Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2150065	**(X3) Date Survey Completed** 07/12/2019
Name of Provider or Supplier Community Cancer Institute	**Street Address, City, State** 785 N Medical Center Dr West Ste 102, Clovis, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review and the lack of documentation of enrollment in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS, review of random patient sampling results and interview with the technical consultant /technical supervisor, it was determined that; the laboratory failed to enroll in an approved program or programs for Hematology and Routine Chemistry. The findings included: a. The laboratory analyzes and reports the following tests: Hematology (Complete Blood Count with Auto Diff/Manual Diff), Routine Chemistry, Urinalysis, and Endocrinology). b. Based on review and the lack of documentation for the third quarter (Q3-2018) and first quarter (Q1-2019) it was revealed that; the laboratory was not enrolled in a proficiency testing program. c. For thirteen (13) out of thirteen (13) random patient sampling test results reviewed covering period from 9/4/2018 to 6/24 /2019, the laboratory analyzed and reported Complete Blood Count (CBC) and Routine Chemistry tests even though the laboratory was not enrolled in a proficiency testing program. d. Based on the laboratory's testing volume declaration submitted for 2018-2019, the laboratory analyzed and reported 235,584 Routine Chemistry and Hematology tests. e. The technical consultant /technical supervisor confirmed (7/12 /2019, 10:30) that the laboratory was not enrolled in a proficiency testing program

	during the above quarters even though the laboratory analyzed and reported patient test results.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory director was not met. The laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. See D 6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a review and the lack of documentation for a proficiency testing enrollment records and interview with the technical consultant /technical supervisor it was determined that the laboratory director failed to ensure the proficiency testing samples are tested as required under subpart H of this part.