysis prior to patient testing on the above dates, and none

	was provided. 6. During an interview on 02/04/2025 at 11:02 AM in the facility conference room, TC-1 confirmed the laboratory failed to document quality control results prior to patient testing for five of ten reviewed patients tested in 2024.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor observation, review of Siemens Diemension EXL chemistry analyzer operator's guide, maintenance logs, corrective action logs, and confirmed in interview, the laboratory failed to document corrective actions for unacceptable cuvette temperatures for 27 of 154 reviewed days in 2024. Findings Included: 1. During a tour of the facility on 02/03/2024 at 01:20 PM, the surveyor observed one Siemens Diemension EXL chemistry analyzer performing patient testing (Serial Number: 2009181C). 2. Review of Siemens Diemension EXL chemistry analyzer operator's guide (Version: 2011/09) revealed the following acceptable cuvette temperature range for patient testing: "Operating Temperature: ...Cuvette Temperature: 36.8 C to 37.2 C" 3. Review of laboratory maintenance logs for the Siemens Diemension EXL chemistry analyzer in 2024, revealed the following days temperatures were not within acceptable operating limits: January 2024 a. 01/20 Temperature recorded: 36.7 C b. 01/21 Temperature recorded: 36.7 C c. 01/23 Temperature recorded: 36.7 C d. 01/26 Temperature recorded: 36.7 C e. 01/29 Temperature recorded: 36.7 C f. 01/30 Temperature recorded: 36.7 C July 2024 g. 07 /24 Temperature recorded: 36.7 C h. 07/25 Temperature recorded: 36.7 C August 2024 i. 08/24 Temperature recorded: 36.7 C j. 08/26 Temperature recorded: 36.7 C k. 08/28 Temperature recorded: 36.7 C September 2024 l. 09/02 Temperature recorded: 36.7 C m. 09/03 Temperature recorded: 36.7 C n. 09/04 Temperature recorded: 36.7 C o. 09/07 Temperature recorded: 36.7 C p. 09/08 Temperature recorded: 36.7 C q. 09 /09 Temperature recorded: 36.7 C r. 09/10 Temperature recorded: 36.7 C s. 09/11 Temperature recorded: 36.7 C t. 09/12 Temperature recorded: 36.7 C u. 09/29 Temperature recorded: 36.7 C October 2024 v. 10/04 Temperature recorded: 36.7 C w. 10/05 Temperature recorded: 36.7 C x. 10/09 Temperature recorded: 36.7 C y. 10 /10 Temperature recorded: 36.6 C z. 10/11 Temperature recorded: 36.6 C aa. 10/12 Temperature recorded: 36.6 C bb. 10/14 Temperature recorded: 36.6 C 4. Review of laboratory corrective action logs revealed no documentation for the above days temperatures were not within acceptable operating limits in 2024. The laboratory was asked to provide documentation of corrective actions for the above days, and none were provided. 5. During an interview on 02/03/2025 at 03:12 PM in the facility conference room, TC-1 confirmed the laboratory failed to document corrective actions for unacceptable cuvette temperatures for 27 of 154 reviewed days in 2024. Word Key C- Celsius