

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0896792	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Texas Orthopedic Hospital Laboratory	Street Address, City, State 7401 South Main Street, Houston, 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	An announced validation survey was conducted on 09/20/2023 and 09/21/2023. The laboratory was found to be in compliance with the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the facility and laboratory blood/blood product transfusion policies, patient transfusion records from 2023, and confirmed in interview, the facility failed to A) ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products for four of eight transfusion records reviewed. B) follow its policy to monitor blood transfusions for potential blood transfusion reaction for one of eight transfusions reviewed. Findings included: A. 1. In review of the laboratory policy Transfusion Reaction (10593573, effective 12/2021), it stated "in the event of any type of reaction to blood or blood components the product will be stopped immediately. The physician, hospital laboratory, and hospital pathologist will be notified, and a record of transfusion complication will be completed. Sign and symptoms of a blood transfusion reaction are, but not limited to the following: 1) unexpected bleeding or oozing (surgical site, IV, etc) 2) bloody urine (hemoglobinuria) 3) fever (temp. above 38 C or 100.4 F) 4) elevated temperature above baseline (increase of 2F or 1C) 5) chills 6) hypotension /shock 7) shortness of breath (wheezing, rales) 8) edema - pulmonary or peripheral 9) pain in back, chest or flank 10) generalized uneasiness, sense of impending doom 11) facial flushing/lightheadedness 12) pain or heat at infusion site 13) hives, rash, itching</p>

14) nausea/vomiting/diarrhea 15) oliguria/anuria 16) increased pulse 17) hypertension 18) headache 19) dark plasma (hemoglobinemia) 20) anemia 21) jaundice Nursing. 1. As soon as you suspect an adverse reaction, STOP the transfusion. Do not discard the blood bag or administration set. 2. Start saline infusion to keep vein open rate after replacing Y-blood tubing with regular tubing. Send Y-blood tubing with blood bag to the Laboratory. 3. Notify the physician. 4. Notify the Blood Bank of a possible transfusion reaction and complete the 5. Transfusion Reaction form as soon as possible. Nursing will complete: wrist band #, component type, blood unit #, amount transfused, date and time started, time discontinued, person who discontinued, medication, diagnosis, history of previous transfusion, pregnancy history, IV therapy, symptoms, temperature, BP, and pulse prior to and after transfusion. 6. Collect 10ml plain red top and 5-7ml lavender top. Order an H&H. Immediately send blood samples collected and all transfusion containers (even if empty), the administration set and saline to the Blood Bank. Blood Bank will test these materials to further evaluate the reaction. 7. For possible reactions after hours, page the blood bank technician on-call. Do not send any specimen(s) outside of the hospital. 8. Monitor vital signs every 15 minutes or as indicated by the severity and type of reaction in Nurses Notes. 9. Compare the labels on all blood containers to corresponding patient identification forms to ensure transfusion was the correct blood or blood product and document in 10. Nurses Notes. 11. Collect the first post-transfusion, preferably voided, urine specimen and send to Laboratory immediately. Mark the urine specimen "possible transfusion reaction". 12. Closely monitor intake and output. Note evidence of oliguria or anuria because hemoglobin deposition in the renal tubules can cause renal damage.

2. Random review of the facility transfusion records from January 2023 to June 2023 revealed four of eight patients that met the criteria of a possible transfusion reactions per the above facility policy. 01/26/2023 - Patient Y00009063227 was transfused 1 unit of packed red blood cells (PRBC) from 1014 hours to 1241 hours. Vital signs: Pre transfusion (0950 hours): pulse 70; blood pressure 127/76 During transfusion vital signs (1014 hours): pulse 72; blood pressure of 123/76; One hour after transfusion (1114 hours): pulse 88; blood pressure 150/77 Two hour after transfusion (1216 hours): pulse 71; blood pressure 149/79 After transfusion (1242 hours): pulse 71; blood pressure 123/77 The transfusion records included a nurse's note of "NO" to the question "signs and symptoms of a possible transfusion reaction" The patient chart did not include documentation of reporting to the blood bank of an acute increase in pulse and increase of blood pressure. 03/02/2023-Patient Y00009096961 was transfused 2 units of PRBC from 1320 hours to 1412 hours during surgery. Review of the anesthesia records included documentation "1325 pt suddenly hypotensive ..." Vital signs: Pretransfusion: pulse 77, blood pressure 129/62 Surveyor review of the vital signs on anesthesia records were illegible on anesthesia chart. Review of the anesthesia records did not include any investigation for a possible transfusion reaction. 03/30/2023 - Patient Y00009127033 was transfused 1 unit of PRBC from 1500 hours to 1857 hours. Vital signs: Pre transfusion (1519 hours): pulse 86; blood pressure 124/70 During transfusion vital signs (1539 hours): pulse 71; blood pressure of 156/79; One hour after transfusion (1629 hours): pulse 69; blood pressure 159/84 Two hours after transfusion (1727 hours): pulse 73; blood pressure 144/72 Three hours after transfusion (1824 hours): pulse 72; blood pressure 122/71 After transfusion (1859 hours): pulse 61; blood pressure 134/74 The transfusion records included a nurse's note of "NO" to the question "signs and symptoms of a possible transfusion reaction" The patient chart did not include documentation of reporting to the blood bank of an increase of blood pressure. 5/24/2023 - patient Y00009252759 was transfused 1 unit of PRBC from 1412 hours to 1718 hours. No documentation of the pre transfusion vitals were available for review. No documentation of the 15 min vitals after the start of the transfusion were available for review. One hour after

transfusion (1540 hours): pulse 97; blood pressure 107/57 No documentation of the post transfusion vitals were available for review Review of patient transfusion records included a nurse's note "pt reported generalized itching" at 1428 hours. The patient chart did not include documentation of reporting to the blood bank of the itching after the start of the transfusion. B. 3. In review of the facility policy Administration of Blood and/or Blood Components (approved 11/2021), it stated "Take and record patient's vital signs including temperature: a. Immediately prior to hanging the unit. b. Fifteen (15) minutes after hanging the unit. c. One (1) hour after hanging the unit. d. Every hour until the transfusion is complete. e. When transfusion is complete. f. One (1) hour after transfusion is complete. NOTE: Nursing will record vital signs in Meditech using BCTA. Anesthesia, (O.R.) will record vital signs on the anesthesia record." 4. Random review of the facility transfusion records from January 2023 to June 2023 revealed one of eight patients with no documentation of the vital signs per the above facility policy. 5/24/2023 - patient Y00009252759 was transfused 1 unit of PRBC from 1412 hours to 1718 hours. No documentation of the pre transfusion vitals were available for review. No documentation of the 15 min vitals after the start of the transfusion were available for review. One hour after transfusion (1540 hours): pulse 97; blood pressure 107/57 No documentation of the post transfusion vitals were available for review 5. An interview with the interim VP of Quality on 09/21/2023 at 1400 hours in the conference room confirmed the above findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the operator's manual, laboratory records from 2021 and 2022, and confirmed in interview, the laboratory failed to document four of four calibration verification for the iSTAT CG8+ (pCO2 (pH, partial pressure of carbon dioxide), PO2 (partial pressure of oxygen), Hematocrit (HCT), Sodium (NA), Potassium (K), Glucose (GLU) and ionized Calcium (iCA) and iSTAT Troponin (cTnI) chemistry testing on the iSTAT analyzer for 2021 and 2022. Findings were: 1. Review of the Abbott I-stat operator's manual (Art: 71436-00M), under Calibration Verification,

states the following: "Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of the test. The performance of this procedure over defined intervals may be required by regulatory or accreditation bodies. " 2. Review of laboratory records revealed six iSTATs that were in use for iSTAT CG8+ and cTnI patient testing. SN 312484 SN 307116 SN 308536 SN 353135 SN 373518 SN 373527 3. Review of records from 2021 and 2022 revealed no documentation of the calibration verification for CG8+ and cTnI for the above iSTAT analyzers. 4. In review of the Annual Test Volume and Proficiency Testing Programs Worksheet signed by the laboratory director on 09/19/2023, the laboratory performed 910 iSTAT tests annually. 5. An interview with the administrative laboratory director on 09/20/2023 at 1415 hours in the conference room confirmed the above findings.

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:

Based on review of the laboratory quality control records from 2023 and confirmed in interview, the laboratory failed to monitor the accuracy and precision of the quality control for two of two cartridges on the iSTAT analyzer: the iSTAT CG8+ (pH, pCO₂ (partial pressure of carbon dioxide), PO₂ (partial pressure of oxygen), Hematocrit (HCT), Sodium (NA), Potassium (K), Glucose (GLU) and ionized Calcium (iCA)) and iSTAT Troponin (cTnI). Findings were: 1. Review of the quality control records from January 2023 to June 2023 revealed the laboratory performed the quality control for the iSTAT CG8+ or the iSTAT cTnI testing on the following dates with no documentation of the laboratory monitoring the accuracy and precision of the analytes over time. CG8+ 1/25/2023 Control level 1 lot: 301145 1/25/2023 Control level 3 lot: 321151 3/20/2023 Control level 1 lot: 301157 3/20/2023 Control level 3 lot: 321151 4/20/2023 Control level 1 lot: 301157 4/20/2023 Control level 3 lot: 321151 5/09/2023 Control level 1 lot: 301157 5/09/2023 Control level 3 lot: 321151 5/18/2023 Control level 1 lot: 301157 5/18/2023 Control level 3 lot: 321151 6/13/2023 Control level 1 lot: 301157 6/13/2023 Control level 3 lot: 321151 cTnI 1/25/2023 Control level 1 lot: 011160 1/25/2023 Control level 2 lot: 021151 3/20/2023 Control level 1 lot: 011160 3/20/2023 Control level 2 lot: 021151 4/20/2023 Control level 1 lot: 011160 4/20/2023 Control level 2 lot: 021151 5/09/2023 Control level 1 lot: 011160 5/09/2023 Control level 2 lot: 021151 5/18/2023 Control level 1 lot: 011160 5/18/2023 Control level 2 lot: 021151 6/13/2023 Control level 1 lot: 011160 6/13/2023 Control level 2 lot: 021151 2. Random review of patient test records confirmed the laboratory performed the following 21 patient testing in 2023. CG8+ 1/19/2023 Patient Acct: Y00009042223 1/23/2023 Patient Acct: Y00009042057 2/07/2023 Patient Acct: Y00009060106 2/08/2023 Patient Acct: Y00009116713 2/09/2023 Patient Acct: Y00009090161 2/10/2023 Patient Acct: Y00009116193 2/14/2023 Patient Acct:

Y00009092925 3/28/2023 Patient Acct: Y00009168382 3/31/2023 Patient Acct: Y00009177785 4/24/2023 Patient Acct: Y00009216676 4/28/2023 Patient Acct: Y00009101926 5/08/2023 Patient Acct: Y00009201081 5/30/2023 Patient Acct: Y00009250058 6/28/2023 Patient Acct: Y00009298527 cTnI 1/12/2023 Patient Acct: Y00009048960 2/03/2023 Patient acct #: Y00009108728 3/10/2023 Patient Acct: Y00009147415 3/22/2023 Patient Acct: Y00009131373 4/03/2023 Patient Acct: Y00009098941 5/01/2023 Patient Acct: Y00009226437 6/15/2023 Patient Acct: Y00009287865 3. An interview with the administrative laboratory director on 09/20/2023 at 1409 hours in the conference room confirmed the above findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy, laboratory quality control records from 2023, and confirmed in interview, the laboratory failed to document monthly quality control for six of six analyzers reviewed for the iSTAT CG8+ (pH, pCO2 (partial pressure of carbon dioxide), PO2 (partial pressure of oxygen), Hematocrit (HCT), Sodium (NA), Potassium (K), Glucose (GLU) and ionized Calcium (iCA)) and iSTAT Troponin (cTnI) chemistry testing on the iSTAT analyzer. Findings were: 1. Review of laboratory records available revealed six iSTATs were in use for iSTAT CG8+ and cTnI patient testing. SN 312484 SN 307116 SN 308536 SN 353135 SN 373518 SN 373527 2. In review of the laboratory policy iSTAT Quality Control (01/2010), it stated "QC Protocol: Liquid controls are run at least monthly per analyzer." 3. In review of the laboratory iSTAT IQCP (effective 1/2023), it stated "QC will include in addition to monthly performance, external QC (two levels) is performed on each lot /shipment for all different types of iSTAT cartridges." 4. Review of the quality control records from January 2023 to June 2023 revealed the laboratory performed monthly quality control for the following analyzers. CG8+ SN 312484 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 307116 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 308536 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 353135 No quality control for three (February 2023, April 2023, June 2023) of six months 1/25/2023 Control level 1 lot: 301145 1/25/2023 Control level 3 lot: 321151 3/20/2023 Control level 1 lot: 301157 3/20/2023 Control level 3 lot: 321151 5/09/2023 Control level 1 lot: 301157 5/09/2023 Control level 3 lot: 321151 5/18/2023 Control level 1 lot: 301157 5/18/2023 Control level 3 lot: 321151 SN 373518 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 373527 No quality control for four (January 2023, February 2023, March 2023 May 2023) of six months 4/20/2023 Control level 1 lot: 301157 4/20/2023 Control level 3 lot: 321151 6/13/2023 Control level 1 lot: 301157 6/13/2023 Control level 3 lot: 321151 cTnI SN 312484 No

quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 307116 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 308536 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 353135 No quality control for three (February 2023, April 2023, June 2023) of six months 1/25/2023 Control level 1 lot: 011160 1/25/2023 Control level 2 lot: 021151 3/20/2023 Control level 1 lot: 011160 3/20/2023 Control level 2 lot: 021151 5/09/2023 Control level 1 lot: 011160 5/09/2023 Control level 2 lot: 021151 5/18/2023 Control level 1 lot: 011160 5/18/2023 Control level 2 lot: 021151 SN 373518 No quality control for six of six months (January 2023, February 2023, March 2023, April 2023, May 2023, June 2023) SN 373527 No quality control for four (January 2023, February 2023, March 2023, May 2023) of six months 4/20/2023 Control level 1 lot: 011160 4/20/2023 Control level 2 lot: 021151 6/13/2023 Control level 1 lot: 011160 6/13/2023 Control level 2 lot: 021151 5. Random review of patient test records confirmed the laboratory performed the following 21 patient testing in 2023. CG8+ 1/19/2023 Patient Acct: Y00009042223 1/23/2023 Patient Acct: Y00009042057 2/07/2023 Patient Acct: Y00009060106 2/08/2023 Patient Acct: Y00009116713 2/09/2023 Patient Acct: Y00009090161 2/10/2023 Patient Acct: Y00009116193 2/14/2023 Patient Acct: Y00009092925 3/28/2023 Patient Acct: Y00009168382 3/31/2023 Patient Acct: Y00009177785 4/24/2023 Patient Acct: Y00009216676 4/28/2023 Patient Acct: Y00009101926 5/08/2023 Patient Acct: Y00009201081 5/30/2023 Patient Acct: Y00009250058 6/28/2023 Patient Acct: Y00009298527 cTnI 1/12/2023 Patient Acct: Y00009048960 2/03/2023 Patient acct #: Y00009108728 3/10/2023 Patient Acct: Y00009147415 3/22/2023 Patient Acct: Y00009131373 4/03/2023 Patient Acct: Y00009098941 5/01/2023 Patient Acct: Y00009226437 6/15/2023 Patient Acct: Y00009287865 6. An interview with the administrative laboratory director on 09/20/2023 at 1409 hours in the conference room confirmed the above findings. She was unaware that quality control must be performed for each analyzer or that they needed to be performed every month.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 manufacturer's instructions, laboratory policy and records from 2023, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions when establishing its normal range study for one of one reagent (Recombiplastin Reagent) to determine International Normalized Ratio (INR) on the ACL TOP 350 analyzer. Findings included: 1. In review of the Instructions for use for the Recombiplastin 2G reagent (Lot N0925455, exp 09/2024), it stated "Ranges were calculated as recommended by CLSI document C28-A.9 These results were obtained using a specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should verify its own normal range." 2. In review of the CLSI document C28-A.9, under Protocol Outline for Obtaining Reference Values and Establishing Reference Intervals, it stated "establish selection (or exclusion) and partition criteria and an appropriate questionnaire designed to reveal these criteria in

the potential reference individuals. Execute an appropriate written consent form for participation in the reference interval study and have the reference individual complete the questionnaire." 3. Review of the laboratory policy Establishing-Verifying a Normal Reference Interval for Coagulation, it stated "either 120 or 20 normal donors following these screening guidelines: Donors should be healthy and have no known pathological conditions. Don't use patients that are at the hospital for a medical reason. Donors should not be on medication affecting coagulation, including (but no limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high dose aspirin, etc. Donors should span the adult age range. Donors should be equally divided between male/female Ensure there are less than $10 \times 10^9/L$ platelets in the plasma 4. Review of the validation studies performed in 06/2023 for the new ACL TOP 350 analyzer (SN 23024000) included documentation for a normal reference range study to determine the normal reference interval that included 40 specimens. No documentation was provided as to the age, sex and/or health status of the 40 patients. 5. In review of the Annual Test Volume and Proficiency Testing Programs Worksheet signed by the laboratory director on 09/19/2023, it stated the laboratory performed 5114 Prottime testing annually. 6. An interview with the administrative laboratory director on 09/20/2023 at 1600 hours in the conference confirmed the above findings. She stated that the original specimen ID were not used, and she was unable to verify the age, sex, or health of the specimens. She acknowledged that the laboratory needs a process to ensure the donors used met the criteria per their policy. Key: Recombiplastin - A high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the quantitative determination in human citrated plasma of Prothrombin Time (PT) and Fibrinogen on IL Coagulation Systems INR - The INR is equal to the ratio of the patient's PT (in seconds) to the laboratory's established normal mean PT (in seconds), then raised to the power of the ISI.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records from 2021 to 2022 and confirmed in interview, the laboratory failed to document the comparison studies for two of two tests (CG8+ and cTnI) on the iSTAT analyzer twice a year. Findings were: 1. Review of laboratory records available revealed six iSTATs were in use for iSTAT CG8+ (pH, pCO2 (partial pressure of carbon dioxide), PO2 (partial pressure of oxygen), Hematocrit (HCT), Sodium (NA), Potassium (K), Glucose (GLU) and ionized Calcium (iCA)) and iSTAT Troponin (cTnI) chemistry testing on the iSTAT analyzer. . SN 312484 SN 307116 SN 308536 SN 353135 SN 373518 SN 373527 2. Review of the laboratory records available revealed no documentation of the laboratory performing a comparison of tests for two of two tests (CG8+ and cTnI) for the above six iSTAT analyzers twice a year in 2021 and 2022. 3. In review of the Annual Test Volume and Proficiency Testing Programs Worksheet signed by the laboratory director on 09/19/2023, the laboratory performed 910 iSTAT tests annually. 4. An interview with the administrative laboratory director on 09/20/2023 at 1409 hours in the conference room confirmed the above findings.