Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0724185	04/02/2018
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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review third quarter (Q3-2016), second quarter (Q2-2017), and third quarter (Q3-2017), of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Urea Nitrogen (BUN), Cholesterol, Total and Cholesterol, HDL analytes. The findings included: a. AAB reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: BUN 60% Q3-2016 Chol, HDL 60% Q2-2017 Chol, Total 40% Q3-2017 b. For eleven (11) out of eleven (11) random patient sampling test results reviewed covering period from 2/1/2016 to 3/30 /2018, the laboratory analyzed and reported Routine Chemistry tests during the time proficiency testing results were unsatisfactory. c. The testing personnel affirmed (4/2 /2018, 12:30), that the laboratory received the above unsatisfactory proficiency testing scores for the above analytes.
D2109	TOXICOLOGY CFR(s): 493.845(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review first quarter (Q1-2017) of the American Association of Bioanalysts

	(AAB) proficiency testing records, and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Phenytoin and Valproic Acid analytes. The findings included: a. AAB reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Phenytoin 60% Q1-2017 Valproic Acid 60% Q1-2017 b. Based on the laboratory's annual testing volume submitted for 2017-2018, the laboratory analyzed and reported 27 Phenytoin and 196 Valproic Acid tests. c. The testing personnel affirmed (4/2/2018, 12:30), that the laboratory received the above unsatisfactory proficiency testing scores.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review first quarter (Q1-2016), second quarter (Q2-2016), third quarter (Q3-2016), and third quarter (Q3-2017) of the American Association of Bioanalyts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to verify the accuracy of the above analytes with an artificial score of 100%. The findings included: Q1-2016 a. AAB reported the following artificial 100% proficiency testing scores. Analyte: Value Acceptable Reported: Range: Lipase 1# 11 15-28 Lipase 2# 6 12-22 Folate 2? >24 9.8-18.2 Note: True Lipase score should have been 60%. True Folate score should have been 50% Q2-2016 Analyte: Value Acceptable Reported: Range: Bili, Direct 2# 5.1 2.9-4.4 Lipase 1# 52 27-50 Lipase 5# 60 29-54 Note: True Bili, Direct score should have been 50% True Lipase score should have been 60% Q3-2016 Analyte: Value Acceptable Reported: Range: Beta-2 Macroglob 1# 15 1.12-2.08 Beta-2 Macroglob 2# 10 0.75-1.4 Bili, Direct 1# 2.2 1-1.8 Bili, Direct 2# 6.9 3.7-5.5 Note: True Beta-2-Macroglobulin should have been 0%. True Bili, Direct score should have been 0%. Q3-2017 Analyte: Value Acceptable Reported: Range: Bili, Direct 1# 1.8 0.7-1.5 Bili, Direct 2# 6.8 3.7-5.6 Myoglo 2? 653 255-474 Beta-2- Microglo 1? 0 1.51-2.8 Note: True Bili, Direct score should have been 0%. True Myoglobin, 2v score should have been 50% True Beta-2-Microglobulin score should have been 50% b. Based on the AAB proficiency testing footnotes, "# sign = This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. the listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." Based on the AAB proficiency footnotes, " ?= This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus." c. For eleven (11) out of eleven (11) random patient sampling test results reviewed covering period from 2/1/2016 to 3/30/2018, the laboratory analyzed and reported the above unsatisfactory proficiency testing results and yet the laboratory has no documentation of corrective actions. d. The testing personnel affirmed (4/2/2018, 12:30), that the laboratory received the above unsatisfactory proficiency testing scores for the above analytes.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review first quarter (Q1-2016), second quarter (Q2-2016), second quarter (Q2-2017), and third quarter (Q3-2017) of the American Association of Bioanalyts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: Tumor Marker: a. Q1-2016, AAB reported an unsatisfactory proficiency testing score of 50% for Carcinoembryonic Antigen (CEA) Specimen 2: Value reported 533.3, Mean 55.7 Grading range 39-72.4. Q3-2017, AAB reported an unsatisfactory proficiency testing score of 50% for Thyroglobulin Specimen 2: Value reported 29.6, Mean 16.9, Grading range 10.7-23.1. Immunochemistry: a. Q2-2016, AAB reported an unsatisfactory proficiency testing score of 50% for Parathyroid Hormone (PTH) Specimen 1, Value reported 128, Mean 74, Grading range 55.5-92.5. Q3-2017, AAB reported an unsatisfactory proficiency testing score of 50% for Parathyroid Hormone (PTH) Specimen 1, Value reported 26.1, Mean 20.15, Grading range 15.1-25.2. Hematology: a. Q2-2017, AAB reported an unsatisfactory proficiency testing score of 0% for Erythrocyte Sedimentation Rate (ESR), and Reticulocyte (Retic) Count. ESR specimen 1, Value reported 11, Mean 76.3, Grading range 46-107. ESR specimen 2, Value reported 45, Mean 11.5, Grading range 4-19. Retic specimen 2, Value reported 2.0, Mean 0.76, Grading range 0.3-1.3 Chemistry: a. Q3-2017, AAB reported an unsatisfactory proficiency testing score of 60% for Bilirubin (Bili), Direct Specimen: Value reported 2.7, Mean 0.8, Grading range 0.4-1.2. b. For eleven (11) out of eleven (11) random patient sampling test results reviewed covering period from 2/1/2016 to 3/30/2018, the laboratory analyzed and reported patient tests even though the laboratory received the above unsatisfactory proficiency testing results. c. The testing personnel affirmed (4/2/2018, 12:30), that the laboratory received the above unsatisfactory proficiency testing scores.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results and interview with the testing personnel, it was determined that the laboratory failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. See D 2087, D 2109, D5215, and D5217.