Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2082398	07/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Complete Care Southlake	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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. 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 Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, the submitted Centers for Medicaid and Medicare Services (CMS)-209 form, testing personnel records, and confirmed in staff interview, the laboratory failed to follow its own policy to assess employee competency for 3 of 18 testing persons (TP3, TP13, and TP14) in 2021. The findings include: 1. Review of "Laboratory Procedure Training for Technical Personnel" revealed, "3. Skills Competency Is Documented ...Two sets of Competency checks are completed during the first year-one at 6 months and one at 12 months." 2. Review of

	the laboratory's submitted CMS-209 revealed 18 testing personnel listed to perform moderate complexity testing. 3. Review of personnel records for TP3 revealed a hire date of 08/01/2021 and initial training for Hematology and Chemistry on 08/16/2021. The 6-month competency assessments for the above specialties for TP3 were performed on 04/20/2022, 8 months after the initial training. Review of personnel records for TP13 revealed a hire date of 09/28/2021 and initial training for Hematology and Chemistry on 09/28/2021. The 6-month competency assessments for the above specialties for TP13 were performed on 10/22/2021, 24 days after the initial training. Review of personnel records for TP14 revealed a hire date of 09/28/2021 and initial training for Hematology and Chemistry on 09/28/2021. The 6-month competency assessments for the above specialties for TP14 were performed on 10/08 /2021, 10 days after the initial training. The laboratory failed follow its own written policy for performing competency assessments for TP3, TP13 and TP14. 4. During an interview on 07/12/2022 at 11:05 am, the Technical Consultant confirmed the above findings.
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, random review of patients' records and logs (06/03/2022 - 07/01/2022), and confirmed in staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for specimens with instrument flags for 1 of 7 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. Review of the laboratory's policy titled "CBC Sysmex XP-300" 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 (06/03/2022 - 07/01 /2022) revealed the following 1 of 7 patients with the AG flag. Further review of the "CBC AG Flag Log" revealed the laboratory repeated the testing after 15 minutes and the AG flag remained unresolved. The laboratory 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: 06/03/2022; Patient 30572 4.

	During an interview on 07/12/2022 at 1:03 pm, the Technical Consultant, after review of the laboratory records, confirmed the above findings. Note: This is a repeat deficiency from the previous survey conducted on 01/28/2021. Word Key: CBC=Complete Blood Count
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure 2 of 2 transport media vials did not exceed their expiration date. Findings included: 1. During a tour of the laboratory on 07/12/2022 at 3:30 pm, the surveyor observed the following expired transport media in the cabinet: 2 vials of Para-Pak C&S Culture & Sensitivity stool transport media Lot# 359250, expiration date 06/10 /2022 2. During an interview on 07/12/2022 at 3:30 pm, the Technical Consultant confirmed the above findings.