Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2064081	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Complete Care Camp Bowie	6006 Camp Bowie, Fort Worth, 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	Laboratory representatives were present at the entrance conference conducted 03/09 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 03/09 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
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: I. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), manufacturer's instructions, quality control (QC) records, patient records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the MetLac 12 cartridge on the Piccolo Xpress chemistry analyzer. Findings: 1. Review of the laboratory's "Piccolo IQCP (Individualized Quality Control Plan)" for the Metlac12 cartridge stated: "After performing a risk assessment (covering the specimen, the environment, the testing personnel, the reagents and the test system), quality control recommendations and

verifying our QA plan was sufficient to assess the testing we perform on this meter, there is a manageable risk associated with running liquid QC on this test per the manufacturer's instructions (which is less stringent than what CLIA requires). The manufacturer recommends running external liquid control samples with each new lot /shipment, every 30 days, when training or retraining new operators, when patient results do not match the symptoms or clinical condition or when the laboratory conditions have changed significantly ... We will run external liquid control samples with each new lot/shipment, every 30 days, when training or retraining new operators, when patient results do not match the symptoms or clinical condition or when laboratory conditions have changed significantly" Review of the laboratory's risk assessment revealed: "Additional points QC is run per manufacturer's recommendation and less than the CLIA requirements for 2 levels of controls for each day of patient testing. We performed a 10 day external liquid QC study upon implementation of this analyzer. All values were within the expected ranges. In addition, we have been running waived tests on the Piccolo analyzer with the same QC requirements and have documented the stability of the analyzer through these results." The laboratory's IQCP failed to support its reduction in frequency to every 30 days. 2. Review of the Piccolo Metlac 12 Panel assay sheet revealed: "Quality Control ...Abaxis recommends control testing to follow federal, state, and local guidelines." 3. Review of QC records from December 2020 through February 2021 revealed the laboratory performed quality control on the following dates on the Piccolo Xpress chemistry analyzer Metlac 12 cartridge (random sampling): QC level 1 lot #2004021-1, expiration date 09/30/21 QC level 2 lot #2004021-2, expiration date 09/30/21 QC level 1 and 2 was performed on 12/18/2020, 01/05/2021, 02/04/2021 4. Review of patient records revealed the laboratory failed to perform QC every day of patient testing. Refer to D5447, I. 5. During an interview on 03/09/2020 at 1:15 pm, technical consultant confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the Metlac 12 chemistry cartridge. II. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), manufacturer's instructions, quality control (QC) records, patient records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the cardiac panel cartridge on the Alere Triage analyzer. Findings: 1. Review of the laboratory's "Triage meter IQCP (Individualized Quality Control Plan)" for the cardiac panel cartridge stated: "After performing a risk assessment (covering the specimen, the environment, the testing personnel, the reagents and the test system), quality control recommendations and verifying our QA plan was sufficient to assess the testing we perform on this meter, there is a manageable risk associated with running liquid QC on this test per the manufacturer's instructions (which is less stringent than what CLIA requires). The manufacturer recommends running external liquid control samples with every 30 days with continued use of the same reagent lot number and with each new lot of reagents ... We will run an internal quality control device (QCD) daily on the Triage meter. We will run liquid external quality control material on new lots/shipments and every 30 days as applicable" Review of the laboratory's risk assessment revealed: "Additional points QC is run per manufacturer's recommendation and less than the CLIA requirements for 2 levels of controls for each day of patient testing. We performed a 10 day external liquid QC study upon implementation of this analyzer. All values were within the expected ranges." The laboratory's IQCP failed to support its reduction in frequency to every 30 days. 2. Review of the Alere Triage user's manual stated: "TOTAL QUALITY ASSURANCE ... QUALITY CONTROL SAMPLES It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total intergrety of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features

inherent in the Alere Triage tests. The Alere Triage tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Alere Triage tests reduce the impact of procedural errors, ensure reagent integrity, and assurance that patient results are accurate each and every time a test is performed. Based on CLIA guidelines and other regulating bodies, Alere makes the following QC recommendations: Run two levels of POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every thirty days with continued use of the reagent lot number. Run the QC Device daily." 3. Review of QC records from December 2020 through February 2021 revealed the laboratory performed quality control on the following dates on the Alere Triage analyzer for the cardiac panel cartridge (random sampling): QC level 1 lot #03652, expiration date 05/21 QC level 2 lot #03665, expiration date 05/21 QC level 1 and 2 was performed on 12/07/2020 QC level 1 lot #03654, expiration date 06/04/21 QC level 2 lot #03668, expiration date 06/30/21 QC level 1 and 2 was performed on 01/06 /2021, 01/19/2021 QC level 1 lot #03657, expiration date 09/09/21 QC level 2 lot #03667, expiration date 09/14/21 QC level 1 and 2 was performed on 02/18/2021 4. Review of patient records revealed the laboratory failed to perform QC every day of patient testing. Refer to D5447, II. 5. During an interview on 03/09/2020 at 3:00 pm, technical consultant confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the cardiac panel cartridge. III. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), manufacturer's instructions, quality control (QC) records, patient records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the D-Dimer cartridge on the Alere Triage analyzer. Findings: 1. Review of the laboratory's "Triage meter IQCP (Individualized Quality Control Plan)" for the D-Dimer cartridge stated: "After performing a risk assessment (covering the specimen, the environment, the testing personnel, the reagents and the test system), quality control recommendations and verifying our QA plan was sufficient to assess the testing we perform on this meter, there is a manageable risk associated with running liquid QC on this test per the manufacturer's instructions (which is less stringent than what CLIA requires). The manufacturer recommends running external liquid control samples with every 30 days with continued use of the same reagent lot number and with each new lot of reagents ... We will run an internal quality control device (QCD) daily on the Triage meter. We will run liquid external quality control material on new lots/shipments and every 30 days as applicable" Review of the laboratory's risk assessment revealed: "Additional points QC is run per manufacturer's recommendation and less than the CLIA requirements for 2 levels of controls for each day of patient testing. We performed a 10 day external liquid QC study upon implementation of this analyzer. All values were within the expected ranges." Two levels of liquid QC were NOT performed every 8 hours of operation, as required for nonmanual coagulation test systems. The laboratory's IQCP failed to support its reduction in frequency to every 30 days. 2. Review of the Alere Triage user's manual stated: "TOTAL QUALITY ASSURANCE ... QUALITY CONTROL SAMPLES It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total intergrety of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features inherent in the Alere Triage tests. The Alere Triage tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Alere Triage tests reduce the impact of procedural errors, ensure reagent integrity, and assurance that patient results are accurate each and every time a test is performed. Based on CLIA guidelines and other regulating bodies, Alere makes the following QC recommendations: Run two levels of POS and NEG external liquid control samples as appropriate with each new

	lot of reagents and once every thirty days with continued use of the reagent lot number. Run the QC Device daily." 3. Review of QC records from December 2020 through February 2021 revealed the laboratory performed quality control on the following dates on the Alere Triage analyzer for the D-Dimer cartridge (random sampling): QC level 1 lot #C3654, expiration date 06/04/21 QC level 2 lot #C3667, expiration date 06/17/21 QC level 1 and 2 was performed on 12/11/2020, 01/02/2021 QC level 1 lot #C3654, expiration date 06/04/21 QC level 2 lot #C3658, expiration date 06/30/21 QC level 1 and 2 was performed on 01/14/2021 QC level 1 lot #C3657, expiration date 07/09/21 QC level 2 lot #C3669, expiration date 07/14/21 QC level 1 and 2 was performed on 02/10/2021 4. Review of patient records revealed the laboratory failed to perform two levels of liquid QC every 8 hours of patient testing. Refer to D5545. 5. During an interview on 03/09/2020 at 3:00 pm, technical consultant confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days and failed to test two samples of control material each 8 hours of testing for the D-Dimer cartridge.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the Piccolo Xpress analyzer for the Metlac 12 cartridge for 10 of 10 days in 2021 (random sampling 01 /2021-02/2021). Findings: 1. Review of the Piccolo Metlac 12 Panel assay sheet revealed: "Quality Control ...Abaxis recommends control testing to follow federal, state, and local guidelines." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency for each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for the Metlac 12 cartridge on the Piccolo Xpress analyzer. Refer to D5445, I. 3. A random sampling of QC and patient records from January 2021 through February 2021, revealed the following dates QC was not performed and patients were tested on the Piccolo Xpress analyzer for the Metlac 12 cartridge: 02/01/2021- Patient ID:32113 02 /03/2021- Patient IDs: 32127, 32128, 32126 QC last performed on 01/05/2021 02/17 /2021- Patient IDs: 32268, 32266, 02/18/2021- Patient ID: 32288 02/19/2021- Patient ID: 32303 02/20/2021- Patient IDs: 32312, 32319 02/21/2021- Patient ID: 32326 02 /23/2021- Patient IDs: 32356, 32349 02/24/2021- Patient ID: 32366 02/25/2021- Patient IDs: 32378, 32370 QC last performed on 02/04/2021 Note: The Metlac 12 cartridge tested for the following chemistry analytes: glucose, blood urea nitrogen (BUN), creatinine, sodium, potassium, chloride, carbon dioxide, calcium, phosphorus, magnesium, albumin, and lactate. 4. During an interview on 03/09/2021 at 1:15 pm, the technical consultant confirmed the laboratory failed to perform QC every day of patient testing. II. Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the

	Alere Triage for the cardiac cartridge for 6 of 6 days in 2021 (random sampling 01 /2021-02/2021). Findings: 1. Review of the Alere Triage user's manual stated: "TOTAL QUALITY ASSURANCE ... QUALITY CONTROL SAMPLES It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total intergrety of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features inherent in the Alere Triage tests. The Alere Triage tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Alere Triage tests reduce the impact of procedural errors, ensure reagent integrity, and assurance that patient results are accurate each and every time a test is performed. Based on CLIA guidelines and other regulating bodies, Alere makes the following QC recommendations: Run two levels of POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every thirty days with continued use of the reagent lot number. Run the QC Device daily." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency for each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for the cardiac cartridge on the Alere Triage analyzer. Refer to D5445, II. 3. A random sampling of QC and patient records from January 2021 through February 2021, revealed the following dates QC was not performed and patients were tested on the Alere Triage analyzer for the cardiac cartridge: 02/11/2021- Patient ID: 32216 02/16 /2021- Patient IDs: 32255, 32254 QC last performed 01/19/2021 02/28/2021- Patient ID: 32402 03/04/2021- Patient ID: 32447 03/05/2021- Patient ID: 32458 03/08/2021- Patient ID: 32489 Note the cardiac cartridge tested for troponin, myoglobin and creatinine kinase-MB (CK-MB) analytes. 4. During an interview on 03/09/2021 at 3: 00 pm, the technical consultant confirmed the laboratory failed to perform QC every day of patient testing.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of liquid QC material each 8 hours of operation for the D-Dimer analyte on the Alere Triage analyzer for 6 of 6 days in 2021 (random sampling). Findings: 1. Review of the Alere Triage user's manual stated: "TOTAL QUALITY ASSURANCE ... QUALITY CONTROL SAMPLES It is still valuable to apply the traditional approach to quality control by testing quality control samples. These controls will check the total intergrety of the system. The interval for analyzing these controls, however, can be extended due to the many other Total Quality Assurance features inherent in the Alere Triage tests. The Alere Triage tests have been designed to maximize Total Quality Assurance in any testing environment. The combination of the QC features of the Alere Triage tests reduce the impact of procedural errors, ensure reagent integrity, and assurance that patient results are accurate each and every time a test is performed. Based on CLIA guidelines and other regulating bodies, Alere

	makes the following QC recommendations: Run two levels of POS and NEG external liquid control samples as appropriate with each new lot of reagents and once every thirty days with continued use of the reagent lot number. Run the QC Device daily." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency for each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for D-Dimer on the Alere Triage analyzer. Refer to D5445, III. 3. A random sampling of QC and patient records from January through February 2021, revealed the following dates QC was not performed each 8 hours of testing using two levels of control materials on each day of patient testing and patients were analyzed for the D-Dimer analyte on the Alere Triage meter: 02/11 /2021- Patient ID: 32216 02/16/2021- Patient IDs: 32255, 32254 02/24/2021- Patient IDs: 32361, 32363 02/25/2021- Patient ID: 32371 03/05/2021- Patient ID: 32458 03 /08/2021- Patient ID: 32489 QC was last performed on 02/10/2021 at 8:43 am The laboratory failed to include two levels of liquid QC material and electronic QC each 8 hours of operation for the D-Dimer analyte on the Alere Triage analyzer. 4. During an interview on 03/09/2021 at 3:00 pm, the technical consultant confirmed the above findings.
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 policy, hematology quality control (QC) records, corrective action logs, and confirmed in interview, the laboratory failed to document corrective actions for QC failures for 14 of 114 runs in 2021 (random review 01/2021-02/2021). Findings: 1. Review of the laboratory's policy "QUANTITATIVE QUALITY CONTROL" revealed: "RESULTS ... A. ACCEPTABLE QC RESULTS Control values fall within established ranges before any patient tests are run for any given day of testing. If all values are within acceptable limits, review the data for shifts or trends, record any Actions Taken in the Corrective Action Log, the Weekly QC Review Log and the LIS (if any), and begin to process patient samples B. UNACCEPTABLE QC RESULTS When control results are not within the acceptable limits perform the following steps to help resolve the "out of control" result and bring the controls back within limits. 1. Stop all testing immediately. The "out of control" situation must be investigated, and the problem(s) resolved with corrective actions documented. Routine testing may commence or else the troubleshooting must be elevated." 2. Review of Sysmex hematology QC records and corrective action log revealed the laboratory performed three levels of control QC twice a day. Further review of the QC records and corrective action log revealed the laboratory failed to document corrective actions for QC failures in 2021 on the following dates and times: QC normal control lot #03370711, expiration date 03/10/2021 01/07/2021 Normal

control p.m. run 17:34 hours QC failed for HCT, PLT, MXD %, NEUT%, MDX#, RDW-SD, RDW-CV 17:39 hours QC was repeated and failed for HCT, MCHC, PLT, RDW-SD, RDW-CV 18:21 hours QC was repeated and failed for PLT, RDW-SD, RDW-CV 01/08/2021 Normal control a.m. run 00:39 hours QC failed for PLT, RDW-SD, RDW-CV 00:40 hours QC was repeated and failed for PLT, RDW-SD, RDW-CV 01/08/2021 Normal control p.m. run 13:10 hours QC failed for WBC, PLT, RDW-SD, RDW-CV 13:21 hours QC was repeated and failed for HCT, PLT, RDW-SD, RDW-CV 13:24 hours QC was repeated and failed for PLT, RDW-SD, RDW-CV 01/09 /2021 Normal control a.m. run 00:15 hours QC failed for WBC, HCT, PLT, NEUT#, RDW-SD, RDW-CV 00:16 hours QC was repeated and failed for WBC, NEUT%, LYM#, RDW-SD, RDW-CV 00:18 hours QC failed for HCT, PLT, RDW-SD, RDW-CV 01/13/2021 Normal control p.m. run 12:35 hours QC failed for HCT, PLT, LYM%, MXD#, RDW-SD, RDW-CV 15:19 hours QC was repeated and failed for HCT, PLT, LYM%, RDW-SD, RDW-CV 15:21 hours QC was repeated and failed for HCT, PLT, LYM%, RDW-SD, RDW-CV 01/14/2021 Normal control a.m. run 00:11 hours QC failed for HCT, PLT, RDW-SD, RDW-CV 00:13 hours QC was repeated and failed for HCT, PLT, RDW-SD, RDW-CV 00:14 hours QC was repeated and failed for HCT, PLT, RDW-SD, RDW-CV 01/15/2021 Normal control a.m. run 00:15 hours QC failed for PLT, NEUT#, RDW-SD, RDW-CV 00:18 hours QC was repeated and failed for WBC, HGB, PLT, RDW-SD, RDW-CV 01/15/2021 Normal control p. m. run 12:59 hours QC failed for HCT, PLT, RDW-SD, RDW-CV 13:00 hours QC was repeated and failed for HCT, PLT, RDW-SD, RDW-CV 01/21/2021 Normal control p.m. run 14:50 hours QC failed for LYM% 14:52 hours QC was repeated and passed 01/23/2021 Normal control p.m. run 12:17 hours QC failed for LYM%, MXD%, RDW-SD, RDW-CV 12:18 hours QC was repeated and passed QC low control lot# 03360710, expiration date 03/10/2021 QC normal control lot# 03360711, expiration date 03/10/2021 QC high control lot #03360712, expiration date 03/10 /2021 02/04/2021 Normal control p.m. run 13:20 hours QC failed for WBC, RBC, HGB, HCT, PLT, LYM#, MXD#, NEUT# 13:49 hours QC was repeated and passed High control p.m. run 13:15 hours QC failed for MXD% 13: 17 hours QC was repeated and passed 02/18/2021 Low control p.m. run 12:14 hours QC failed for RBC, HCT, MCH, MCHC 12:21 hours QC was repeated and failed for HCT, MCV, MCHC, RDW-SD, RDW-CV 12:22 hours QC was repeated and failed for HCT, MCV, MCHC, PLT, RDW-SD, RDW-CV 02/20/2021 High control a.m. run 00:23 hours QC failed for WBC, RBC, HGB, MCH, MCHC, PLT, LYM#, MXD#, NEUT# 08:04 hours QC was repeated and passed 02/24/2021 Normal control p.m. run 14:31 hours QC failed for WBC, MXD%, NEUT%, MXD#, NEUT# 14:32 hours QC was repeated and failed for WBC, MXD%, NEUT%, MXD#, NEUT# 14:34 hours QC was repeated and passed 15:06 hours QC was repeated and passed The laboratory failed to document corrective action for the above QC failures. 3. During an interview on 03/09 /2021 at 12:00 hours, the technical consultant confirmed the laboratory failed to document corrective action for QC failures. Word Key: HCT- hematocrit PLT- platelet MXD- mixed cell NEUT- neutrophil LYM- lymphocyte RDW- red blood cell distribution width MCHC- mean cell hemoglobin concentration MCH- mean cell hemoglobin HGB- hemoglobin WBC- white blood cell