Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088854	05/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
The Hospital At Westlake 360	5656 Bee Cave Road Bldg L 2nd Floor, Austin, 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 facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policies and procedures, TAT (Turn Around Time) reports, interview, and LIS (Laboratory Information System) query, the laboratory failed to have a mechanism to monitor whether samples for Lactic Acid performed on the Vitros 350 were spun within 15 minutes of collection for four of 24 samples tested in March 2022. Findings follow. A. Review of the Vitros Instructions for Use, version 11.0 Pub No C-212EN, (also used as the laboratory's policy and procedure) under Specimen Collection Preparation and Storage at Plasma under Specimen Collection and Preparation at Special Precautions stated, "Centrifuge specimens and remove the plasma from the cellular material within 15 minutes of collection." B. Review of the TAT report for March 2022 showed 3 specimens in the 20-24 minute range: Patient ID# Order Date & Time Collection Date & Time Received Date & Time 177841 03/04/2022 20:56 03/04/2022 22:53 03/04/2022 23:15 178043 03/20/2022 8:27 03/20/2022 8:20 03/20/2022 8:40 178152 03/29/2022 4:00 03/29/2022 9:00 03/29/2022 9:20 Review of the TAT report for March 2022 showed 1 specimen in the 30-34 minute range: Patient ID# Order Date & Time Collection Date & Time Received Date & Time 178164 03/28/2022 15: 49 03/28/2022 15:50 03/28/2022 16:22 C. Interview with the Technical Consultant, as listed on the CMS form 209, on May 12, 2022 at 1130 hours in the office explained it was difficult to determine whether the spin within 15 minutes of collection was being

	met because most of these examples were from patients collected in the ER, and the tubes would have been brought to the lab for processing, sometimes before the physician orders testing. D. LIS Query showed an annual test volume of 274 in 2021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, MNPT (Mean Normal Prothrombin Time) study, interview, and LIS (Laboratroy Information System) query, the laboratory failed to follow their procedure for establishing the MNPT for 1 of 2 studies reviewed on the ACLTOP CTS 300 for Prothrombin Time (PT). Findings follow. A. Review of the laboratory's policy and procedure titled Establishing Geometric Mean, approved 07/20/2021, stated, "The INR calculation uses the mean normal Protime (MNPT) as one of its denominators. The minimum requirement for calculating a MNPT is using 20 fresh samples from healthy individuals... The mean is then input into the ACLTOP under normal mean. The instrument will then automatically calculate the INR." B. Review of the current MNPT study from 08/06 /2021 showed the study was performed using 17 specimens, with a geometric mean of 11.46 and 2SD (range) of 9.7 - 13.3 seconds. C. Interview with the Technical Consultant, as listed on the CMS 209, on May 11, 2022 at 1330 hours in the break room acknowledged the study was conducted using 17 specimens because of the tube shortage. D. LIS query showed annual test volume for PT in 2021 was 89.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. 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 the laboratory's policies and procedures, temperature charts, interview, and transfusion records, the laboratory failed to ensure the blood bank refrigerator was operating properly when 4 out of 39 temperature charts were showing a temperature of 10 degrees Celsius. Findings follow. A. Review of the laboratory's policy and procedure titled Blood Storage and Expiration of Units, revised 02/06 /2019, under Procedure at Storage stated, "Blood and blood products will be stored in their original containers and are kept in a specific refrigerator and freezer (if appropriate) designed for that purpose. Both will have a circulating fan and will be kept at the proper temperature at all times (1-6C for packed RBC's and autologous units. No freezer is used at this time). " B. Review of the blood bank refrigerator chart wheels reviewed from 05/02/2022 - 08/06/2021 showed 4 weeks from 08/06/2021 - 09 /03/2021 where the temperature recorded was 10 degrees Celsius. C. Interview with the General Supervisor, as listed on the CMS form 209, on May 12, 2022 at 1120 hours in the office acknowledged they didn't catch that. Interview with the General Supervisor on May 12, 2022 at 1125 in the breakroom stated the screw that held the pin in place probably wasn't screwed down properly. D. Review of the transfusion records from 08/06/2021 - 09/03/2021 showed one patient, patient ID number XLM0241, was transfused one unit of blood, W221621 202291.