Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088854	06/27/2024
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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, proficiency test (PT) records, and interview, the laboratory failed to test PT samples the same number of times it routinely tests patients for four out of five events reviewed for 6 out of 30 CBC (Complete Blood Count) and chemistry specimens. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing Procedure, revised 07/11/2023, under Specific Policies stated, "...This laboratory will test proficiency testing specimens in the same manner as we test patients' specimens. We will use personnel who are authorized by the laboratory director and who routinely test patients' specimens. We will also use methods, and instruments that routinely test patients' specimens. We will test the proficiency specimens integrated into the routine workload using the same number of replicates used for patients' testing...." B. Review of the laboratory's policy and procedure titled Critical Values, revised 03/20/2019, under policy stated, "...Critical values, once they are verified, must be called to the patient care unit responsible for the patient and/or the patient's provider..." Critical Values Chart from the procedure CHEMISTRY Low High Total Bilirubin 15.0 Mg /dL Albumin 0.5 6.0 M/dL Creatinine 3.0 Mg/dL Calcium 6 mg per dL 13.0 mg per dL Carbon Dioxide 10 mEq per L 40.0 mEq per L Chloride 77 121 mEq per L Glucose (Adults) 40 mg per dL 500 Magnesium 1 mg per dL 5.0 mg per dL Phosphorus 1 mg per dL Potassium 3.0 mEq per L 6.0 mEq per L Sodium 120 mEq

	per L 160.0 mEq per L DRUG LEVELS Acetaminophen 150 mg per dL Salicylate 30 mg per dL C. Review of the American Proficiency Institute (API) Hematology PT testing records for CBCs from the 2nd and 3rd events of 2023, and the 1st event of 2024 showed the PT was distributed to multiple testing personnel and revealed specimens XE-09 was tested in duplicate on 07/17/2023 by testing personnel #2 (as listed on the CMS-209 form); XE-15 was tested on 11/13/2023 and 11/27/2023 by testing personnel #2; and XE-03 was tested twice on 03/08/2024 by testing personnel #4. All three specimens were normal with no indication they should be repeated. Review of the American Proficiency Institute (API) Chemistry Core PT testing records from the 1st and 2nd events of 2024 showed the PT was distributed to multiple testing personnel and revealed specimens CH-01 was tested on 01/12/2024 and repeated on 01/19/2024 by testing personnel #5; CH-04 was tested in positions 4, 5, and 7 on the Vitro on 01/11/2024 and TDM-04 was tested in positions 1 and 2 on the Vitros on 01/11/2024 by testing personnel #4. CH-01 was repeated for Blood Urea Nitrogen (BUN), Creatinine, Sodium, Chloride, Carbon Dioxide (CO2), Amylase, Lipase, Calcium, Magnesium, Phosphorus, Total Protein, Aspartate Aminotransferase (AST), Alkaline Phosphatase (ALKP), Creatinine Kinase (CK), Total Bilirubin that did not meet the repeat criteria. CH-04 was repeated for Glucose, BUN, Sodium, Chloride, CO2, Amylase, Lipase, Magnesium, Phosphorus, Total Protein, AST, ALKP, CK, Total Bilirubin that did not meet the repeat criteria. D. Interview with Technical Supervisor on June 27, 2024 at 1400 hours confirmed the findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in an interview with laboratory personnel, the laboratory failed to achieve successful performance in two of three testing events for the subspecialty Compatibility testing (See D2181).
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e)

	Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in an interview with laboratory personnel, the laboratory failed to attain a score of at least 80 percent for the subspecialty of Compatibility Testing in two out of three testing events in 2023 and 2024 for Immunohematology. Findings follow. A. Review of the CASPER Report 155 Individual Laboratory Profile revealed the laboratory received the following unsuccessful performance for Compatibility Testing in the specialty of Immunohematology in two out of three events: 2023 API 2nd event 80% 2024 API 1st event 0% Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. For Compatibility Testing, any score less than 100% is unsatisfactory performance. B. Review of the API PT Performance Evaluation for the 1st, 2nd, and 3rd testing events from 2023 and the 1st testing event from 2024 PT records revealed the laboratory received a score of 80% in the 2nd event of 2023 and 0% for the 1st event of 2024. The laboratory received a score of 80% when the laboratory reported AUT-10 as Compatible, and the Expected result was Incompatible. The laboratory received a score of 0% when they failed to submit the results by the submission due date. C. Interview with the General Supervisor on June 25, 2024 at 1700 hours in the office confirmed the findings.
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 nursing and laboratory policies and procedures, transfusion records, pre-survey paperwork, and interview, the facility failed to follow its policy and procedure for recording vital signs used to identify blood and blood product transfusion reactions for seven (7) out of eight (8) units reviewed. Findings follow. A. Review of the nursing policy and procedure titled "Blood and Blood Product - Adverse Reaction to Transfusion," revised 07/2021, under Procedure stated, "... 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..." The policy does not define what constitutes a vital sign. The policy required vital signs every 30 minutes during the transfusion. B. Review of the laboratory's policy and procedure titled Suspected Transfusion Reaction, revised 06/10/2021, under Principle 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..." The policy does not define what constitutes a vital sign. The policy required vital signs every 30 minutes during the transfusion. B. Seven (7) out of eight (8) randomly selected units transfused reviewed were missing vital signs: 1. Medical Record Number (MR#) 880114518 Unit # W221623656777 packed red blood cells Started 10/09/2023 at 0523 Stopped 10/09/2023 at 0820 Vitals taken at: 05:37 (prior), 0600 (15 minute), 0630 (30 minute), 0700 (1 hour), 0800 (2 hours), 0820 (post) Per policy, missing 1 hour 30-minute vital signs 2. Medical Record Number (MR#) 880114518 Unit # W221623617050 packed red blood cells Started 10/09/2023 at 1148 Stopped 10/09/2023 at 1500 Vitals taken at: 1145 (prior), 1203 (15 minute), 1218 (30 minute), 1248 (1 hour), 1348 (2 hours), 1455 (3 hours), 1512 (post) Per policy, missing 1 hour 30-minute vital signs and 2 hour 30 minute vital signs 3. Medical Record Number (MR#) 880042126 Unit # W221623618747 packed red blood cells Started 11/01/2023 at 2316 Stopped 11/02/2023 at 0216 Vitals taken at: 2316 (prior), ? (15 minute), ? (30 minute), 0025 (1 hour), 0151 (2 hours), 0216 (post) Per policy, missing 1 hour 30-minute vital signs 4. Medical Record Number (MR#) 880042126 Unit # W221623952855 packed red blood cells Started 11/02/2023 at 1210 Stopped 11/02/2023 at 1432 Vitals taken at: 1209 (prior), 1225 (15 minute), 1240 (30 minute), 1310 (1 hour), 1410 (2 hours), 1432 (post) Per policy, missing 1 hour 30-minute vital signs 5. Medical Record Number (MR#) 880042126 Unit # W221623657462 packed red blood cells Started 11/02/2023 at 2236 Stopped 11/03 /2023 at 0200 Vitals taken at: 2223 (prior), 2251 (15 minute), 2310 (30 minute), 0010 (1 hour), 0200 (post) Per policy, missing 1 hour 30-minute vital signs and 2 hour vital signs 6. Medical Record Number (MR#) 880123087 Unit # W22162410855 packed red blood cells Started 03/13/2024 at 1735 Stopped 03/13/2024 at 2000 Vitals taken at: 1715 (prior), 1750 (15 minute), 1605[1805?] (30 minute), 1905 (1.5 hour), 2005 (post) Per policy, missing 1 & 2 hour vital signs 7. Medical Record Number (MR#) 880123514 Unit # W221623656777 packed red blood cells Started 06/09/2024 at 1513 Stopped 06/09/2024 at 1900 Vitals taken at: 1512 (prior), 1628 [1528?] (15 minute), 1543 (30 minute), 1615 (1 hour), 1712 (2 hours), 1900 (post) Per policy, missing 1 hour 30-minute vital signs, 2 hour 30 minute vital signs The Transfusion Record form was missing the 1 hour 30-minute vital signs and 2 hour 30 minute and 3 hour 30 minute vital signs. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed approximately 12 units were transfused in 2023. D. Interview with the General Supervisor on June 26, 2024 at 1630 hours in the office confirmed the 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 IQCP (Individualized QC plan), quality control (QC) records, patient testing records, query, and interview, the laboratory failed to perform external QC every 14 days on the iSTAT used to test blood gases for pH, partial Carbon

	Dioxide (PCO2), and partial Oxygen (PO2) for five (5) out of eight (8) patients tested over a 6-month period. Findings follow. A. Review of the IQCP plan stated, "iStat Blood gases test system qualifies for an Option 1 external control versus internal control study over a 14-day period. The Laboratory has documentation of the successful performance of the control study for a 14-day period. The IQCP control procedure for iStat Blood Gases testing using the G3+ cartridge will include: Documentation of system QC device results every 8 hours. 1. perform and document 2 levels of external controls with each new lot, each shipment, and twice each month for the current lot in use. New testing personnel should also run QC to verify their ability to perform the testing. 2. Perform 2 levels of liquid controls and system QC device whenever results are questioned by the practitioner. If the laboratory fails to perform the IQCP control process correctly, or an external control fails after 1 repeat, or proficiency testing fails, the laboratory must successfully repeat the 14-day study of external and internal controls..." B. Review of QC records from 06/30/2023 - 09/31 /2023 and 02/01/2024 - 04/30/2024 revealed external QC was performed: 1. 06/30 /2023 2. 07/12/2023 3. 08/03/2023 4. 09/01/2023 5. 02/02/2024 6. 03/01/2024 7. 04/01 /2024 C. Review of patient testing records showed patient testing was performed on 1. 08/19/2023 185289 2. 08/24/2023 185383 3. 09/18/2023 185253 4. 03/30/2024 188176 5. 04/17/2024 187762 D. Review of the test count query showed approximately 25 blood gases were performed in 2023. E. Interview with Technical Consultant on June 26, 2024 at 1130 hours confirmed the findings.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency test (PT) records, and interview, the laboratory director failed to ensure PT samples were tested the same number of times it routinely tests patients for four out of five events reviewed (refer to D2010).
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in an interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction of the laboratory (refer to D6089).

D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in an interview with laboratory personnel, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the subspecialty of Compatibility Testing for two out of three testing events in 2023 and 2024 (refer to D2181).