Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0935759	03/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Amarillo Specialty Hospital, Dba Texas	1540 Research St, Amarillo, 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 unannounced complaint investigation (TX00559757) was completed on March 11, 2026 and the laboratory failed to be in compliance with 42 CFR Part 493, Requirements for Laboratories for the following conditions: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The complaint was substantiated.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the CMS 116, laboratory test menu, and confirmed in interview, the laboratory failed to ensure enrollment in proficiency testing (PT) for three of three regulated blood gas analytes tested on the Abbott i-STAT in 2024, 2025, and 2026. The findings included: 1. During an unannounced complaint investigation completed on March 11, 2026, it was confirmed the laboratory was performing blood gas analysis for pH, pCO2, and pO2 on an Abbott iSTAT device. 2. Surveyor requested proficiency testing records for 2024, 2025, and proof of enrollment for 2026, and none could be provided. 3. In an interview on March 11, 2026, at 1420, in the conference room, the technical consultant (TC) 2, as listed on the CMS 209 personnel form,

	confirmed the laboratory was not enrolled in proficiency testing for the blood gas testing performed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policy, laboratory quality control (QC) documentation, patient test list, and confirmed in interview, the laboratory failed to perform two levels of quality control for five of twelve months in 2025 (Refer to D5401), and failed to have a mechanism in place to detect immediate errors in QC for records reviewed from October 2025 through February 2026 when patient testing for blood gases were being performed on the Abbot iSTAT analyzer (Refer to D5441).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control documentation, patient test list, and confirmed in interview, the laboratory failed to perform two levels of quality control for five of twelve months in 2025 (January, February, March, April, and August of 2025) when patients had pH, PCO2, PO2, and lactic acid testing performed on the i-STAT analyzer. The findings included: 1. Review of the laboratory policy titled "IQCP - Control Plan Monthly Performances" included the following instruction: "Every month, a minimum of 2 levels of Quality Controls must be performed on each cartridge type kept in storage to verify stability. "At least two levels of Quality controls will also be performed on ever new shipment and/or lot numbers of the cartridges." 2. Review of the laboratory QC records for 2025 did not include 2 levels of QC documented for January, February, March, April, and August 2025. Surveyor asked the technical consultant (TC) 2, as listed on the CMS 209 personnel form, if the records were available, and no QC records could be provided. 3. Review of patient testing included the following 24 patients with ABG testing performed on the iSTAT from January 2026 through May 13, 2025 (the first acceptable QC date in 2025): January 2025: 3 days, 3 patients Date: Patient Account Number 01/16/2025, 901000512 01/27/2025, 901000510 01/31/2025, 901000523 February 2025: 3 days, 3 patients Date: Patient Account Number 02/12/2025, 901000529 02/16/2025, 901000522 02/25/2025, 901000540 March 2025: 8 Days, 7 patients Date: Patient Account Number 03/02/2025, 901000540 03/08/2025, 901000559 03/18/2025, 901000545 03/19/2025, 901000546 03/19/2025, 901000545

	03/27/2025, 901000575 03/29/2025, 901000580 03/30/2025, 901000579 April 2025: 8 Days, 6 patients Date: Patient Account Number 04/01/2025, 901000581 04/02/2025, 901000581 04/03/2025, 901000546 04/03/2025, 901000574 04/05/2025, 901000546 04/06/2025, 901000546 04/09/2025, 901000589 04/19/2025, 901000602 May 1, 2025, through May 12, 2025: 2 days, 2 patients 05/10/2025, 901000602 05/11/2025, 901000605 August 2025 (last acceptable QC 7/4/2025, next acceptable QC on 9/6 /2025): 4 days, 3 patients 08/18/2025, 901000699 08/22/2025, 901000717 08/24 /2025, 901000717 09/04/2025, 901000757 4. In an interview on March 11, 2026 at 15: 51, in the office, technical consultant (TC) 2, confirmed that the monthly QC had not been documented for the above months.
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. This STANDARD is not met as evidenced by: Based on review of laboratory control procedures, quality control records, assay value sheets, laboratory patient records, and confirmed in interview, the laboratory failed to have a mechanism in place to detect immediate errors in quality control for records reviewed from October 2025 through February 2026 when patient blood gas testing was being performed. The findings included: 1. Review of the laboratory policy titled "IQCP - Control Plan Monthly Performances" included the following instruction: "Every month, a minimum of 2 levels of Quality Controls must be performed on each cartridge type kept in storage to verify stability. At least two levels of Quality controls will also be performed on ever new shipment and/or lot numbers of the cartridges." 2. Review of the laboratory policy titled "I-Stat: Process for Aqueous Control Checks" did not include instructions for the verification of QC results against the laboratorys acceptability criteria. 3. Review of monthly QC documentation from January 2025 through February 2026, did not include the acceptability criteria for Levels 1 and 3 used in the monthly aqueous QC. Surveyor asked how the testing personnel knew if the QC was acceptable or unacceptable when QC was performed, and no documentation could be provided. The technical consultant (TC)2, as listed on the CMS 209 personnel form, stated the testing personnel made sure to run the QC every month, and that was it. 4. Review of the i-STAT TriControls Value Assignment sheets, obtained from the manufacturer's website from testing personnel 3 while surveyor was onsite, included the following days when quality control was outside of the manufacturers acceptable limits, and patient testing continued, for records reviewed from October 2025 through February 2026: November 2025: QC performed on 11/4/2025 for the iSTAT cartridge lot D25233: QC Level 1, Lot 301183, CLEW A50 included an pO2 acceptability of 67 - 97 mmHg. pO2 QC result obtained: 101 mmHg. December 2025: QC performed on 12/10/2025 for the iSTAT cartridge lot D25304 and D25325: QC Level 1, Lot 301183, CLEW A51 included an pO2 acceptability of 67 - 97 mmHg. pO2 QC result obtained: 93 for the iSTAT cartridge

	lot D25304 pO2 QC result obtained: 104 for the iSTAT cartridge lot D25325 January 2026: QC performed on 1/20/2026 for the iSTAT cartridge lot D25325: QC Level 1, Lot 301183, CLEW A51 included an pO2 acceptability of 67 - 97 mmHg. pO2 QC result obtained: 97 mmHg 5. Review of patient test records included 23 total patients had testing performed from the expiration of the last acceptable QC performed on 10/2 /2025 (11/2/2025), to the next acceptable QC performed on 2/9/2026: November 2025: 4 days and 3 different patients 11/18/2025: 901000920 11/21/2025: 901000927 11/24/2025: 901000927 11/27/2025: 901000920, 901000921, 901000927 December 2025: 3 days and 3 different patents 12/04/2025: 901000929 12/16/2025: 901000816 12/18/2025: 901000957 January 2026, 12 days and 14 different patients 01/01/2026: 901000918 01/05/2026: 901000971 01/15/2026: 901001012, 901001033 01/16/2026: 901001012 (tested twice) 01/19/2026: 901001041 (tested twice) 01/22/2026: 901001045 01/23/2026: 901001047, 901001035 01/25/2026: 901001024, 901001040, 901001035 (tested twice) 01/27/2026: 901001035 (tested twice) 01/28/2026: 901001035 01/29/2026: 901001035, 901001029 01/31/2026: 901001068 (tested twice), 901001063, 901001029 February 2026, 2 days, 3 different patients 02/02 /2026: 901001040, 901000993 02/04/2026: 901001029 6. In an interview on 3/11 /2026 at 15:45 hours, in the office, TC2 confirmed testing personnel did not have a way to ensure quality control was within acceptability during monthly QC.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory the laboratory Individualized Quality Control Plan (IQCP) for blood gas testing on the Abbott i-STAT instrument, quality assessment (QA) records, quality control records, and interview, the laboratory failed to have an ongoing mechanism in place for the monitoring of quality control to correct problems in the analytic system for records reviewed from January 2025 through February 2026. The findings included: 1. Review of the laboratory policy titled "IQCP - CG4+ Cartridge", effective March 20, 2023 and signed by the laboratory director, section "IQCP - Quality Assessment" included the following information: "Ongoing monitoring of QC failures, proficiency testing failures, analyzer, and tech errors will be maintained by the Director of Respiratory and/or Lab Manager. These failures will be addressed as needed in updated risk assessments ..." 2. In interview on March 11, 2026, at 1410, in the conference room, technical consultant (TC)2 confirmed the laboratory was not enrolled in proficiency testing. 3. In an interview on March 11, 2026, at 1545, in the office, TC2 confirmed the laboratory did not have a mechanism in place to detect QC failures. 4. In an interview on March 11, 2026, at 1623, in the conference room, TC 1 and TC 2 confirmed the laboratory IQCP Quality Assessment policy failed to identify and correct problems for blood gas testing on the iSTAT from January 2025, through February 2026.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient

	identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final test reports and confirmed in interview, the laboratory failed to ensure the patient final test report included the name and the address of the laboratory location where blood gas (ABG) testing was performed for three of three random patients reviewed in 2026. The findings included: 1. Review of the following three final test report for random patients with ABG testing performed in 2026 did not include the Name or the address of the facility location in which the testing occurred: Date of Testing: Account number 02/04/2026: 901001029 02/26/2026: 901001077 03 /09/2026: 901001106 2. In an interview on 3/11/2026 at 16:40 hours, in the conference room, technical consultant (TC 1), confirmed the address and name of the facility where the ABG testing occurred was not on the patient final report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, laboratory quality control documentation, laboratory quality assurance policy, and interviews, the laboratory director failed to ensure enrollment in proficiency testing for three of three regulated blood gas analytes (pH, pO2, pCO2), from January 2024 through February 2026 (D6014), failed to ensure the quality control program could detect immediate errors in the analytic system for QC records reviewed from January 2025 through February 2026 (D6020 I), and failed to ensure the quality assessment policies as part of the IQCP to reduce the frequency of quality control from every day of patient testing to once a month, failed to identify and correct failures in quality control procedures and proficiency testing procedures (D6020 II).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the CMS 116, laboratory test menu, and confirmed in interview, the laboratory director failed to ensure enrollment in proficiency testing (PT) for three of three regulated blood gas analyte testing on the Abbott i-STAT, pH, pO2, pCO2, from January 2024 through February 2026. Refer to D2000.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: I. Based on a review of laboratory quality control (QC) procedures, QC records, patient records, and interview, the laboratory director failed to ensure the laboratory had a quality control program in place to that could detect immediate errors in the analytic system for blood gas testing on the Abbott i-STAT instrument for QC records reviewed from October 2025 through February 2026. Refer to D5441. II. Based on review of laboratory documents, laboratory QC records, the laboratory director failed to ensure the quality assessment policies as part of the IQCP to reduce the frequency of quality control from every day of patient testing to once a month, failed to identify and correct failures in quality control procedures and proficiency testing procedures. Refer to D5791.