Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1015130	07/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Compassionate Cancer Care	11180 Warner Ave, Ste 351, Fountain Valley, CA	

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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel competency documentations, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory failed to retain documentations of personnel competency for at least 2 years. The findings included: b. There were no documentations of personnel competency available for 2021. c. The laboratory failed to retain the documentations of personnel competency for at least 2 years. b. The laboratory technical consultant and the laboratory staff affirmed (7/15/2022 @10:35 am) that there were no documentations of personnel competency available for 2021, see D-5209.
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 CMS 209 and the documentations of personnel competency records, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures to assess personnel competency timely. The findings included: a. The laboratory failed

	to follow written policies and procedures to assess and retain documentations of personnel competency in 2001. b. Review of the current CMS 209, a "Laboratory Personnel Report (CLIA)", which indicates 10 testing personnel (TP). c. Review of the last CLIA CMS 209 (9/17/2021) , which had listed 3 TP. d. There were 8 new TP on the 2022 CMS 209 form, when compared with 2021 CMS 209 form in the 9/17 /2021 survey. d. The technical consultant affirmed (7/15/2022 @10:35 am) that there were no documentations of personnel competency available in 2021.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation the laboratory's digital thermometer device (DT) and review of the temperature log, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory failed to follow the manufacturer instructions to ensure and monitor the refrigerator temperature and maintain the quality of the laboratory's control materials and the patient samples in the refrigerator. The findings included: a . The laboratory staff failed to follow the manufacturer instructions for the use of a Fisher digital thermometer. b. The laboratory used a Fisher DT which features 1) Alarm (On/Off), 2) Current temperature, 3) Lo/Hi mode (setting for acceptable temperature range), 4) Min/Max mode (indicating the lowest or higher temperature ever reached in the past before reset), and 5) Reset. c. At the time (7/15/2022 @ 11:15 am) the DT indicated Alarm was at Off position. a current temperature of 6 oC, Min 4 oC and Max 14 oC, (no date or time provided by the DT for the Min 4 oC, Max 14 oC recorded) d. The Alarm went off when the laboratory staff turned the DT to "On" from "Off" position, which indicated that the temperature was once out of acceptable temperature range, sometime in the past. e. The laboratory staff pressed the mode to Lo/Hi, it showed "Lo" at 10 oC and "Hi" at 30 oC, which indicated that the laboratory had set the refrigerator's acceptable temperature range to this DT: 10 to 30 oC to monitor the condition of the refrigerator. f. The laboratory has established the acceptable temperature range between 4 to 10 oC to maintain the quality of the CBC control materials and/patient specimens in the refrigerator. g. The laboratory staff failed to ensure the temperatures of the refrigerator maintained within the acceptable temperature range, 4 to 10 oC consistently.
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 observation of the laboratory blood drawing station and checked various blood collection tubes in the tube racks, and interview with the laboratory staff, it was determined that the laboratory failed to ensure that the phlebotomist did not use outdated blood collection tubes for the patient blood drawing. The findings included: a. The laboratory failed to remove outdated blue top blood collection tubes which were expired on 6/30/2022. b. The laboratory kept outdated blue top tubes in the rack at the blood drawing station at the time of survey (7/15/2022 @ 10:45 AM). c. The laboratory failed to ensure the phlebotomist did not use outdated blood collecting tubes.
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 observation of the blood drawing station, digital thermometer device (DT), review of the laboratory records, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures (P&P) to maintain an ongoing quality assessment, and to ensure accuracy, reliability, and timely of the patient test results reports. The findings included: a. The laboratory failed to follow written policies and procedures, and maintain an ongoing mechanism to monitor, assess, and ensure accuracy, reliability and timely of the patient test result reports including: 1. documenting personnel competency and retaining of the documentations (see D-3039 and D-5209), 2. monitoring DT and constantly maintaining temperature within the acceptable temperature range (see D-5413), 3. removing outdated blood collection tubes (see D-5417) 4. providing pertaining Expected values/reference intervals (see D-5807)
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test result reports, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory failed to provide pertinent "reference intervals or "normal" values as determined by the laboratory performing the tests. The findings included: a. The laboratory performs complete blood counts (CBC) testing using Celldyn Emerald to report WBC, WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet Count (Plt). b. The laboratory's patient CBC result reports provided Hgb and Hct the same pertinent "Expected values" (Reference intervals), respectively for Male and Female. c. The laboratory provided Hgb pertinent "Expected values" for Male, and Female between 12.0 and 18.0 g/dL. d. The

	laboratory provided Hct pertinent "Expected values" for Male, and Female between 37.0 and 51.0 %. e. The technical consultant affirmed (7/15/2022 @11:50 am) that the Hgb and Hct pertinent "Expected values" are the same for both Male and Female.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation of the blood drawing station and digital temperature device (DT), review of the laboratory records and patient test result reports, and interview with the technical consultant (TC) and the laboratory staff, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were maintained to identify failures in quality as they occur. The findings included: a. The laboratory director failed to follow and maintain an ongoing quality assessment for ensuring accuracy, reliability and timely of the patient test result reports and to provide quality laboratory operations (see D-5791).