Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0955926	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Innovative Bioanalysis Lab	3188 Airway Ave Suite D, Costa Mesa, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the third quarter (Q3-2017) of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Culture ID. The findings included: a. Q3-2017, AAB reported 66.7% for Culture ID. b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 9/28/2017 to 11/6/2017, the laboratory analyzed and reported Culture ID, during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (5/1/2019, 1300), that the laboratory received the above unsatisfactory proficiency test score.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 of the first quarter (Q1-2017) of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rheumatoid

	Factor (RF). The findings included: a. Q1-2017, AAB reported 60% for RF analyte. b. For three (3) out of five (5) random patient sampling test results reviewed covering period from 2/14/2017 to 3/22/2017, the laboratory analyzed and reported RF analyte during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (5/1/2019, 1300), that the laboratory received the above unsatisfactory proficiency test score.
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 of the first quarter (Q1-2019) of the American Association of Bioanalyts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Creatinine Kinase (CK), and Cholesterol, Total analytes. The findings included: a. Q1-2019, AAB reported the following unsatisfactory testing score Analyte: Score: Event/Year: CK 0% Q1-2018 Chol, Total 60% Q1-2019 b. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/8/2019 to 3/22/2019, the laboratory analyzed and reported CK, and Chol, Total tests during the approximate time the laboratory failed the proficiency testing. c. The technical consultant confirmed (5/1/2019, 1300) that the laboratory received the above unsatisfactory proficiency testing score for CK, and Cholesterol, Total analytes.
D2121	HEMATOLOGY CFR(s): 493.851(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 of the second quarter (Q2-2018) of the American Association of Bioanalyts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for White Blood Cell (WBC) count. The findings included: a. Q2-2018, AAB reported the following unsatisfactory testing scores. Analyte: Score: Event/Year: WBC PMN 0% Q2-2018 WBC Lymph 0% Q2-2018 WBC Mono 50% Q2-2018 b. For three (3) out of three (3) random patient sampling test results reviewed covering period from 6/15/2018 to 6/27 /2018 the laboratory analyzed and reported Complete Blood Count (CBC) with WBC differentials that cannot be assured. c. The technical supervisor confirmed (5/1/2019, 1300), that the laboratory received the above unsatisfactory proficiency test score.
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 of the first quarter (Q1-2018) American Association of Bioanalysts (AAB) proficiency testing records and interview with the technical consultant, it was determined that the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. The findings included: a. Q1-2018, AAB proficiency testing, the laboratory received an artificial 100% score for High Density Lipoprotein (HDL, Cholesterol) analyte. Spec.: Reported Grading Mean: Value: Range: 1# 56 24-45 34.8 2 # 148 75-139 107.1 3# 75 33-61 46.6 4# 29 12-23 17.6 5# 15 7-12 9.3 Q2-2018 Spec.: Reported Grading Mean: Value: Range: 1# 3 12-22 16.9 2 # 10 30-57 43.5 3# 49 71-132 71 4# 1 6-12 8.9 5# 7 23-43 33.4 Note: True score for HDL, Cholesterol should have been 0% for Q1-2018, and Q2-2018. b. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/8/2019 to 3/22/2019, the laboratory analyzed and reported HDL, Chol tests that results cannot be assured. c. The technical consultant confirmed (5/1/2019, 1300) that the laboratory received the above artificial 100% score for HDL, Chol and that the laboratory did not have a corrective action taken for the true proficiency testing scores.
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 reviews of the American Association of Bioanalysts (AAB) proficiency testing performance summary records, and interview with the technical consultant, 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: a. AAB reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Microalbumin, Quantitative 0% Q1-2019 Creatinine, Quantitative 0% Q1-2019 b. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/8/2019 to 3/22/2019, the laboratory analyzed and reported Urine Microalbumin/Creatinine tests during the approximate time the laboratory failed the proficiency testing. c. The technical consultant confirmed (5/1/2019, 1300) that the laboratory received the above unsatisfactory proficiency testing scores.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on reviews of the American Association of Bioanalysts (AAB) proficiency performance summary records, random patient sampling test results, and interview with the technical consultant it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2020, D 2075, D 2087, D 2121, D 5215, and D 5217.