Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1010428	10/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Synergy Hematology Oncology	5363 Balboa Blvd, Ste 345, Encino, 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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the second quarter (Q3-2019) of the American Association of Bioanalysts (AAB) proficiency testing records, ten (10) random patient test results from 01//03/2019 to 10//21/2020 and interview with the technical supervisor, it was determined that the laboratory failed to participate in a testing event is unsatisfactory performance and results in a score of 0% for the testing event. The findings included: 1. The CLIA Casper Report 0096D and AAB Q3-2019 proficiency event reported an unsatisfactory score of 0% for the Hematology performance summary of Q3-2019, which included: Erythrocyte (RBC), Hemoglobin (HGB), Hematocrit (HCT), Leukocyte (WBC) count, Platelet count, White Blood (WBC) Differential. Also, the laboratory policies and procedure manual, under Proficiency Testing Policy, "Upon receiving PT samples, laboratory will': Items 1 through 8 were not followed. 2. The technical superior affirmed 10/22/2019 11:45 a. m. (survey date) that laboratory failed to submit the proficiency challenges for AAB Q3-2019. 3. The laboratory's testing declaration (10/20/2020) reported 28,800 hematology patient tests performed (annually).

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 the surveyor's observation, examination of laboratory reagents, patient test reports covering the period from 01/03/ 2019 to 10/ 21/2020, and interview with the laboratory technical supervisor (TS), it was determined that the laboratory failed not to use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, 10/2/2020 at approximately 11:00 a.m. the examiner found in the phlebotomy basket expired vacutainer test tubes (Trace Element Serum vacutainer test tube, Lot 9126535, expiration date of 2020-05-31, PTT Plasma preparation vacutainer test tube K2E, Lot 9065694, expiration date 20-03-31, Sodium Heparin vacutainer test tube, Lot 8187715, expiration date 2019-11-30). 2. The technical superior affirmed on 10/22/2020 at 11:45 a.m. that the vacutainer test tubes had exceeded their expiration dates and the quality and reliability of the patients test results were in question.