Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2064081	09/14/2022
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory maintenance logs from 1/1/2022 to 8/31/2022, patient records, and confirmed in interview revealed the laboratory failed to document five of 36 weekly, two of eight monthly, and one of three quarterly scheduled maintenance following the manufacturer's instructions on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's instructions titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 12. Cleaning and Maintenance revealed the following for the XP-300 Hematology analyzer (SN#:A5293). "To ensure proper functioning of the instrument, it is necessary to periodically clean an service the instrument. Perform maintenance according to the schedule below. And record the results in the Maintenance checklist." 2. Further review of the manufacturer's instructions titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) in Chapter 12.1 Maintenance schedule revealed: "Weekly Clean SRV tray (see 12.5) Every month (or every 1,500 samples Clean TD (see 12.6) Clean waste chamber (see 12.7) Every 3 month (or every 4,500 samples) Clean SRV (see 12.8)" 3. Review of

	the laboratory's maintenance logs titled SYSMEX XP 300 MAINTENANCE revealed the following scheduled maintenance's: Weekly Clean SRV tray Monthly Clean RBC and WBC Transducer Clean Waste Chamber Quarterly Clean Sample Rotor Valve (SRV) 4. Further review of the laboratory's maintenance logs from 1/1/22 to 8/31/22 revealed no documentation of the following maintenance. Five of 36 weekly maintenance reviewed 5/8/22-5/14/22 5/22/22-5/28/22 6/12/22-6/18/22 7/24/22-7/30 /22 8/21/22-8/27/22 Two of eight monthly maintenance reviewed June, 2022 July, 2022 One of three quarterly maintenance reviewed June, 2022 5. Review of the laboratory's patient records for the above timeframe revealed 15 patients had CBC testing performed. 5/8/2022 Patient ACCT: 39527 5/8/2022 Patient ACCT: 39530 5/14 /2022 Patient ACCT: 39602 5/27/2022 Patient ACCT: 39778 5/27/2022 Patient ACCT: 39780 5/27/2022 Patient ACCT: 39782 5/27/2022 Patient ACCT: 39783 6/13 /2022 Patient ACCT: 40077 6/14/2022 Patient ACCT: 40085 6/14/2022 Patient ACCT: 40087 7/28/2022 Patient ACCT: 40688 7/29/2022 Patient ACCT: 40696 7/29 /2022 Patient ACCT: 40698 8/21/2022 Patient ACCT: 40991 8/22/2022 Patient ACCT: 40997 6. An interview with the technical consultant on 9/13/2022 at 1:10 pm in the breakroom confirmed the above findings. Key: CBC=Complete Blood Count
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's product insert, the laboratory's policy, the simulator QC run logs from January 2022 to August 2022, patient records, and confirmed in an interview found the laboratory failed to document a simulator QC run for one of 25 days reviewed following the manufacturer's instructions on cardiac panel test on one of one Alere Triage Meter Pro instrument. The findings were: 1. Review of the manufacturer's product insert titled Triage Cardiac Panel Product Insert (Catalog#: 97000HS. 2014 Alere.) under Testing Patient Specimens Procedural Notes revealed "For each day of patient testing, perform QC Device testing." 2. Further review of the manufacturer's product insert titled Triage Cardiac Panel Product Insert under Quality Control Consideration Performing Alere Triage System revealed "Use the QC Device to ensure proper function of the meter. Perform QC Device testing for the following conditions:...Each day of patient testing...." 3. Review of the laboratory's policy titled Laboratory Procedure Cardiac Panel Triage signed by the LD on 3/3/2020 under C. QC Simulator for Triage Meter revealed "2. QC Simulator Frequency Testing with the QC Simulator is performed: Each day patient tests are performed...." 4. An interview with the technical consultant on 9/13/2022 at 3:00 pm in the lab confirmed QC Device named in the product insert was as the same as QC simulator named by the laboratory. 5. Random review of the Triage simulator QC run logs from 1/1/2022 to 8/31/2022 revealed one of 25 days reviewed did not have documentation of QC simulator run on the day of patient testing on Triage Meter Pro (SN: 77123). 1/30/2022 6. Review the laboratory's patient records for the above date revealed the laboratory performed one patient Cardiac panel testing. 1/30/2022 Patient ACCT: 38164. 7. An interview with the technical consultant on 9/13/2022 at 3:11 pm in the breakroom confirmed the above findings. Key: QC=Quality Control LD=Laboratory Director

D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's reagent replace logs from 3/2/2022 to 8/18/2022, QC logs, patient records, and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent for two of four days reviewed on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's instructions titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 4. Reagents revealed two reagents were used in the XP-300 Hematology analyzer (SN#:A5293). Cellpack Stromatolyser-WH 2. Random review of the reagent replace logs from 3/2/2022 to 8 /18/2022 revealed two of four days reviewed had no documentation of a quality control run after the following reagent change on the Sysmex XP-300 hematology analyzer. 3/2/2022 at 1:47 pm Stromatolyser-WH Lot#Y1006 Exp 11/17/2022 8/18 /2022 at 1:19 pm Cellpack Lot#Y2027 Exp 03/20/2023 3. Review of the laboratory's QC logs for the above dates revealed the next QC was performed on the following date and time after reagent changes: Reagent change 3/2/2022 at 1:47 pm Stromatolyser-WH Next QC 3/3/2022 at 00:12 am. Reagent change 8/18/2022 at 1:19 pm Cellpack Next QC 8/19/2022 at 00:06am 4. Review of the patient records for the above dates revealed the laboratory performed nine patient CBC testing after the reagent change with no documentation of a quality control run before next QC runs. 3 /2/2022 at 3:50 pm Patient ACCT: 38586 3/2/2022 at 6:46 pm Patient ACCT: 38588 3 /2/2022 at 10:10 pm Patient ACCT: 38586 8/18/2022 at 2:04 pm Patient ACCT: 40946 8/18/2022 at 3:26 pm Patient ACCT: 40947 8/18/2022 at 7:31 pm Patient ACCT: 40950 8/18/2022 at 8:01 pm Patient ACCT: 40951 8/18/2022 at 10:19 pm Patient ACCT: 40953 8/18/2022 at 10:36 pm Patient ACCT: 40954 5. An interview with the technical consultant on 9/13/2022 at 1:10 pm in the breakroom confirmed the above findings. Key: QC=Quality Control CBC=Complete Blood Count