

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0930143	<b>(X3) Date Survey Completed</b> 10/05/2021
<b>Name of Provider or Supplier</b> Biological Laboratory, Inc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2122</b>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records, interview with the technical supervisor (TS), and testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent which is unsatisfactory performance. The findings included: 1. On the date of the survey October 5, 2021 at approximately 3:00 p.m. based on review of the PT scores, the laboratory obtained for Hematology WBC first event for the year 2021 (Q-1 2021) an overall score of 0% and for Prothrombin Time Quantitative (PT-Q) for the second event of 2021 (Q2-2021) a score of 40%. The results were as follow: WBC Overall score 0% Sample Reported Expected Score 1 22.9 14.6 - 19.9 U 2 3.7 2.4 - 3.3 U 3 10.1 6.4 - 8.7 U 4 8.7 5.6 - 7.7 U 5 3.6 2.4 - 3.4 U PT-Q Overall score 40% Sample Reported Expected Score 6 34.8 37.6 - 51.0 U 7 19.5 19.7 - 26.8 U 8 10.0 A 9 35.5 37.4 - 50.8 U 10 10.0 9.0 - 12.3 U 2. The TS and TP affirmed on 08/05 /2021at approximately 3:30 p.m. that the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the surve , the laboratory performed approximately 145,832 Hematology samples (quarterly) during the time the laboratory received unsatisfactory PT performance scores.</p>
<b>D3005</b>	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p>

This STANDARD is not met as evidenced by:  
 Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisor (TS) and testing personnel (TP) on October 5, 2021 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, RNA extraction, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using the COVID-19 PCR Combo kit and amplification method on the BioRad instrument. 2. During the laboratory tour on 10/5/2021 at approximately 1:00 p.m. the surveyor observed that RNA extraction and sample template addition were all performed in the same area of Cytology sample processing without unidirectional flow. 3. The TS and TP confirmed by interview on October 5, 2021 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in an unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 130,582 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.

**D5205**

**COMPLAINT INVESTIGATIONS**  
 CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's policies and procedures, ten (10) randomly chosen patient samples, and quality assurance records; and interview with the technical supervisor (TS) and testing personnel (TP) on October 5, 2021, it was determined that the laboratory failed to have a system in place to ensure that all complaints are investigated and documented . The findings included: 1. The laboratory did not have any system in place to investigate and document complaints by sample submitters as well as by the laboratory staff. 2. The TS and TP affirmed on October 5, 2021 at approximately 3:30 p.m. that the laboratory did not have any system in place to investigate and document all complaints. 3. According to the laboratory sample volume declaration at the time of the survey, the laboratory performed 1,700,312 samples annually.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
 CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory tour, lack of calibration records, and interview with the laboratory technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to follow the BioTek manufacturer's instructions on the use of a calibration plate provided by the manufacturer. The findings included: 1. The laboratory used the BioTek fluorescent wavelength reader for various ELISA and EIA General Immunology test procedures. 2. The laboratory did not have available the calibration plate provided by the manufacturer or documentation of performing calibration on the instrument. 3. The TS and TP affirmed on October 5, 2021 at approximately 12:45 p.m. that no calibration was performed on the BioTek instrument since relocation on the laboratory to the current location six (6) years ago. . 5. According to the testing volume declaration at the time of the survey, the laboratory performed 46,984 General Immunology samples annually.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must 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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records for policies and procedures, proficiency testing results, lack of calibration documentation, and interview with the technical supervisor and laboratory personnel on October 5, 2021; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2122, D5437, and D5205.

**D6083**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's direct observations of the laboratory's SARS-CoV-2 PCR testing processes and interview with the laboratory supervisor and testing personnel on October 5, 2021; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005.