Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2121677	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Beaumont Heart & Vascular Surgery Center	755 North 11th Street, Suite P3970b, Beaumont, 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	Based upon findings made during an onsite validation survey completed January 3, 2024 the laboratory failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1250 Condition: Analytic Systems: 493. 1403 Condition: Laboratories performing moderate complexity testing; laboratory director:
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 the laboratory policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory quality assurance program failed to establish and maintain the quality control programs for the specialties of Chemistry and Hematology in 2022 and 2023. (See D5441 and D5445)
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 upon review of the CMS Application Form 116, policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to establish and maintain the quality control program for Chemistry and Hematology in the 14 months between September 2022 and November 2023. The findings included: 1. Review of the CMS Application Form 116 found the laboratory defined the days of operation (in the shared space with CLIA 45D2122986) as: Monday 8:00 AM to 5:00 PM Wednesday 8:00 AM to 5:00 PM Thursday 8:00 AM to 5:00 PM 2. Review of the policy titled Quality Control and Assessment (signed by the Laboratory Director 03/30/2020) found on pages 1-2 under the heading PROCEDURE FOR PERFORMANCE OF CONTROL MATERIALS: "1. ABBOTT i-STAT (Chem 8+) - Moderate Run the electronic control each eight hours of operation. prior to running patient samples, and after any significant maintenance has been performed. Run the two levels of Abbott i-STAT chemistry controls in the following situations every 30 days. a. Change in reagent lot number. b. New Shipment of reagent c. Service call or component replacement d. Selective maintenance procedures. 2. AVOXIMETER (O2 Saturation, Hemoglobin) - Moderate Run daily yellow and orange filter checks Run the level 1 and Level 3 controls every 30 days, and at least one level once per week and after any significant maintenance has been performed. Controls should be run with each new lot or shipment of cuvettes. 3. HEMACHRON SIGNATURE ELITE (ACT Testing) - Moderate Run internal QC every 8 hours of operation (internal schedule within instrument) Run the Normal and Abnormal control every 30 days or after any significant maintenance has been performed. Controls should be run with each new lot or shipment of cuvettes." Continued review of the policy found on page 3: "When performing testing on the iSTAT, Avoximeter and Hemochron, it is not necessary to evaluate shifts and trends or Levy-Jennings charts when reviewing quality control, as quality control testing is performed every 30 days, under normal testing circumstances." 3. Review of quality control records (used to document quality control results for CLIA 45D2121677 and 45D2122986) found the laboratory failed to test quality control materials at least once each month (as per their own policy) for each of the three platforms as follows: a. Avoximeter 1000E - There was no documentation of quality control materials tested for 8 of 8 months between September 2022 and April 2023 during the hours of operation as defined on the CMS Application 116. b. Hemochron Jr. Activated Clotting Time - There was no documentation of quality control materials tested for 3 of 8 months between September 2022 and April 2023 during the hours of operation as defined on the CMS Application 116 when patients were tested as follows: November 2022 December 2022 April 2023 c. Abbott iSTAT - There was no documentation of quality control materials tested for 3 of 8 months between September 2022 and April 2023 during the hours of operation as defined on the CMS Application 116 when patients were tested as follows: January 2023 February 2023 April 2023 The laboratory had no documentation available for review to evaluate the performance of quality control time. 4. Review of patient test records found the laboratory tested and reported results for patient specimens as follows: a. Avoximeter 1000E - The laboratory tested and reported results for 16 patient specimens without quality control

	materials being tested in 8 of 8 months as follows: Patient 4003979 was tested October 31, 2022 4 patient specimens tested in November 2022 Patient 4003984 tested twice on November 2, 2022 Patient 4004039 tested November 14, 2022 2 patient specimens tested in December 2022 Patient 4004080 tested December 8, 2024 Patient 4003124 tested December 15, 2022 5 patient specimens tested in February 2023 Patient 4004241 tested February 1, 2023 Patient 4004218 tested 3 times on February 1, 2023 Patient 4004270 tested February 13, 2023 2 patients tested in March 2023 Patient 4004361 tested March 14, 2023 Patient 4003283 tested March 23, 2023 3 patient specimens tested in April 2023 Patient 4004470 tested April 17, 2023 Patient 4004473 tested April 19, 2023 Patient 4004325 tested April 27, 2023 b. Hemochron Jr. Activated Clotting Time - The laboratory tested and reported results for 73 patient specimens without quality control materials being tested in 3 of 8 months as follows: November 2022 - 24 patient specimens tested as follows: November 1 - Patients 1405280 and 1407289 November 2 - Patient 4003997 November 3 - Patient 4004012 November 4 - Patient 1407757 November 7 -Patient 1407294 November 11 - Patient 1407294 November 14 - Patients 4004034, 4004002, and 4004028 November 15 - Patient 1403453 November 16 - Patients 4003985 and 4002484 November 17 - Patients 4004047, 4001855 and 4004045 November 18 - Patients 1407291, 1406819 and 1407290 November 28 - Patients 4004044, 4004052 and 4004050 November 29 - Patients 1407311 and 1407300 December 2022 - 15 patients tested as follows: December 5 - Patients 4004059 and 4004058 December 6 - Patient 1407328 December 7 - Patient 4004041 December 8 - Patients 4004047 and 4004084 December 9 - Patient 1405866 December 12 - Patient 4004092 December 13 - Patients 1407331, 1407320 and 1406775 December 14 - Patient 4004131 December 28 - Patient 4004110 and 1 patient without patient ID entered on log sheet December 30 - Patient 1407299 April 2023 - 23 patients tested as follows: April 3 - Patients 4004417 and 4004366 April 4 - Patient 1407480 April 5 - 1 patient without patient ID entered on log sheet April 6 - Patients 4004436 and patient 4004437 April 12 - Patient 400411 April 13 - Patients 400942 and 4004431 April 14 - Patients 1407472 and 1407485 April 17 - Patient 4004471 April 19 - Patients 4004469 and 4004474 April 20 - Patient 4004485 April 24 - Patients 4004494, 4004486 and 4004482 April 25 - Patients 1407505 and 1407484 April 26 - Patient 4000329 April 27 - Patient 4004325 April 28 - Patient 1401358 c. Abbott iSTAT - The laboratory tested 14 patient specimens without testing quality control materials as defined in their own IQCP in 3 of 8 months January 2023 - 6 patients tested as follows: January 10 - Patient 1407368 January 11 - Patient 4004124 January 12 - Patients 4004153 and 4004179 January 26 - Patient 400418 January 30 - Patient 4004141 February 2023 - 4 February 9 - Patient 4002322 February 10 - Patient 1404101 February 13 - Patient 4004252 February 27 - Patient 4004346 April 2023 - 4 April 4 - Patient 1407480 April 10 - Patients 4004421 and 1402137 April 12 - Patient 4004452 5. During interview of the Technical Consultant conducted on January 3, 2024 at 3:17 PM, she confirmed that the laboratory did not test quality control materials each month if they were previously documented for the month on dates when CLIA 45D2122986 had tested external quality control material. She went on to confirm that she did not have Levy-Jennings Graphs or another means to evaluate the performance of control materials over time.
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 upon review of the CMS Application Form 116, policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to follow it's own Individualized Quality Control Plan (IQCP) for 3 of 3 platforms in Chemistry and Hematology in 8 of 8 months between September 2022 and April of 2023. The findings included: 1. Review of the CMS Application Form 116 found the laboratory defined the days of operation (in the shared space with CLIA 45D2122986) as: Monday 8:00 AM to 5:00 PM Wednesday 8:00 AM to 5:00 PM Thursday 8:00 AM to 5:00 PM 2. Review of the policy titled Quality Control and Assessment (signed by the Laboratory Director 03/30/2020) found on pages 1-2 under the heading PROCEDURE FOR PERFORMANCE OF CONTROL MATERIALS: "1. ABBOTT i-STAT (Chem 8+) - Moderate Run the electronic control each eight hours of operation. prior to running patient samples, and after any significant maintenance has been performed. Run the two levels of Abbott i-STAT chemistry controls in the following situations every 30 days. a. Change in reagent lot number. b. New Shipment of reagent c. Service call or component replacement d. Selective maintenance procedures 2. AVOXIMETER (O2 Saturation, Hemoglobin) - Moderate Run daily yellow and orange filter checks Run the level 1 and Level 3 controls every 30 days, and at least one level once per week and after any significant maintenance has been performed. Controls should be run with each new lot or shipment of cuvettes. 3. HEMACHRON SIGNATURE ELITE (ACT Testing) - Moderate Run internal QC every 8 hours of operation (internal schedule within instrument) Run the Normal and Abnormal control every 30 days or after any significant maintenance has been performed. Controls should be run with each new lot or shipment of cuvettes." 3. Review of quality control records (used to document quality control results for CLIA 45D2121677 and 45D2122986) found the laboratory failed to test quality control materials at least once each month and with each new shipment and lot change (as per their own policy) for each of the three platforms as follows: a. Avoximeter 1000E - There was no documentation of quality control materials tested for 8 of 8 months (between September 2022 and April 2023) during the hours of operation as defined on the CMS Application 116. September 2022 -The lab used cuvette lot 7863732 October 2022 - The lab used cuvette lot 7863732 November 2022 - The lab used cuvette lot 7863732 December 2022 -(no documentation of lot number) January 2023 - The lab used lot 7975683 February 2023 -The lab used lot 7975683 March 2023 - The lab used lot 7975683 April 2023 -The lab used lot 7975683 b. Hemochron Jr. Activated Clotting Time - There was no documentation of quality control materials tested for 3 of 8 months (between September 2022 and April 2023) during the hours of operation as defined on the CMS Application 116. December 2022 - The cartridge lot in use was G2JlR193 January 2023 - The cartridge lot in use was G2JLR193 April 2023 - The cartridge lot in use was lot J2JLR263 c. Abbott iSTAT - There was no documentation of quality control materials tested for 3 of 8 months(between September 2022 and April 2023) during the hours of operation as defined on the CMS Application 116. January 2023 - cartridge lot in use was H22288A February 2023 - cartridge lot in use was H22309 April 2023 -cartridge lot in use was H22339 4. Review of patient test records found the laboratory tested patient specimens without testing quality control materials with each new lot of reagents as follows: a. Avoximeter 1000E - The laboratory tested 16 patient specimens without quality

	control materials being tested in 6 of 8 months as follows: Patient 4003979 was tested October 31, 2022 4 patient specimens tested in November 2022 Patient 4003984 tested twice on November 2, 2022 Patient 4004039 tested November 14, 2022 2 patient specimens tested in December 2022 Patient 4004080 tested December 8, 2024 Patient 4003124 tested December 15, 2022 5 patient specimens tested in February 2023 Patient 4004241 tested February 1, 2023 Patient 4004218 tested 3 times on February 1, 2023 Patient 4004270 tested February 13, 2023 2 patients tested in March 2023 Patient 4004361 tested March 14, 2023 Patient 4003283 tested March 23, 2023 3 patient specimens tested in April 2023 Patient 4004470 tested April 17, 2023 Patient 4004473 tested April 19, 2023 Patient 4004325 tested April 27, 2023 b. Hemochron Jr. Activated Clotting Time - The laboratory tested 62 patients without testing quality control materials as defined in their own IQCP in 3 of 8 months as follows: November 2022 - 24 patients tested as follows: November 1 - Patients 1405280 and 1407289 November 2 - Patient 4003997 November 3 - Patient 4004012 November 4 - Patient 1407757 November 7 -Patient 1407294 November 11 - Patient 1407294 November 14 - Patients 4004034, 4004002, and 4004028 November 15 - Patient 1403453 November 16 - Patients 4003985 and 4002484 November 17 - Patients 4004047, 4001855 and 4004045 November 18 - Patients 1407291, 1406819 and 1407290 November 28 - Patients 4004044, 4004052 and 4004050 November 29 - Patients 1407311 and 1407300 December 2022 - 15 patients tested as follows: December 5 - Patients 4004059 and 4004058 December 6 - Patient 1407328 December 7 - Patient 4004041 December 8 - Patients 4004047 and 4004084 December 9 - Patient 1405866 December 12 - Patient 4004092 December 13 - Patients 1407331, 1407320 and 1406775 December 14 - Patient 4004131 December 28 - Patient 4004110 and 1 patient without patient ID entered on log sheet December 30 - Patient 1407299 April 2023 - 23 patients tested as follows: April 3 - Patients 4004417 and 4004366 April 4 - Patient 1407480 April 5 - 1 patient without patient ID entered on log sheet April 6 - Patients 4004436 and patient 4004437 April 12 - Patient 400411 April 13 - Patients 400942 and 4004431 April 14 - Patients 1407472 and 1407485 April 17 - Patient 4004471 April 19 - Patients 4004469 and 4004474 April 20 - Patient 4004485 April 24 - Patients 4004494, 4004486 and 4004482 April 25 - Patients 1407505 and 1407484 April 26 - Patient 4000329 April 27 - Patient 4004325 April 28 - Patient 1401358 c. Abbott iSTAT - The laboratory tested 14 patient specimens without testing quality control materials as defined in their own IQCP in 3 of 8 months January 2023 - 6 patients tested as follows: January 10 - Patient 1407368 January 11 - Patient 4004124 January 12 - Patients 4004153 and 4004179 January 26 - Patient 400418 January 30 - Patient 4004141 February 2023 - 4 February 9 - Patient 4002322 February 10 - Patient 1404101 February 13 - Patient 4004252 February 27 - Patient 4004346 April 2023 - 4 April 4 - Patient 1407480 April 10 - Patients 4004421 and 1402137 April 12 - Patient 4004452 5. During interview of the Technical Consultant conducted on January 3, 2024 at 3:17 PM, she confirmed that the laboratory did not test quality control materials each month if they were previously documented for the month on dates when CLIA 45D2122986 had tested external quality control material.
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. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory quality assurance program failed to identify that the laboratory had not established and maintained the quality control programs for the specialties of Chemistry and Hematology in 2022 and 2023. (See D5441 and D5445)
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 the CMS Report 209 Laboratory Personnel Report, electronic mail submission and staff interview, the laboratory director failed to provide overall management and direction of the laboratory services for Chemistry and Hematology. (See D6020, D6021 and D6028)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory director failed to establish and maintain the quality control programs for the specialties of Chemistry and Hematology in 2022 and 2023. (See D5441 and D5445)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control records,

	patient test records, and interview of facility personnel, the laboratory director failed to ensure the quality assurance programs for Chemistry and Hematology identified and corrected problems in 2022 and 2023. (See D5791)
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel the laboratory director failed to ensure that the technical consultant provided proper supervision and technical oversight of the quality control program for Chemistry and Hematology in 2022 and 2023. (See D6042)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel the technical consultant failed to establish and maintain the quality control program for Chemistry and Hematology in 2022 and 2023. (See D5441 and D5445)