Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2155298	**(X3) Date Survey Completed** 10/14/2021
Name of Provider or Supplier Optimum Bio Lab, Inc	**Street Address, City, State** 1910 S Archibald Ave Ste D, Ontario, 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**
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) 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 American Proficiency Institute (API) Proficiency Testing (PT) records and interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to attain a score of least 80 percent of acceptable responses for Rheumatoid Factor (RA/FR) for the third event of 2020 (Q3-2020) and for Anti-HIV for the second event of 2021 (Q2-2021) PT. The findings included: 1. Based on review of PT records for Q3-2020, API reported an unsatisfactory score of 40% for RA/RF analyte as follow: Sample Result Expected Performance RF-11 Positive Negative Unacceptable RF-12 Positive Positive Acceptable RF-13 Positive Negative Unacceptable RF-14 Negative Negative Acceptable RF-15 Negative Positive Unacceptable 2. Based on review of PT records for Q2-2021, API reported an unsatisfactory score of 60% for Anti-HIV testing as follow: Sample Result Expected Performance VM-06 R-Positive R- Positive Acceptable VM-07 NR-Negative NR-Negative Acceptable VM-08 R-Positive NR-Negative Unacceptable VM-09 NR-Negative R- Positive Unacceptable VM-10 R-Positive R- Positive Acceptable 3. Based on the laboratory's testing declaration at the time of the survey on October 14, 2021 the laboratory reported approximately 3,660 General Immunology tests results which include both RF and Anti-HIV analytes during the time the laboratory had unsatisfactory PT testing scores. 3. The TS affirmed that the laboratory received the above unsatisfactory General Immunology RF and HIV analytes PT scores.
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 American Proficiency Institute (API)) proficiency testing (PT) records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for multiple Chemistry analytes for the years 2019 and 2021. The finding included: 1. Based on review of PT records for the third event 2019 (Q3-2019) and first event 2021 (Q1-2021) API reported the following unsatisfactory scores for the following analytes: Q3-2019: Total Bilirubin 40%, Total Calcium 0%, Total Cholesterol 0%, CO2 0%, Creatinine 0%, Glucose 0%, and Urea Nitrogen 40%. Q1-2021: Cholesterol HDL 0% and Creatinine 20%. 2. Based on the laboratory testing declaration submitted at the time of the survey on October 14, 2021 the laboratory analyzed and reported approximately 38,800 Routine Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed on 10/14 /2021 at approximately 2:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and Corrective Action Forms (CAR) documents for unsatisfactory proficiency test scores, and interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to undertake appropriate training to correct problems associated with the proficiency testing (PT) failures and document remedial actions taken. The findings included: 1. The laboratory obtained unsatisfactory scores for the Chemistry analytes specified in D2087. 2. Review of the documentation for CAR for the third event 2019 and fist event 2021 of the API proficiency testing events, indicate the laboratory failed to provide appropriate training and document actions taken necessary to correct problems associated with PT failures. 3. The TS affirmed on October 14, 2021 at approximately 1:45 p.m. that the laboratory failed to provide appropriate training for the testing personnel and document actions taken to correct problems associated with PT failures. 4. Based on the annual test volume reported on 10/14/2021, the laboratory performed and reported approximately 215,260 Routine Chemistry test.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed

	when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review the laboratory's policies & procedures, proficiency testing performance records, lack of corrective action records and documentation, and interview with the laboratory technical supervisor; it was determined that the laboratory director failed to ensure that an approved corrective action plan policy exists and is followed when any proficiency testing results are found to be unsatisfactory performance. The findings include: See D2076, D2087, and D2094.