



TEXAS BIOMEDICAL RESEARCH INSTITUTE

HEALTH STARTS WITH SCIENCE

Biosafety Labs in the U.S.: A Texas Biomed Perspective

A quick-start guide to understanding high-biocontainment laboratories in the U.S.

Overview

Texas Biomed set up the first privately-owned and operated BSL-4 lab in the country, which opened in 2000. We have six BSL-3 labs, and more than 100 BSL-2 labs. Biocontainment labs in the United States are some of the safest places in the world to conduct biological research. They are designed to prevent the accidental release of pathogenic organisms, such as viruses like SARS-CoV-2, HIV, Ebola virus and many others, while providing a safe and secure environment in which to study these harmful organisms, potential treatments and vaccines. Facility design combined with strict safety protocols, such as air locks, negative air flow and disinfecting showers, help ensure maximum protection for staff and the community. There are also multiple layers of regulation and oversight to verify best practices are followed.

Of course, there can never be a 100% guarantee that accidents won't happen – research of any kind carries intrinsic risk. That is why at Texas Biomed, we cultivate a strong culture of safety, open communication and accountability. We regularly train our teams and practice drills so that we are prepared to mitigate potential exposures should they occur. Our business is infectious diseases and protecting the global community from them – that starts right here in our labs.

What's the difference between BSL-1 and BSL-4?

Biocontainment labs are ranked from biosafety level (BSL) 1 to 4, with BSL-4 being the highest. The levels define the required safety equipment and protocols based on how pathogens spread and what treatments are available.

Biosafety Level (BSL)	Agents (bacteria, viruses or toxins that...)	Examples	Key safety measures & equipment
1	We know don't pose a threat.	Non-pathogenic E. coli, Saccharomyces cerevisiae (yeast)	Standard procedures. Protective clothing and eyewear as needed.
2	Are associated with human disease and pose a moderate hazard.	Staphylococcus aureus, Hepatitis viruses	Agents that may cause splashes or aerosols are handled in biosafety cabinets or containment device. Respiratory protection as needed. Self-closing doors.
3	May cause serious or potentially lethal disease through inhalation.	Tuberculosis, Simian immunodeficiency virus (SIV), SARS-CoV-2	Infectious agents handled in biosafety cabinet. Additional protective clothing & gloves. Two sets of self-closing doors. Negative airflow.
4	Have high risk of aerosol-transmitted infection, are frequently fatal & no vaccines or treatments are available. Or transmission risk is unknown.	Ebola, Marburg, Anthrax	Entry and exit sequences. Dedicated ventilation system. Airtight doors. Double-door autoclave pass through. Full-body, air-supplied, positive-pressure suit for suit labs; full gowns/gloves for cabinet labs.

Texas Biomed labs and scientific studies are regulated internally through the Vice President for Research Office under the following committees:

- Internal Animal Care and Use Committee
- Institutional Biosafety Committee (IBC) (all of which have community participants)
- Recombinant DNA Committee
- Institutional Review Board (IRB)

We are externally reviewed by:

- Centers for Disease Control (CDC) and United States Department of Agriculture's (USDA) Federal Select Agent program
- National Institutes of Health (NIH) Office of Lab Animal Welfare (OLAW)
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
- Dual Use Research of Concern policy of the NIH's Office of Science Policy (OSP)
- And partner organizations

Culture of Safety

We have established a robust and reliable safety system that has worked well for more than 20 years. Our team runs practice drills regularly and our researchers are trained to report anything out-of-the-ordinary that occurs in the lab. If someone even suspects something has the potential for release or exposure, our team follows the full procedures for potential exposure to a pathogen.

Facility Designed for Safety

Facility design and standard operating procedures significantly minimize the risk of a pathogen inadvertently exiting a lab. For example, the negative air flow and air locks ensure nothing wafts into the hallway. Anything potentially harmful is also only handled in a biosafety cabinet, so any vapors or splashes are in that smaller, well-ventilated space. In the BSL-4, bacterial a bacterial spore or viral particle won't make it past the decontamination shower. Researchers take off their boots in the lab and take a seven-minute decontamination shower in their pressurized space suits. The sterilization solution and procedure ensures no live particles are detected. Researchers wear scrubs inside their space suits. The scrubs are first autoclaved – heated and steamed to such a high temperature it kills or inactivates anything that might be on the scrubs – and then laundered. Researchers take a regular/personal shower before donning their street clothes. In the BSL-3, specialty personal protective equipment is also worn, and gloves, coats and eye wear are worn in a BSL-2.

Critical for Public Health

Biosafety labs provide a well-regulated space to safely study deadly infectious diseases, both known and unknown. "There will be another COVID-19, and the need to study these organisms," says Jean Patterson, Ph.D., who led the establishment of the BSL-4 at Texas Biomed. "We can't make a vaccine unless we can grow the organism in the lab. We can't make a treatment unless we can grow it, put it in an animal and cure it. This is the only way to be prepared."

Facts and Stats

- **8** | BSL-4 labs in the U.S. registered with the U.S. Federal Select Agent Program as of 2019
- **199** | BSL-3 labs in the U.S. registered with the U.S. Federal Select Agent Program as of 2019
- **8,360** | individuals authorized to work on BSAT by the U.S. Federal Select Agent Program as of 2019
- **50+** | maximum- and high-containment facilities (BSL-4) around the globe in 2017, according to the World Health Organization.
- **Hundreds** | total number BSL-3 and BSL-4 labs in the U.S. is often a moving target because only those working with Select Agents are required to register with the CDC. Counts can differ if you include cabinet labs versus suit labs. Also, some labs built to BSL-4 standards may only be working with BSL-3 agents.
- **0** | In 2019, none of the relatively small number of reported releases or losses of select agents and toxins in the U.S. resulted in a risk to public or agricultural health, according to the 2019 Federal Select Agent Program Report.