

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2171583	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Medical City Heart & Spine Hospital Pulmonary Lab	Street Address, City, State 11970 N Central Expressway, Dallas, 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 onsite validation survey was conducted on 08/25-08/26/2026. The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1409 Technical Consultant
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of ABL90 Flex Plus blood gas analyzer operator's guide, room temperature logs, and confirmed in staff interview, the laboratory failed to ensure the defined room humidity range did not exceed the operator's specifications for 2 of 2 ABL90 Flex Plus blood gas analyzers. Findings included: 1. Review of the ABL90 Flex Plus blood gas analyzer operator's guide stated: "Chapter 13 Specifications Specification Value Relative Humidity 10-80%" 2. Review of the laboratory's "Room Temperature Log" revealed an acceptable room humidity range of 5% to 85%. The laboratory's defined acceptable humidity range of 5% to 85% exceeded the manufacturer's acceptable humidity range of 10-80% for the two ABL90 Flex Plus blood gas analyzers. 3. During an interview in the office on 07/21/2026 at 2:32 PM, 08

/25/2026 at 2:00 PM, the respiratory supervisor, after a review of the records, confirmed the laboratory failed to ensure the defined room humidity range did not exceed the operator's specifications for 2 of 2 ABL90 Flex Plus blood gas analyzers.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, verification studies for the ABL90 Flex Plus blood gas analyzer, laboratory reference ranges, laboratory test records, and confirmed in interview, the laboratory failed to ensure the normal range for 14 of 14 blood gas parameters were verified by the laboratory's verification studies in 2026 (February) for 2 of 2 ABL90 Flex Plus blood gas analyzers. Findings included: 1. Review of the laboratory's policy "# HPLAB.1.0070" titled "LABORATORY METHOD VALIDATION" stated: "I. INTENDED USE: To perform validation /verification of each non-waived test/method/instrument system before use in patient testing. This verification includes accuracy, precision, analytic sensitivity, reportable range of patient test results, and establishment of reference ranges before methods are implemented. The methodperformance [sic] specifications are validated or verified in the location in which the patient testing will be performed ... II. POLICY ... I. Reference Ranges: Developed or verified according to Policy Lab 1.0100." Review of laboratory's policy "# LAB.1.0100" titled "LABORATORY REFERENCE RANGES" stated: "I. PURPOSE: The laboratory must provide useful clinical data. Reference intervals (normal ranges) are important to allow a clinician to assess patient results against an appropriate population. II. POLICY/PROCEDURE: A. The reference range must be established or verified for each analyte and specimen source (blood, urine, cerebrospinal fluid), when appropriate. 1. The reference range will be established during validation of a new procedure or instrument, and the range must be approved by the appropriate medical director." 2. According to verification studies, the laboratory added two ABL90 Flex Plus blood gas analyzers to their test menu on 03 /2026. The laboratory's "Method Instrument Validation Summary" for one ABL90 Flex Plus blood gas analyzers stated: I have reviewed the validation data for accuracy, precision, linearity, and reportable range for the ABL90 Flex Plus-SN: 09R0665N024, and the performance of the method is considered acceptable for patient testing." The laboratory's "Method Instrument Validation Summary" for the second ABL90 Flex Plus blood gas analyzers stated: I have reviewed the validation data for accuracy, precision, linearity, and reportable range for the ABL90 Flex Plus-SN: 092R0665N025, and the performance of the method is considered acceptable for patient testing." Further review of the verification studies for the ABL90 Flex Plus blood gas analyzers revealed the laboratory did NOT perform a normal range (reference range) study as required. 3. Review of the laboratory's policy # "POC. 8.400" titled "RT-ABG ABNORMAL VALUES" listed the normal ranges for the parameters tested on the ABL90 Flex Plus analyzer as follows: Adult ABG Normal Range pH 7.35 - 7.45 [sic] PCO2 35 - 45 mmHg PO2 80 - 100 mmHg HCO3 19 25 -

	mmol/L THB 12 - 16 g/dL COHB 0 - 1.5% CO OXY HGB 95 - 100% METHB 0.0 - 1.5 Adult VBG Normal Range pH 7.326 - 7.426 PCO2 41 - 51 mmHg PO2 30 - 50 mmHg Adult Electrolytes Normal Range Sodium 136 - 145 mmol/L Potassium 3.5 - 5.1 mmol/L Lactate 0.4 - 1.9 mEq/L Calcium Ionized 1.17 - 1.32 (12Y - 59 Y) Glucose 70 - 110 mg/dL The laboratory was asked to provide the studies used to obtain these normal ranges, and none were provided. 4. Review of laboratory test records identified 514 patients who had a blood gas analysis performed from March 1, 2026, through June 11, 2026, on the ABL90 Flex Plus blood gas analyzers. 5. During an interview on 08/25/2026 at 1:13 PM, the laboratory representatives, after a review of records, confirmed the laboratory failed to ensure the normal range for 14 of 14 blood gas parameters were verified by the laboratory's verification studies in 2026 (February) for 2 of 2 ABL90 Flex Plus blood gas analyzers. ABG - arterial blood gas pH - potential of hydrogen PCO2 - partial pressure of carbon dioxide PO2 - partial pressure of oxygen THB - total hydrogen C0HB - carboxyhemoglobin CO OXY HGB - oxyhemoglobin METHB - methomoglobin mmHg - millimeters of mercury mmol/L - millimole per liter g/dL - grams per deciliter VBG- venous blood gas mEq/L - milliequivalents per liter Y - years mg/dL - milligrams per deciliter
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory's room temperature logs and confirmed in interview, the laboratory failed to document corrective action when room temperature and humidity were not documented for 22 of 92 days in 2026 (March - May). Findings included: 1. Review of the laboratory's "Room Temperature Log" from March 2026 through May 2026 revealed the laboratory had an established acceptable temperature range of 59 degrees F to 86 degrees F and humidity range of 5% to 85%. 2. Further review of the laboratory's "Room Temperature Log" revealed 22 of 92 days from March 2026 through May 2026 when room temperature and humidity was not documented. Next to each date was an "action" box documented with a code "3". The legend at the bottom of the page indicated that a code of "3" meant the laboratory failed to record temperature and an action was taken. The following dates on the log were dates when the laboratory failed to record temperature and humidity, and the action code was documented with a "3". March: 14, 15, 21, 22, 28, 29 April: 4, 11, 12, 18, 19, 25, 26, 30 May: 2, 3, 9, 10, 16, 17, 30, 31 The laboratory was asked to provide documentation of the corrective action taken when temperature and humidity were not recorded on the log, and none was provided. 3. During an interview on 08/25/2026 at 2:00 PM, the respiratory supervisor, after a review of the records, stated that the laboratory did not take any corrective action when they failed to document the temperature and humidity, confirming the above findings. Word Key: F - Fahrenheit

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 policies, ABL90 Flex Plus blood gas analyzer operator's guide, room temperature logs, verification studies for the ABL90 Flex Plus blood gas analyzer, laboratory reference ranges, laboratory test records, and confirmed in staff interview, the laboratory failed to establish an effective QA system to monitor, assess, and correct problems in the laboratory for the analytical phase of testing. Findings included: 1. Review of the laboratory's policy "Individualized Quality Control Plan (IQCP): Blood Gas Systems: Radiometer ABL 90 Flex Series Systems" stated: "Quality Assessment (QA): All IQCP QA monitoring is part of the lab's overall QA plan and is an ongoing review process for the IQCP. The lab has a review system for the ongoing monitoring of the effectiveness of the lab's IQCP. The lab has a review system for, but not limited to, specimen, environment, testing personnel,, [sic] reagent, and test system. In addition, if there is a complaint on a test result and/or unacceptable QC and proficiency test result, the lab investigates and takes corrective action. It may be necessary to change the IQCP." Note the laboratory did not develop an IQCP plan for the laboratory's ABL90 Flex Plus blood gas analyzer. 2. The laboratory failed to ensure the defined room humidity range did not exceed the operator's specifications for 2 of 2 ABL90 Flex Plus blood gas analyzers. Refer to D5413. 3. The laboratory failed to ensure the normal range for 14 of 14 blood gas parameters were verified by the laboratory's verification studies in 2026 (February) for 2 of 2 ABL90 Flex Plus blood gas analyzers. Refer to D5421. 4. The laboratory failed to document corrective action when room temperature and humidity were not documented for 22 of 92 days in 2026 (March - May). Refer to D5781.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to have 3 of 6 technical consultants who met the qualification requirements of 493.1411 of this subpart. The laboratory failed to ensure 3 of 6 individuals employed met the minimum education requirements of a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution to qualify as a technical consultant for blood gas analysis. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license

issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to employ one or more individuals who were qualified to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests. The laboratory failed to ensure 3 of 6 individuals employed met the minimum education requirements of a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution to qualify as a technical consultant for blood gas analysis. Findings included: 1. Review of the CMS-209 listed the six technical consultants. 2. Review of personnel documents for Technical Consultant-1 (TC-1) revealed he did not meet the requirements as stated in CFR 493.1411 to qualify as a technical consultant for moderate complexity testing (blood gas analysis). Review of personnel documents for Technical Consultant-1 (TC-5) revealed she did not meet the requirements as stated in CFR 493.1411 to qualify as a technical consultant for

moderate complexity testing (blood gas analysis). Review of personnel documents for Technical Consultant-1 (TC-6) revealed he did not meet the requirements as stated in CFR 493.1411 to qualify as a technical consultant for moderate complexity testing (blood gas analysis). 3. During an interview on 08/25/2026 at 11:17 AM, the laboratory representatives, after a review of records, confirmed laboratory failed to employ one or more individuals who were qualified to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests (blood gas analysis).