## Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2082398	**(X3) Date Survey Completed** 01/28/2021
Name of Provider or Supplier Complete Care Southlake	**Street Address, City, State** 321 W Southlake Blvd Suite 140, Southlake, 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 entrance conference was held with laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of laboratory policies, review of patients' records (01/19/2021 - 01/26 /2021) and confirmed in staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for specimens with instrument flags for 3 of 3 patients. Findings included: 1. Review of the manufacturer's instructions for the Sysmex XP-300 stated the following: "Histogram Flags ... ...When the histogram flags are

	displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following:...Flag:[AG]; Probable sample cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc; Correction (reference): 1) Check smear, etc" 2. The laboratory policy titled "CBC Sysmex XP-300" (signed by the Laboratory Director 03/04/2020) stated the following: "Platelet Flags: Sysmex states AG flags can be generated in the presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Any platelet count with AG flags will be repeated on the original properly obtained and well mixed sample. If there is any question regarding the suitability of the sample, a fresh sample should be obtained, and reprocessed. If the AG flag remains after repeat testing, inform the physician of the instrument flag and stat [sic] the result cannot be reported. If the provider determines the platelet count is needed for patient evaluation, send the blood sample to a reference laboratory for confirmatory analysis." 3. Review of patients' CBC records generated from the Sysmex XP-300 hematology analyzer (01/19/2021 - 01/26 /2021) revealed the following 3 of 3 patients with the AG flag. Further review revealed the laboratory failed to repeat the testing and failed to check a blood smear for presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, or precipitation of fibrin. Date of test: 01/19/2021; Patient 23257 Date of test: 01/20/2021; Patient 23289 Date of test: 01/24/2021; Patient 23380 The laboratory failed to repeat the testing and failed to check a blood smear for presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, or precipitation of fibrin. 4. In an interview on 01/28 /2021 at 2:50PM in the breakroom, the Technical Consultant, after review of the laboratory records, confirmed the above findings. Word Key: CBC=Complete Blood Count
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 review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of maintenance records from June 2020 to January 2021 and confirmed in staff interview, it was revealed the laboratory failed to have documentation of performing all required maintenance. Findings included: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer under the section titled "12.1 Maintenance schedule" revealed: Daily: Clean TD chambers and diluted sample lines Check trap chamber level and discard Weekly: Clean SRV tray Every Month: Clean TD Clean waste chamber Every 3 months Clean SRV 2. The laboratory policy titled "CBC Sysmex XP-300" (signed by the Laboratory Director 03/04/2020) stated the following: "A. Weekly Maintenance: 1. Clean SRV (sample rotor valve) Tray. (See Sysmex XP-300 Instructions for Use for details) ...f. Document on the maintenance log. B. Monthly Maintenance: Clean the waste chamber. Approximately 15 minutes. (See Sysmex XP-300 Instructions for Use of details) ...g. Document on the maintenance log ...2. Clean the WBC and RBC transducers. Approximately 7 minutes. (See Sysmex XP-300 Instructions for Use for details)" 3. A review of the laboratory's Sysmex XP-300 analyzer's maintenance

	records revealed quarterly (every 3 months) maintenance was scheduled for 06/2020, 09/2020 and 12/2020. Further review of the maintenance records from June 2020 to January 2021 revealed the laboratory failed to have documentation of weekly maintenance for the following 6 of 32 weeks, complete monthly maintenance for 6 of 8 months, and quarterly maintenance for 2 of 3 quarters: a. June 2020 No documentation of Weekly Maintenance for Week 3 and Week 4 No documentation of monthly maintenance to Clean RBC and WBC transducer and Clean Waste Chamber. No documentation of Quarterly maintenance. b. July 2020 No documentation of weekly maintenance for Week 4 No documentation of monthly maintenance to Clean Waste Chamber. c. August 2020 No documentation of monthly maintenance to Clean RBC and WBC Transducer d. September 2020 No documentation of monthly maintenance to Clean RBC and WBC transducer and Clean Waste Chamber. e. October 2020 No documentation of Weekly Maintenance for Week 3 and Week 4 No documentation of monthly maintenance to Clean RBC and WBC transducer and Clean Waste Chamber. f. November 2020 No documentation of monthly maintenance to Clean RBC and WBC transducer. g. December 2020 No documentation of Weekly Maintenance for Week 4 No documentation of Quarterly maintenance. The laboratory failed to have documentation of performing all required weekly, monthly, and quarterly maintenance. 4. In an interview on 01/28/2021 at 2:50PM in the breakroom, the Technical Consultant, after review of the laboratory records, confirmed the above findings. Word Key: SRV=Sample Rotor Valve TD=Transducer
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 review of laboratory policy and records, a random review of laboratory environmental logs (June 2020 and November 2020), and confirmed in staff interview, the laboratory failed to document corrective action taken when room temperatures were not within the acceptable range. Findings included: 1. Review of the laboratory policy titled "Quality Assessment Plan" stated, "The quality assessment plan is an on-going plan, specifically designed to ensure the reliability, predictive value, and timeliness of laboratory data used to determine the appropriateness of care, diagnosis, and treatment of patients ...D. Quality Assessment Plan Quality Assessment is the continuous process of monitoring the effectiveness of the IQCP practices, processes, and resources to monitor the effectiveness of the IQCP. Included are the following: ...3. Environmental Reviews ...c. Corrective Action logs that may be associated with temperatures or humidity that may be out of acceptable range." 2. Review of laboratory records revealed the laboratory utilized an IQCP(Individualized Quality Control Plan) for the Piccolo chemistry analyzer and the Alere Triage analyzer. 3. A random review of the laboratory's records titled "Temperature and Humidity Log" revealed an acceptable room temperature range of 20 - 24 C. Further

	review revealed the following days when the refrigerator temperature was not within the acceptable range: 06/05/2020; Room temperature = 25C 06/06/2020; Room temperature = 25C 06/09/2020; Room temperature = 25C 11/19/2020; Room temperature = 25C 11/20/2020; Room temperature = 25C 11/21/2020; Room temperature = 26C 11/22/2020; Room temperature = 25C 4. In an interview on 01/28 /2021 at 2:50PM in the breakroom, the Technical Consultant was asked to provide documentation of corrective action taken when refrigerator temperatures were not within the acceptable range. No documentation was provided. This confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) 209 form, review of laboratory policy, review of the laboratory's personnel records, and staff interview, it was revealed the Technical Consultant failed to perform competency assessments on 5 of 14 testing persons for moderately complex testing in 2020. Findings included: 1. A review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) 209 form (signed by the laboratory director on 01/26/2021), revealed the laboratory identified 14 (TP 1 - TP 14) testing persons performing moderate complexity testing. 2. The laboratory policy titled, "Job Descriptions" (signed by the laboratory director 03/04/2020) stated, "Technical Consultant. The technical consultant is responsible for technical and scientific oversight of the laboratory. A. Duties and Responsibilities: Evaluates and documents performance and competency of individuals responsible for testing at six months and twelve months in the first year of employment and yearly, thereafter ..." 3. Review of the laboratory personnel records revealed the technical consultant failed to perform yearly competency assessments for following testing personnel : Testing Person 3 Date of Evaluation 09/28/2020 Evaluated by TP 1 Testing Person 4 Date of Evaluation 10/21/2020 Evaluated by TP 1 Testing Person 6 Date of Evaluation 10/21 /2020 Evaluated by TP 1 Testing Person 10 Date of Evaluation 10/17/2020 Evaluated by TP 1 Testing Person 11 Date of Evaluation 09/28/2020 Evaluated by TP 1 The Technical Consultant failed to perform competency assessments on 5 of 14 testing persons for moderately complex testing in 2020. 4. In an interview on 01/28/2021 at 2: 50PM in the breakroom, the Technical Consultant, after review of the laboratory records, confirmed the above findings