Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132023	04/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
The Emergency Clinic At The Pearl	2015 Broadway Street, Suite B, San Antonio, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Roche CoaguChek XS, review of patient test records from January 2023 to December 2023, and staff interview, the laboratory failed to following the manufacturer's instructions for 15 of 16 patients tested. The findings included: 1. A review of the manufacturer's instructions for the Roche CoaguChek XS (2022-02 V5.0) under the section titled "Purpose" determined: "This system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication." 2. A review of CoaguChek XS testing records from January 2023 to December 2023 identified the laboratory performed testing on 16 patients. 3. A review of the patients records determined 15 of the 16 patients did not have a history of taking oral anticoagulation medication. They were: Date Identification Number 1/4 RODAN002 1/4 ZAMSA00 1/15 STOJE01 1 /17 MOTMA000 2/17 PAPWI000 4/28 NORST000 8/25 FRYBA000 10/21 LEWMI000 10/23 MCOJA000 11/17 DIALA000 11/23 MONPE000 11/30 SALMA007 12/13 MERSE000 12/22 BARRA004 12/22 MEACA001 4. The technical consultant confirmed the findings in an interview conducted on 04/11/2024 at 1300 hours in the office.
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 review of the laboratory's maintenance logs from January 2022 to December 2023 and staff interview, the laboratory failed to perform manufacturer required maintenance on the Sysmex XP-300 hematology analyzer for four of eight quarters in 2022 and 2023. Findings include: 1. A review of the laboratory's maintenance log "XP-300 MAINTENANCE LOG" determined quarterly maintenance was required on the Sysmex XP-300 hematology analyzer: a. Clean Sample Rotor Valve (SRV) 2. Further review of the laboratory's maintenance logs from January 2022 to December 2023 identified four months in which Clean Sample Rotor Valve (SRV) maintenance was not performed. They were: July 2022 January 2023 April 2023 July 2023 3. The laboratory was asked to provide documentation of maintenance, and none was provided. 4. The technical consultant confirmed the findings in an interview on 04/11 /2024 at 1048 hours in the office.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 review of the laboratory's temperature and humidity log from April 2022 to February 2023 and staff interview, the laboratory failed to have documentation of performing corrective actions on 34 of 333 days when the maximum temperature exceeded the laboratory's acceptable range. The findings included: 1. A review of the laboratory's temperature and humidity log revealed the laboratory monitored the minimum and maximum temperature of the room temperature and refrigerator. The acceptable ranges were: Room Temperature: a. Minimum 20C b. Maximum 24C Refrigerator: a. Minimum 2C b. Maximum 8C 2. Further review of the temperature records identified 34 test days where the documented temperatures recorded exceeded the acceptable ranges. They were: Room Temperature: Date Temperature 05/05/2022 19.2C 05/26/2022 17.3C 05/28/2022 18.8C 06/05/2022 28.2C 06/06/2022 29C 06/09 /2022 18.5C 06/11/2022 17.8C 06/16/2022 19.6C 06/26/2022 19C 07/11/2022 19.5C 08/11/2022 25.6C 01/13/2023 19.4C 01/14/2023 18.7C 01/15/2023 18.6C 01/19/2023 18.9C 01/20/2023 18.7C 01/22/2023 19.2C 01/26/2023 18.6C 01/27/2023 19.1C 01/28 /2023 18.4C 01/29/2023 19.4C 02/03/2023 19.7C 02/04/2023 18.9C 02/05/2023 18.8 C 02/09/2023 18.2C 02/10/2023 19.8C 02/11/2023 18.7C 02/14/2023 19.7C 02/15 /2023 19.6C 02/18/2023 19.5C 02/19/2023 19.6C 02/24/2023 19.4C 02/25/2023 19.3 C Refrigerator: Date Temperature 04/01/2022 1.7C 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. The technical consultant confirmed the findings in an interview conducted 04/11/2024 at 1225 hours in the office.