Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D1088854	04/22/2021
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
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility and laboratory's blood/blood product transfusion policies and procedures, interview, and transfusion records, the facility failed to have defined criteria to identify transfusion reactions following the administration of blood and blood products. Findings follow. 1. Review of the facility's policy and procedure titled Blood and Blood Product- Adverse Reaction to Transfusion, effective 09/02 /2005, under PROCEDURE stated, "Changes in vital signs may be an indication of an acute adverse reaction to a transfusion. Patients receiving blood or blood product transfusion shall have vital signs assessed prior to the infusion, fifteen minutes after initiation of the transfusion and every 30 minutes during the transfusion and upon completion of the transfusion. Vital signs and patient assessment should also be initiated any time there is a suspected reaction to the transfusion. Acute reactions may include allergic, febrile non-hemolytic, septic reactions, circulatory overload and hemolytic reactions. Listed below are signs and symptoms that may be associated with an acute transfusion reaction and can aid in their recognition. Fever with or without chills, defined as 2 degrees F (Fahrenheit) increase in body temperature associated with the transfusion. Shaking chills with or without fever Pain at transfusion site, in chest of flanks. Blood pressure changes, usually acute, either hypertension or hypotension Respiratory distress, including dyspnea, tachypnea, or hypoxemia. Skin changes, including flushing, itching, urticaria, or localized or generalized edema. Nausea with or without vomiting. Circulatory shock in combination with fever, severe chills, hypotension and high-output cardiac failure.

	Circulatory collapse without fever and chills may be the most prominent finding in anaphylaxis." The procedure did not have defined criteria for the change in blood pressure, pulse, or respiratory rate. 2. Review of the laboratory's policy and procedure titled Suspected Transfusion Reaction, revised 01/24/2019, stated, "all personnel involved in ordering and administering transfusions must be able to recognize transfusion reactions, so that if one should occur, the transfusion can be stopped, and corrective actions taken promptly. Listed below are the signs and symptoms that may be associated with transfusion reactions. Materials needed A Transfusion Reaction Report Acute (onset within minutes or hours) Immune Reactions Hemolytic Febrile Non-hemolytic Urticarial Anaphylactive Transfusion related Acute lung Injury Non-Immune Reactions Hemolytic Septic Circulatory Metabolic Coagulopathy Hypothermia Citrate Toxicity Hyperkalemia Hypokalemia Embolic" The procedure did not have defined criteria for the change in temperature, blood pressure, pulse, or respiratory rate. 2. Interview with the technical supervisor, on the CMS 209, on April 15 at 1125 hours in the staff lounge confirmed the change in blood pressure, pulse, and respiratory rate were not defined in the policy. 3. Review of the transfusion records from 2020 showed 47 transfusions were performed.
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, laboratory records and interview, the laboratory failed to have a procedure for their mean normal Pro-thrombin Time (MNPT) study used to calculate the INR (International Normalized Ratio) for 1 of 1 lot changes in 2020. Findings follow. 1. The MNPT procedure when the laboratory changed lots of thromboplastin was requested on April 14, 2021 at 1530 hours, but not provided. 2. Review of the laboratory's records showed a MNPT study had been performed on 9/10/2020 for the current lot of HemosIL RecombiPlasTin 2G of thromboplastin. The study included men and women and a survey for whether the participants were on anti-coagulants or aspirin. 3. Interview with the technical consultant on April 15, 2021 at 1120 hours in the staff lounge confirmed the laboratory did not have a written procedure for the MNPT.

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 manufacturer's instructions, maintenance logs, interview, and the pre-survey worksheets, the laboratory failed to perform weekly maintenance for the diluent dispenser used in the measuring of diluents used in the preparation of cell suspensions for testing performed using the Ortho Workstation for ABO and Rh blood typing and Antibody screening for transfusions. Findings follow. A. Review of the MTS Dispenser instructions for use, revision 10/13/2008, under cleaning stated, "the dispenser should be cleaned on a weekly basis as follows: 1. Remove the dispenser from the diluent bottle. Dispense diluent until the outlet line is empty. 2. Rinse and decant the inside of the cap with 70% Isopropyl Alcohol. 3. Rinse and decant the inside of the cap with copious amounts of deionized or distilled water. 4. Aspirate with 70% Isopropyl Alcohol a minimum of 15 times through the dispenser into a water receptacle. 5. Remove dispenser from the 70% Isopropyl Alcohol solution...." B. Review of the laboratory's Quality Control Record for Ortho Workstation Daily Checks maintenance log did not include a column for the documentation of the weekly cleaning of the diluent pump. C. Interview with the technical supervisor, on the CMS form 209, on April 15, 2021 at 1340 hours in the office confirmed they were not performing the cleaning, and contacted Ortho technical support who confirmed the maintenance was not in the user manual or listed on the maintenance log, but forwarded the instructions for use for the diluent pump to the technical supervisor during the survey. D. Review of the Annual Test Volume & Proficiency Testing Program Worksheet showed the laboratory had an estimated annual volume of 105 ABO typing, 105 Rh typing, and 105 Antibody screening for transfusions.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, quality control (QC) records, interview, and pre-survey worksheets, the laboratory failed to have control procedures that detected immediate errors that occurred due to test system failure, adverse environmental conditions, and operator performance using HemosIL Controls on the ACL TOP to test PT (Pro-thrombin Time) and APTT (Activated Partial

Thromboplastin Time) for 3 of 3 months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Control Policy and Procedures, revised 04/18/2018, stated under "Quantitative Analysis...Tolerance Limits for Quantitative Analysis on Vitros, Sysmex, Hemachron [replaced by ACL TOP], Triage, and Istat. The following tolerance limits will be used to determine a QC failure: When running 2 controls, 1 control is greater than 2 standard deviations from the mean." And, stated under "Standards for Controls: Quantitative Analysis: ... Evaluating two levels of controls: Accept the run when both controls are within 2SD limits. Report patient results. Reject the run when one control exceeds 2 SD limits. Do not report patient results. Reject the run when both controls exceed 2 SD limit. Do not report results." B. ACL TOP QC (Quality Control) Statistic Report 1. Review of the HemosIL Normal Control 1 from 10/01/2020 - 12/31/2020 for PT showed a target mean of 12.0 with a 1SD of 0.6, 2SD of 1.2. a. 10/01/2020 - 10/31/2020 showed 91 out of 94 points were within 1SD, 3 points between 1SD and 2SD. b. 11/01/2020 - 11 /30/2020 showed 93 out of 93 points were within 1SD. c. 12/01/2020 - 12/31/2002 showed 96 out of 97 points were within 1SD, 1 point outside 2SD. 2. Review of the HemosIL Abnormal Control 3 from 10/01/2020 - 12/31/2020 for PT showed a target mean of 37.8 with a 1SD of 2.8, 2SD of 5.6. a. 10/01/2020 - 10/31/2020 showed 94 out of 96 points were within 1SD, 2 points between 1SD and 2SD. b. 11/01/2020 - 11 /30/2020 showed 95 out of 95 points were within 1SD. c. 12/01/2020 - 12/31/2002 showed 95 out of 96 points were within 1SD, 1 point between 1SD and 2SD. 3. Review of the HemosIL Normal Control 1 from 10/01/2020 - 12/31/2020 for APTT showed a target mean of 29.9 with a 1SD of 1.7, 2SD of 3.4. a. 10/01/2020 - 10/31 /2020 showed 97 out of 97 points were within 1SD. b. 11/01/2020 - 11/30/2020 showed 92 out of 93 points were within 1SD, 1 point between 1SD and 2SD. c. 12/01 /2020 - 12/31/2002 showed 91 out of 96 points were within 1SD, 4 points between 1SD and 2SD. 4. Review of the HemosIL Abnormal Control 3 from 10/01/2020 - 12 /31/2020 for APTT showed a target mean of 54.0 with a 1SD of 3.6, 2SD of 7.2. a. 10 /01/2020 - 10/31/2020 showed 101 out of 101 points were within 1SD. b. 11/01/2020 - 11/30/2020 showed 92 out of 93 points were within 1SD, 1 point between 1SD and 2SD. c. 12/01/2020 - 12/31/2002 showed 92 out of 97 points were within 1SD, 5 points between 1SD and 2SD. C. Review of the quality control statistics performed at installation 04/17/2019 for PT and APTT on the ACL TOP showed the 1SD for PT: Normal Control 1 SD was 0.3, Abnormal Control 3 SD was 1.4; and the 1SD for APTT: Normal Control 1 SD was 0.85, Abnormal Control 3 SD was 1.8. D. Interview with the technical consultant, on the CMS form 209, on April 15, 2021 at 1345 hours in the staff lounge confirmed they used the statistics obtained at installation and multiplied the 1SD by 2 to establish the target 1SD. When asked for reference material for the establishment of the SD, was unable to provide one. Phone interview with the technical consultant on April 21, 2021 at 1630 hours acknowledged that it was a miscommunication with the testing personnel entering the SD into the ACL TOP and Vitros that 1SD was multiplied by 2 instead of entering 2 times 1SD for a 2SD. E. Review of the Annual Test Volume & Proficiency Testing Program Worksheet showed the laboratory had an estimated annual volume of 642 Coagulation tests. NOTE: Multiplying 1SD by 2 to establish a target 1SD is equivalent to a working 2SD, thus making 2SD a working 4SD, essentially masking immediate errors due to test system failure, adverse environmental conditions, and operator performance. II. Based on review of the laboratory's policies and procedures, quality control (QC) records, interview, and pre-survey worksheets, the laboratory failed to have control procedures that detected immediate errors that occurred due to test system failure, adverse environmental conditions, and operator performance using BioRad Assayed Multiqual Controls on the Vitro 350 to test Sodium, Total Protein, and Alkaline Phosphatase for 1 of 1 months reviewed. Findings follow. A. Review of

	the laboratory's policy and procedure titled Quality Control Policy and Procedures, revised 04/18/2018, stated under "Quantitative Analysis...Tolerance Limits for Quantitative Analysis on Vitros, Sysmex, Hemachron [replaced by ACL TOP], Triage, and Istat. The following tolerance limits will be used to determine a QC failure: When running 3 controls, 1 control is equal to or greater than 3 standard deviations from the mean. When running 3 controls, 2 controls are in and 1 control greater than 2 standard deviation but less than 3SD for two consecutive days." And, stated under "Standards for Controls: Quantitative Analysis: ...Evaluating three levels of controls: Accept the run when all three controls are within 2SD limits. Report patient results. Accept the run when two out of three controls are within 2 SD control limits and 1 control is within 3SD. Report patient results. Reject the run when 2 or more levels of control exceed 2SD limits. Do not report patient results. Reject the run when two of three levels of controls are within 2 SD and 1 control exceeds 3 SD control limit. Do not report results." B. Randomly selected chemistry analytes were reviewed on the Vitros 350. Review of the Vitros 350 QC Individual Reports showed the following for the BioRad Controls Levels 1, 2, & 3: 1. From 09/01/2020 - 09/30 /2020 for the analyte Sodium (Na) showed: a. Level 1 had a target mean of 115.60 with a 1SD of 0.92, 2SD of 1.84: there were 30 points, 1 point exceeded 1 SD, and 1 point exceeded 3SD. The calculated SD was 0.38. b. Level 2 had a target mean of 145.9 with a 1SD of 1.28, 2SD of 2.56: there were 31 points, 1 point exceeded 1 SD. The calculated SD was 0.61. c. Level 3 had a target mean of 167.3 with a 1SD of 1.54, 2SD of 3.08: there were 31 points, all within 1 SD. The calculated SD was 0.70. 2. From 09/01/2020 - 09/30/2020 for the analyte Total Protein (TP) showed: a. Level 1 had a target mean of 3.75 with a 1SD of 0.105, 2SD of 0.21: there were 33 points, 1 point exceeded 1 SD. The calculated SD was 0.34. b. Level 2 had a target mean of 5.20 with a 1SD of 0.085, 2SD of 0.17: there were 33 points, 6 points exceeded 1 SD. The calculated SD was 0.059. c. Level 3 had a target mean of 6.80 with a 1SD of 0.149, 2SD of 0.298: there were 32 points, 2 points exceeded 1 SD, and 1 outside 2SD. The calculated SD was 0.100. 3. Review of the BioRad Level 1, 2, & 3 from 09 /01/2020 - 09/30/2020 for Alkaline Phosphatase (ALKP) showed: a. Level 1 had a target mean of 33 with a 1SD of 2.5, 2SD of 5.0: there were 32 points, 1 point exceeded 1 SD. The calculated SD was 1.4. b. Level 2 had a target mean of 137 with a 1SD of 7.8, 2SD of 15.6: there were 32 points, all within 1 SD. The calculated SD was 2.5. c. Level 3 had a target mean of 237 with a 1SD of 16.4, 2SD of 32.8: there were 32 points, 1 point exceeded 1SD. The calculated SD was 5.5. C. Interview with the technical consultant, on the CMS form 209, on April 15, 2021 at 1345 hours in the staff lounge confirmed they multiplied the 1SD by 2 to establish the target 1SD. When asked for reference material for the establishment of the SD, was unable to provide one. Phone interview with the technical consultant on April 21, 2021 at 1630 hours acknowledged that it was a miscommunication with the testing personnel entering the SD into the ACL TOP and Vitros that 1SD was multiplied by 2 instead of entering 2 times 1SD for a 2SD. D. Review of the Annual Test Volume & Proficiency Testing Program Worksheet showed the laboratory had an estimated annual volume of 17577 chemistry tests performed on the Vitros 350. NOTE: Multiplying 1SD by 2 to establish a target 1SD is equivalent to a working 2SD, thus making 2SD a working 4SD, essentially masking immediate errors due to test system failure, adverse environmental conditions, and operator performance. KEY:SD = standard deviation