Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0673541	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
East Texas Family Medicine Pa	4201 South Loop 256, Palestine, 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 a review of instrument instruction manuals and confirmed in interview, the laboratory failed to follow manufacturers' instructions for quality control (QC) requirements for two of two new McKesson 120 Urine Analyzers since they were put in use for patient testing in March 2022. The findings include: 1. In a tour of the laboratory on 5/10/2022 at 09:20 hours, the practice manager stated the laboratory received two new McKesson 120 Urine Analyzers for patient testing. The urine analyzer in the patient "Pod A" was received 3/23/2022, and the urine analyzer placed in the laboratory was received 5/3/2022. 2. Review of the McKesson 120 Urine Analyzer Instruction manual Section 7 "Quality Control" stated: "Test known positive and negative specimen/controls at the following events in accordance with local, state, and/or federal regulations or accreditation requirements. - A new canister of strips is opened - A new operator uses the analyzer - Test results seem inaccurate - After performing maintenance or service on the analyzer" 3. Surveyor queried for the quality control records for the two McKesson 120 Urine Analyzers and none was provided. 4. In an interview on 5/10/2022 at 09:50 hours, in the hallway, the practice manager stated that the laboratory did not maintain a record of the QC performed on the two McKesson 120 Urine analyzers.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on surveyor observation, manufacturer requirements, and confirmed in interview, the laboratory failed to monitor and document the temperature for the storage of 40 of 40 BD vacutainer tubes in use for patient testing since May 1st, 2022. The findings include: 1. In a tour of the facility on 5/10/2022 at 09:10 hours the surveyor observed a drawer full of the following 40 vacutainer blood collection tubes in administration pod B since May 1st, 2022: - 3 Red Top BD Vacutainer Tubes - Lot 106827, EXP 3/31/2023 - 37 Greiner bio-one K2E K2EDT Purple Top tubes - Lot B21123LJ, EXP 4/13/2023 2. Surveyor queried 5/10/2022 at 09:12 hours for the temperature records for pod B, and none was provided. 3. Review of manufacture instructions had the following temperature storage requirements. - BD Red Top Vacutainer Tubes: 4(degrees) Celsius(C) - 25(degrees) C - Greiner bio-one storage: 4 (degrees)C - 25(degrees) C 4. In an interview on 5/10/2022 at 09:15 hours, the practice manager stated that the laboratory was not monitoring temperatures in all areas where laboratory supplies were being stored. .