Citation and Notification of Penalty

Company Name: State of California Department of Public Health and its successors
Inspection Site: 850 Marina Bay Parkway
Richmond, CA  94804

Citation 1 Item 1  Type of Violation: General

Title 8 CCR Section 3203(a)(4)(B). Injury and Illness Prevention Program.
(a) Effective July 1, 1991, every employer shall establish, implement and maintain an effective Injury and Illness Prevention Program (Program). The Program shall be in writing and, shall, at a minimum:
(4) Include procedures for identifying and evaluating work place hazards including scheduled periodic inspections to identify unsafe conditions and work practices. Inspections shall be made to identify and evaluate hazards:
(B) Whenever new substances, processes, procedures, or equipment are introduced to the workplace that represent a new occupational safety and health hazard;

Prior to and during the course of the inspection, including but not limited to, on March 18, 2021, the employer failed to implement and maintain an effective Injury and Illness Prevention Program to identify and evaluate work place hazards when it did not evaluate mechanical and chemical hazards associated with the laboratory procedures for the new COVIDNet Hit-Picking on Hamilton STARLet process as required by the Viral and Richettsial Disease Laboratory Injury and Illness Prevention Plan in the following instances:

Instance 1: The employer failed to identify and evaluate the mechanical hazards for the new process of automated pipetting of ATPs-L specimens with an automated piece of equipment outside of a BioSafety Cabinet.

Instance 2: The employer failed to identify and evaluate the chemical hazards for handling specimens contained in hazardous substances.

Date By Which Violation Must be Abated: Corrected During Inspection
Proposed Penalty: $600.00
Citation and Notification of Penalty

Company Name: State of California Department of Public Health and its successors
Inspection Site: 850 Marina Bay Parkway
Richmond, CA  94804

Citation 1 Item 2   Type of Violation: General

Title 8 CCR Section 5199(f). Aerosol Transmissible Diseases.
(f) Laboratories.
(1) This subsection applies to laboratory operations where employees perform procedures capable of aerosolizing ATPs-L.
(2) The biological safety officer shall perform a risk assessment in accordance with the methodology included in Section II of the BMBL for each agent and procedure involving the handling of ATPs-L. The biosafety officer shall record the safe practices required for each evaluated agent/procedure in the Biosafety Plan.
(4) Biosafety Plan (BSP). The employer shall establish, implement, and maintain an effective written Biosafety Plan to minimize employee exposures to ATPs-L that may be transmitted by laboratory aerosols. The BSP may be incorporated into an existing Exposure Control Plan for bloodborne pathogens or an ATD Exposure Control Plan as described in subsection (d), and shall do all of the following:
(D) Include a requirement that all incoming materials containing ATPs-L are to be treated as containing the virulent or wild-type pathogen, until procedures have been conducted at the laboratory to verify that a pathogen has been deactivated or attenuated.

Prior to and during the course of the inspection, including but not limited to, on March 18, 2021, the employer failed to establish, implement, and maintain an effective written Biosafety Plan in the following instances:
Instance 1:
The employer failed to ensure the biological safety officer performed a risk assessment in accordance with the methodology included in Section II of the BMBL on the laboratory procedures for the new COVIDNet Hit-Picking on Hamilton STARLet process capable of aerosolizing ATPs-L.

Instance 2:
The employer failed to ensure the Biosafety Plan included the requirement that all incoming materials containing ATPs-L be treated as containing the virulent or wild-type pathogen, until procedures had been conducted at the laboratory to verify that the pathogen has been deactivated or attenuated.
Instance 3:
On March 18, 2021, the employer failed to develop and implement specific procedures for ensuring that samples containing SARS-CoV-2 received from an off-site laboratory had been deactivated.

Date By Which Violation Must be Abated: Corrected During Inspection
Proposed Penalty: $600.00

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Kathy Garner
Compliance Officer / District Manager