

BioScience Laboratories Gains CDC Approval to Test All Known Strains of SARS-CoV-2

Salt Lake City, UT; Bozeman, MT, 11 March 2022 – BioScience Laboratories, a Nelson Labs company located in Bozeman, MT, and a leader in topical antimicrobial-product testing in the consumer, pharmaceutical, and medical-device industries, operates a biosafety-level-3 (BSL-3) laboratory that was inspected by the US Centers for Disease Control and Prevention (CDC) on 22 September 2021. The CDC has since confirmed that the Bozeman facility’s BSL-3 lab and related procedures adequately meet CDC guidelines for BioScience Laboratories to test all common and concerning strains of SARS-CoV-2 and other potentially dangerous pathogens.

During the past two years we have seen how rapidly SARS-CoV-2 has mutated, with the Omicron variant being the most recent example. “This recent inspection by the CDC confirms that the appropriate biosafety measures are indeed in place in the Bozeman facility to allow BioScience Laboratories to test all the variants of SARS-CoV-2” said Joe Shrawder, President of Nelson Labs. “BioScience Laboratories is among the first commercial BSL-3 labs to pass this inspection.”

The purpose of the inspection was “to assess whether the importer’s facility has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use,” as stated in a letter from Glen DeGruy, Chief, Program Service Branch, Division of Select Agents and Toxins at the CDC.

CDC inspectors compared the procedures, policies, and practices of BioScience Laboratories to the best practices outlined in the CDC’s Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, a 600-page guidance document that has served in the United States since 1984 as a benchmark for biosafety practices. The inspectors assessed key BSL-3 laboratory operations as detailed by BioScience Laboratories’ own standard operating procedures (SOP) and met with key personnel of the BSL-3 lab to discuss laboratory safety and procedures.

The initial CDC report delivered to BioScience Laboratories contained no high-risk observations. On 4 January 2022 BioScience Laboratories received the CDC’s final report closing out the inspection and allowing for the continued testing of BSL-3 pathogens, including all known SARS-CoV-2 variants.

Learn how BioScience Labs can help you with your clinical studies and support your viral label claims at www.biosciencelabs.com.

About Nelson Labs: Nelson Labs is a global leader in outsourced microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries. Nelson Labs serves over 3,500 customers across 15 facilities in the United States, Mexico, Asia, and Europe. We have a comprehensive array of over 800 laboratory tests supporting our customers from



initial product development and sterilization validation, through regulatory approval and ongoing product testing for sterility, safety, and quality assurance. We are regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues.

Safeguarding Global Health® - with every test we complete.

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