Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0724185	**(X3) Date Survey Completed** 03/30/2023
Name of Provider or Supplier Synergy Hematology Oncology	**Street Address, City, State** 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 Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on March 30, 2023, at 2:30 pm, the laboratory failed to successfully participate in the proficiency testing program for the Cr test. The findings include: 1. The laboratory participated in the AAB PT testing program for the specialty of chemistry in the year 2021. However, it received an unsatisfactory score of 60% at the Q1 and Q3 events for Cr test, resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical consultant on March 30, 2023, at 2:30 pm, affirmed that the laboratory did

	not receive a satisfactory score for the Cr test at the Q1 and Q3 events of PT in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/27 /2023, stated that the laboratory performs approximately 8,586 Cr tests, annually.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on March 30, 2023, at 2:30 pm, the laboratory failed to achieve satisfactory performance for the Cr test in two consecutive testing events. The findings include: 1. The laboratory participated in AAB PT testing program for the specialty of chemistry in the year 2021. However, it received an unsatisfactory score of 60% at both Q1 and Q3 events for Cr test that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two consecutive events resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical consultant on March 30, 2023, at 2:30 pm, affirmed that the laboratory did not receive a satisfactory score for the Cr test at the Q1 and Q3 events of PT in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/27 /2023, stated that the laboratory performs approximately 8,586 Cr tests, annually.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's specimen records, and interview with the laboratory technical consultant on March 30, 2023, at 2:20 pm, the laboratory failed to document the date and time it received specimens. The findings include: 1. The laboratory collected specimens at 2 locations in 2 different cities. At the 1st location, laboratory performed CBC test and send out the sample to the 2nd location for the other tests. However, the 2nd location did not document the date and time it received the specimen for testing. Instead, the laboratory (2nd location) used the 1st location's received date on its report. On the day of the inspection, 3 samples (Accn# 230329015, 230330001, 230329039) were found test pending for which specimens were collected at the 1st location and not received by the laboratory. Therefore, the sample integrity and reported results can not be assured since the received date on the report is not accurate and may have harmed patients. 2. The laboratory technical consultant on March 30, 2023, at 2:20 pm, affirmed that the laboratory did not document the date it received the specimen but used the collection date as received date on the report. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/27/2023, stated that the laboratory performs approximately 95,669 tests in chemistry, annually.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, CBC test records, and interview with the laboratory technical consultant and testing person's assistant on March 30, 2023, at 1:55 pm, the laboratory personnel failed to follow laboratory's policy and procedure to process the sample that had a critical value. The findings include: 1. The laboratory received a sample on March 29, 2023, at 11:47 am and ran CBC test on the sample using Sysmex XN automated instrument. The instrument print out showed PLT result was critical low. According to the laboratory's policy and procedure the critical results should have been confirmed and notified immediately to the physician. However, as of 1:55 pm, March 30, 2023, the patient results were still pending in the laboratory information system. Furthermore, the testing person's assistant notified the results to the physician without confirming the critical results. Therefore, the validity of the patients' test results rendered by the laboratory cannot be assured and may have harmed patient. 2. The laboratory technical consultant on March 30, 2023, at 1:55 pm, affirmed that the laboratory personnel did not follow its procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/27/2023, stated that the laboratory performs approximately 66,834 CBC tests, annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory technical consultant and testing person's assistant during an onsite survey of the laboratory on March 30, 2023, at 1:55 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing moderate complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. (See D6004) 2. The laboratory director failed to ensure the maintenance of an acceptable levels of analytical performance for the Cr tests. (See D6023) 3. The laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. (See D6014)
D6004	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory technical consultant on March 30, 2023, at 2:20 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harm patients. The findings include: See D2016, D2096, D5313, D5401 and D6070.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on February 15, 2023, at 11:45 am, the laboratory failed to achieve satisfactory performance for the WBC differential test in two consecutive testing events and attain a score of at least 80 percent of acceptable responses for the bicarbonate analyte at Q3 testing event in 2022. The findings include: See D2087 and D2130.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on March 30, 2023, at 2:30 pm,

	the laboratory failed to achieve satisfactory performance for the Cr test in two out of three consecutive testing events and attain a score of at least 80 percent of acceptable responses for the Cr analyte at Q1 and Q3 testing events in 2021. The findings include: See D2016 and D2096.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, CBC test records, and interview with the laboratory technical consultant and testing person's assistant on March 30, 2023, at 1:55 pm, the laboratory testing person #1 failed to follow the laboratory's policy and procedure to test and report patient's critical results. The findings include: 1. The laboratory received a sample on March 29, 2023, at 11:47 am and ran CBC test on the sample using Sysmex XN automated instrument. The instrument print out showed PLT result was critical low. According to the laboratory's policy and procedure the critical results should have been confirmed and notified immediately to the physician. However, as of 1:55 pm, March 30, 2023, the patient results were still pending in the laboratory information system. Furthermore, the testing person's assistant notified the results to the physician without confirming the critical results. Therefore, the validity of the patients' test results rendered by the laboratory cannot be assured and may have harmed patient. 2. The laboratory technical consultant on March 30, 2023, at 1:55 pm, affirmed that the laboratory personnel did not follow its procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/27/2023, stated that the laboratory performs approximately 66,834 CBC tests, annually.