Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2122986	**(X3) Date Survey Completed** 01/03/2024
Name of Provider or Supplier Beaumont Heart & Vascular Center	**Street Address, City, State** 755 North 11th Street, Suite P3970-A, 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	An announced validation survey of the laboratory was conducted on 01/03/2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: 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
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 manufacturer instructions, laboratory's policies/procedures, quality control (QC)/quality assurance (QA) records, patient test records and staff interview, the laboratory failed to meet analytic systems requirements for three of three laboratory's test platforms reviewed from September 2022 to April 2023, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Findings included: 1. The laboratory failed to document verification of quality controls over time to monitor QC for shifts and trends for three of three instruments used by the laboratory, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Refer to D5441. 2. The laboratory failed to document quality control as required for one of one Abbott i-STAT chemistry analyzer used by the laboratory. Refer to D5445A. 3. The laboratory failed to document quality control as required for one of one coagulation instrument, the Accriva Hemochron Signature Elite, used by the laboratory to test activated

	clotting time (ACT). Refer to D5445B. 4. The laboratory's Quality Assurance failed to address, identify and correct issues with over time evaluation of quality control and quality control frequency requirements for three of three instruments used by the laboratory. Refer to D5791.
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 laboratory's policies/procedures, quality control (QC) and quality assurance (QA) records and staff interview the laboratory failed to document verification of quality controls over time to monitor QC for shifts and trends for three of three instruments used by the laboratory, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Findings included: 1. Review of laboratory's policy " Quality Assurance Plan" (Reference #010, last revised 06/18/2018) revealed: "POST-ANALYTICAL PHASE ... c. Monitoring of shifts and trends for QC values" 2. Review of laboratory's QA and QC records for the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter for September 2022 to April 2023 revealed there was no documentation of QC review over time to monitor for trends and shifts in the QC values. 3. In an interview on 01/03/2024 at 1451 hours in the break room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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: A. Based on review of manufacturer instructions, laboratory's policies/procedures and Individualized Quality Control Plans (IQCP), quality control (QC) records, patient test records and staff interview, the laboratory failed to document required quality control for the Abbott i-STAT chemistry analyzer used by the laboratory as per its own IQCP

for four of eigth months reviewed from September 2022 to April 2023. Findings included: 1. Review of manufacturer instructions for use revealed: a. The Abbott i-STAT (document ART:714446-00W, dated 13-Feb-2017) instrument user manual revealed: "Verify the performance for each handheld in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance." And, "Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls... along with a representative sample of the new lot..." b. The Abbott i-STAT Chem8+ Cartridge (document ART:765874, R-00 Rev.D, Dated 15-Oct-2021) instructions for use revealed the manufacturer did not specify required frequency of external QC testing. 2. Review of laboratory's policies and procedures revealed: a. Policy "Chem8+ using Abbott ISTAT Analyzer" (Reference #005 last reviewed/signed by the laboratory director on 03/30/2020) revealed: "Electronic QC and internal QC is performed once daily and every 8 hours, respectively." And, "External QC is run each time a new shipment or new lot number of cartridges is opened or every 30 days." b. Policy "Quality Control and Assessment" (Reference #003, last reviewed/signed by the laboratory director on 03/20/2020) revealed: "ABBOTT i-STAT (Chem8+ Cartridge) - 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" And, "INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) FOR THE AVOX, iSTAT Chem8 AND THE HEMACHRON JR ACT (iSTAT ACT AS NEEDED) REPLACING EQC (QC15). ...a. The Abbott i-STAT and or/Hemochron, for ACT testing, has met the risk assessment objectives for the following quality control requirements. ...iii. With acceptable performance the laboratory may perform ... external ACT and Chem8 quality control performance every 30 days or with each new lot of reagent." 3. Review of laboratory's QC records for the Abbott i-STAT chemistry analyzer from September 2022 to April 2023 revealed the laboratory failed to document QC every 30 days as per own IQCP for the following months: September 2022 - No documentation of QC for the month of September 2022 October 2022 - No documentation of QC for the month of October 2022 - Next QC documented Tuesday, 11/22/2022 November 2022 - No documentation of QC until 11/22/2022 -Time elapsed: 82 days without QC, from 09/01/2022 to 11/22/2022 March 2023 - QC exceeded 30 days - Last QC documented Tuesday, 02/14/2023 - Next QC was documented on Tuesday, 03/28/2023 - Time elapsed: 42 days between QC, from 02/14 /2023 to 03/28/2023 4. Review of laboratory's patient test records revealed the laboratory performed testing during hours of operation (Tuesdays and Fridays) when required QC was not documented every 30 days as follows: September 2022 Date Tested Patient MR# 09/13/2022 1407189 09/13/2022 1407195 09/13/2022 1403838 09 /16/2022 1403865 09/16/2022 1407196 October 2022 Date Tested Patient MR# 10/07 /2022 1407221 10/14/2022 1407127 10/18/2022 1407218 10/21/2022 1407285 10/28 /2022 1405162 November 2022 Date Tested Patient MR# 11/01/2022 1403392 11/04 /2022 1407265 11/11/2022 1407284 11/11/2022 1401746 11/11/2022 1400708 11/15 /2022 1403929 11/18/2022 1407278 11/18/2022 1407297 March 2023 Date Tested Patient MR# 03/24/2024 1407456 5. In an interview on 01/03/2024 at 1517 hours in the break room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of manufacturer instructions, laboratory's policies/procedures and Individualized Quality Control Plans (IQCP), quality control (QC) records, patient test records and staff interview, the laboratory failed to document quality control as required for the Accriva Hemochron Signature Elite coagulation instrument, used by the laboratory to test activated clotting

	time (ACT) for four of eight months reviewed from September 2022 to April 2023. Findings included: 1. Review of manufacturer instructions for use revealed: a. For the Hemochron Signature Elite instrument (document HX1101EN): "QC of Instrument Performance The instrument should be tested at two levels once every eight hours of operation. Automatic internal Electronic Quality Control (EQC) can be used to provide a two-level electronic verification of instrument performance, or liquid quality control products can be used." b. For the Accriva direct CHECK Whole Blood Control (document HL1241-01), used with the Hemochron, the manufacturer did not specify required frequency of external (liquid) QC testing. 2. Review of laboratory's policies and procedures revealed: a. Policy "Activated Clotting Time using Hemachron (sic) Signature Elite" (Reference #006 last reviewed/signed by the laboratory director on 06/18/2018) revealed: "Quality Control is performed according to the individualized quality control risk assessment." b. Policy "Quality Control and Assessment" (Reference # 003, last reviewed/signed by the laboratory director on 03 /20/2020) revealed: "HEMOCHRON SIGNATURE ELITE - 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." And, "INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) FOR THE AVOX, iSTAT Chem8 AND THE HEMACHRON JR ACT (iSTAT ACT AS NEEDED) REPLACING EQC (QC15). ...a. The Abbott i-STAT and or/Hemochron, for ACT testing, has met the risk assessment objectives for the following quality control requirements. ...iii. With acceptable performance the laboratory may perform ... external ACT and Chem8 quality control performance every 30 days or with each new lot of reagent." 3. Review of laboratory's QC records for the Accriva Hemochron Signature Elite hematology analyzer from September 2022 to April 2023 revealed the laboratory failed to document QC every 30 days as per its IQCP for the following months: September 2022 - No documentation of QC for the month of September 2022 October 2022 - No documentation of QC for the month of October 2022 - Next QC documented Tuesday, 11/08/2022 - Time elapsed: 68 days without QC, from 09/01 /2022 to 11/08/22 February 2023 - No documentation of QC for the month of February 2023 - Last QC documented Friday, 01/13/2023 March 2023 - QC documented Friday 03/31/2023, - Time elapsed: 77 between QC, from 01/13/2023 to 03/31/2023 4. Review of laboratory's patient test records revealed the laboratory performed testing during hours of operation (Tuesdays and Fridays) when required QC was not documented every 30 days as follows: September 2022 Date Tested Patient MR# 09/09/2022 1407174 09/16/2022 1407181 09/20/2022 1407211 09/23 /2022 1407223 09/23/2022 1407155 09/27/2022 1406220 09/30/2022 1401721 October 2022 Date Tested Patient MR# 10/14/2022 1407268 10/18/2022 1407218 10 /21/2022 1407264 10/21/2022 1407285 10/21/2022 1407211 10/28/2022 1403957 10 /28/2022 1407212 November 2022 Date Tested Patient MR# 11/01/2022 1406974 11 /01/2022 1405280 11/01/2022 1407289 11/04/2022 1407257 February 2023 Date Tested Patient MR# 02/17/2023 1407349 02/17/2023 1407091 02/17/2023 1407386 02 /21/2023 1406380 02/28/2023 1407328 02/28/2023 1407425 02/28/2023 1404060 March 2023 Date Tested Patient MR# 03/03/2023 1407431 03/03/2023 1407429 03/21 /2023 1406995 03/24/2023 1407451 03/28/2023 1404060 03/28/2023 1406995 5. In an interview on 01/03/2024 at 1517 hours in the break room, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid MR# - Medical record number
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 laboratory's policies/procedures, quality control records, patient test records and staff interview, the laboratory's Quality Assurance failed to identify and correct issues with over time evaluation of quality control and quality control frequency requirements for three of three instruments used by the laboratory from September 2022 to April 2023, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Refer to D5441 and D5445A, B.
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 manufacturer instructions, laboratory's policies/procedures, quality control (QC)/quality assurance (QA) records, patient test records and staff interview, the Laboratory Director failed to provide overall laboratory management and direction of laboratory's analytic systems for three of three laboratory's test platforms reviewed from September 2022 to April 2023, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Findings included: 1. The Laboratory Director failed to ensure laboratory's quality control was maintained. Refer to D6020. 2. The Laboratory Director failed to ensure laboratory's quality assurance was maintained. Refer to D6021.
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 manufacturer instructions, laboratory's policies/procedures, quality control (QC)/quality assurance (QA) records, patient test records and staff interview, the Laboratory Director failed to ensure quality control was maintained for three of three laboratory's test platforms reviewed from September 2022 to April 2023, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Refer to D5441 and D5445A, B.
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 manufacturer instructions, laboratory's policies/procedures, quality control (QC)/quality assurance (QA) records, patient test records and staff interview, the Laboratory Director failed to ensure laboratory's quality assurance was maintained for three of three laboratory's test platforms reviewed from September 2022 to April 2023, the Abbott ISTAT, Accriva Hemochron, and Accriva AVOXimeter. Refer to D5791.