Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0724185	10/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Synergy Hematology Oncology	8737 Beverly Blvd Ste 203, Los Angeles, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of hematology constituting unsuccessful PT performance. (See D2130)

D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(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 reviews of proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts) for IgA, IgG, and IgM tests performed on the Beckman AU 480 analyzer, ten (10) randomly selected patients test records from 0105/2019 to 10/02/2020 and an interview with the technical superior (TS), it was determined that the laboratory failed to participate in testing event Q3-2013, constituting unsatisfactory performance resulting in the score of 0%. The findings include: 1. For AAB Q3-2019, CMS reported an unsatisfactory score of 0% for the specialty of general immunology IgA, IgG and IgM, and also failed to follow 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 affirmed 10/21/2020 1:20 p. m. (survey date) that the laboratory failed to participate in the AAB Q3 event of 2019 for specialty of general immunology. 3. Based on the laboratory's testing declaration of 10/20/2020, the laboratory reported approximately 1,245 results for general immunology testing (IgA, IgG, IgM).
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(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 CMS AAB (American Association OF Bioanalysts) proficiency testing (PT) report 0096D (CLIA Application and Survey Summary) for 2019 and 2020 test results, ten (10) randomly selected patients test records from 0105 /2019 to 10/02/2020 and an interview with the laboratory technical supervisor; it was determined that the laboratory failed to participate in the proficiency testing event for Routine Chemistry third event (Q3-2019) for multiple analytes resulting in a 0%score. The findings included: 1. The laboratory received a score of 0% for AAB Q3-2019 PT

	event (nonparticipation) for routine chemistry analytes: ALT (SGPT), albumin, alkaline phosphatase, amylase, AST (SGOT), total bilirubin, total calcium, chloride (CL), total cholesterol, HDL, total CK, creatinine, glucose (non-waived), total iron, LDH, magnesium (MG), potassium, sodium (K), total protein (TP), triglycerides, BUN, and uric acid, and also failed to follow 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 supervisor affirmed 10/21 /2020 at 1:20 p. m. (Survey Date) that an AAB Q3-2019 PT 0% score was received for routine chemistry. 3. Based on the laboratory's annual testing declaration submitted 10/20/2020 the laboratory analyzed and reported approximately 179,000 Routine Chemistry tests.
D2100	ENDOCRINOLOGY CFR(s): 493.843(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 CMS AAB (American Association OF Bioanalysts) proficiency testing (PT) report 0096D (CLIA Application and Survey Summary) for 2019 and 2020 test results, ten (10) randomly selected patients test records from 0105 /2019 to 10/02/2020 and an interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to participate in the proficiency testing event for Routine Chemistry third event (Q3-2019) for multiple analytes resulting in a 0% score. The findings included: 1. The laboratory received a score of 0% in the subspecialty endocrinology for the following analytes: cortisol, estradiol, Free thyroxine (T4), FSH, LH, progesterone, prolactin, testosterone, thyroid-stimulating hormone (TSH), thyroxine (T4), triiodothyronine (T-3) T3 uptake, and also failed to follow the laboratory policies and procedure manual, under Proficiency Testing Policy, "Upon receiving PT samples, laboratory will': Items 1 through 8 were not followed. The technical supervisor affirmed 10/21/2020 at 1:20 p. m. (Survey Date) that an AAB Q3-2019 PT 0% score was received for endocrinology. 2. Based on the laboratory's annual testing declaration submitted 10/20/2020 the laboratory analyzed and reported approximately 7,014 endocrinology test results reported...
D2111	TOXICOLOGY CFR(s): 493.845(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 CMS AAB (American Association OF Bioanalysts) proficiency testing (PT) report 0096D (CLIA Application and Survey Summary) for 2019 and 2020 test results, ten (10) randomly selected patients test records from 0105 /2019 to 10/02/2020 and an interview with the laboratory technical supervisor; it was determined that the laboratory failed to participate in the proficiency testing event for Routine Chemistry third event (Q3-2019) for multiple analytes resulting in a 0%score. The findings included: 1. The laboratory received a score of 0% for AAB Q3-2019 PT event (nonparticipation) for toxicology (therapeutic drugs) analytes: phenytoin and Valproic acid, and also failed to follow 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 supervisor affirmed 10/21/2020 at 1: 20 p. m. (Survey Date) that an AAB Q3-2019 PT 0% score was received for toxicology. c. Based on the laboratory's annual testing declaration submitted 10/20 /2020 the laboratory analyzed and reported approximate number of therapeutic drugs not listed.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing reports from CMS (report 0153D) and AAB (American Association of Bioanalysts) proficiency report, ten (10) randomly selected patients test records from 0105/2019 to 10/02/2020 and an interview with the technical superior (TS)), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for hematology analytes (WBC Differential, RBC, Hematocrit (HCT), Hemoglobin (HGB), white blood cell count (WBC) and Platelets (PLTS). The findings include: 1. Based on CMS PT records (CMS CASPER Report 0153D), it was determined that the laboratory failed to achieve satisfactory performance for the same analytes or tests in two out of three consecutive PT events for the analytes, WBC Differential, RBC, HCT, HGB, WBC and PLTS, resulting in a subsequent unsuccessful performance performed on the Systemax analyzer, and also failed to follow the laboratory policies and procedure manual, under Proficiency Testing Policy, "Upon receiving PT samples, laboratory will': Items 1 through 8 were not followed. The findings include: AAB Q3-2019 AAB Q2-2020 0% 0% 2. The technical superior affirmed on 10/21/2020 1:20 p. m. (survey date) that laboratory failed two consecutive testing events of unsuccessful performance for WBC Differential, RBC, HCT, HGB, WBC and PLTS for the AAB PT events of Q3-2019 and Q2-2020. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/20/2020, stated that the laboratory performed 31,340 automated CBCD tests 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, ten (10) randomly selected 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 11:30 a.m. the examiner found in the phlebotomy basket expired vacutainer test tubes EDTA Lot 9065819, expiration date 2018-18-31). 2. The technical superior affirmed on 10/21/2020 at 1:20 p.m. that the vacutainer test tubes had exceeded their expiration dates and the quality and reliability of the patients test results were in question.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of CMS PT records and the American Association of Bioanalysts (AAB) proficiency testing documents, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H of this part. The findings included: 1. For the analytes: WBC Differential Count, RBC, HCT, HGB, WBC and PLTS Q2-2020 the laboratory repeatedly failed to achieve satisfactory performance for the same analytes or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2130)