| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D0930143 | 10/23/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Biological Laboratory, Inc | 620 W Covina Blvd, San Dimas, 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 |
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| **D2075** | GENERAL IMMUNOLOGY<br>CFR(s): 493.837(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's AAB- Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, seven (7) randomly chosen patients sampling, and interviews with the laboratory's laboratory director (LD), technical supervisor (TS), and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for ANA Panel; AE and ANA Fluorescent Pattern for the second event of 2025 (Q2-2025). The findings included: 1. The AAB-MLE proficiency program gave an unsatisfactory score of 60% for both: ANA Panel; AE and ANA Fluorescent Pattern for Q2-2025. 2. The TS and TP confirmed on October 23, 2025, at approximately 11:25 a.m. that the laboratory received the above proficiency score of 60% for ANA Panel and ANA Fluorescent Pattern as described in 1. 3. From two (2) out of seven (7) patients test results reviewed, ANA test results had been reported during the time the PT survey was unacceptable for which results cannot be assured. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey October 20, 2025, the laboratory tested and reported approximately 1,707 General Immunology tests including ANA. |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>(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 |

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| | event.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the College of American Pathology (CAP) proficiency testing (PT), the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, seven (7) randomly selected patient test records, and interviews with the laboratory's laboratory director (LD), technical supervisor (TS), and testing personnel (TP); the laboratory failed to attain a score of at least 80 percent of acceptable responses for the chemical analyte Vitamin B12 for the second event in 2025 (Q2-2025). The findings include: 1. Review of PT records for Q2-2025, CAP reported an unsatisfactory score report for Vitamin B12 chemical analyte of 60%. 2. The LD, TS, and TP confirmed by interview on October 23, 2025, at approximately 12:30 p.m. that the laboratory obtained the PT score mentioned in statements #1. 3. According to the laboratory's testing declaration submitted on the day of the survey October 23, 20255 and signed by the LD on 10/22/2023, the laboratory performed and reported approximately 24,338 Vitamin B12 patient laboratory test samples during the time the laboratory received unsatisfactory proficiency testing results. |
| **D2098** | ENDOCRINOLOGY<br>CFR(s): 493.843(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the College of American Pathologists proficiency testing (PT) records, PT documentation, and interviews with the laboratory's laboratory director (LD), technical supervisor (TS), and testing personnel (TP); the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the Estradiol Sex Hormone analyte for the second PT event of 2025 (Q2-2025). The findings include: 1. CAP (Q2-2023), Estradiol Sex Hormone analyte = overall score: 60% Specimen Reported Expected Y-06 44 34 - 64 Y-07 5800 1964 - 3649* Y-08 823 548- 1019 Y-09 225 149 - 278 Y-10 4081 1430 - 2658* * = unsatisfactory score reported 2. The LD, TS, and TP affirmed by an interview on October 23, 2025, at approximately 12:10 p.m. that the laboratory obtained the unsatisfactory PT scores for Estradiol for Q2-2025 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 4,766 patient test samples for Estradiol Sex Hormone annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined. |
| **D2109** | TOXICOLOGY<br>CFR(s): 493.845(a)<br><br>(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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the second quarter event in 2025 (Q2-2025) of the laboratory's College of America Pathology (CAP) proficiency testing (PT) records, seven (7) randomly chosen patients sampling, and interviews with the laboratory's laboratory director (LD), technical supervisor (TS), and testing personnel (TP); the laboratory failed to attain a score of at least 80 percent of acceptable responses for the analyte Digoxin. The findings included: 1. CAP reported for Q2-2025, an unsatisfactory PT score for Digoxin analyte of 60% which is an unsatisfactory PT score. 2. The LD, TS, and TP affirmed on October 23, 2025, at approximately 12:00 p.m. that the laboratory received the above unsatisfactory proficiency test scores. 3. Based on the test volume declaration signed by the laboratory director on 08/23/2025, the laboratory tested 216 Digoxin annually. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the proficiency testing results documentation, randomly selected patient test records, and interviews with the laboratory personnel on October 23, 2025; the laboratory director is herein cited due to failure to ensure that several aspects of the analytic phases of the laboratory testing were monitored. The findings include: D2075, D2087, D2098, and D2109. |