PURO™
UV Disinfection Lighting

DISINFECTION IN A FLASH

# Smart Disinfection for Laboratories

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# Introduction

There are thousands of laboratories throughout the United States and the world that require a clean, controlled environment. While the risk of microbial contamination and its potential consequences may vary depending on the type of laboratory, they all share one thing in common — a real challenge with achieving proper disinfection. Furthermore, the consequences of contaminating samples, products, or the environment as a whole can have dire consequences, ranging from product recalls to illnesses to death in patients and consumers.

Whether a laboratory is challenged with keeping its environment safe from unknown pathogens being tested; producing sterile pharmaceutical products; formulating consumer products; or simply maintaining a research laboratory free from contaminants in the air and on surfaces, implementing proper protocols to protect against known and unknown threats can be incredibly difficult.

This white paper, written by PURO Lighting's technology partner Violet Defense, lays out the challenges that laboratories face in disinfecting their spaces to reduce the risks associated with various pathogens, and how advancements in UV disinfection technology will change the way they should think about protecting these environments.

# The Need for Clean, Controlled Environments

> "The events of September 11, 2001 and the *anthrax* attacks in October of that year re-shaped and changed, forever, the way we manage and conduct work in biological and clinical laboratories."
>
> Centers for Disease Control and Prevention

In any type of space, people are at risk from the harmful effects of various microorganisms that can cause infections and illnesses. These microorganisms are resilient, easy to spread, and can survive on surfaces for hours, weeks, and even months.

However, in certain environments, particularly laboratories, the risks associated with these microorganisms can be even greater. Laboratory workers can be subjected to highly infectious agents in the course of their work, but also the products produced in formulation or extraction labs can be contaminated, creating risks for consumers. In addition to the risks to the health and wellness of employees and consumers, laboratories not maintaining clean, controlled environments can create major operational and financial risks, such as product recalls, regulatory observations, fines, or other negative outcomes that may be detrimental to their business.[1]

Therefore, it is essential that people working in and managing these settings not only understand the need for clean, controlled environments, but also the unique challenges that their industries face in achieving these standards.

## HEALTHCARE & CLINICAL DIAGNOSTIC LABORATORIES

As of 2016, the clinical laboratory services market was estimated at $186.1 billion dollars[2] in the United States. As both health care access expands and we continue to reveal new biological threats, the need for diagnostic and research laboratory services is likely to expand. However, while these labs are there to protect public health, it's also important to protect the workers in these labs.

There are an estimated 17,000 commercial medical and diagnostic laboratory establishments.[3] Combining medical, dental, and biotechnology research laboratories, that translates to nearly 441,000 lab workers[4] that are potentially at risk for exposure to infectious agents.

In 1978, Pike and Sulkin identified 4,079 laboratory-associated infections (LAIs) that resulted in 168 deaths.[5] While their research likely did not account for all LAIs, it became the foundation of the approach moving forward on how to prevent LAIs.

Over the next two decades, Harding and Byers continued similar research and found 1,267 overt infections and an additional 663 sub-clinical infections.[5] While the majority (51%) of these infections were in research labs, 45% occurred in clinical or diagnostic labs. Although no specific incidents were identified for many of the cases, it was found that those involved had been consistently working with microbiological agents, working in or around a laboratory, or were around infected animals.

In clinical laboratories, workers often do not know or fully appreciate the infectious nature of the specimens with which they are dealing, making it necessary to have protocols that can effectively maintain healthy environments and protect against all types of pathogens.

## FORMULATION & EXTRACTION LABORATORIES

A key component in the production process of high-quality products, according to the Food and Drug Administration (FDA) is ensuring they are free from contamination. However, contaminated raw materials, poor production conditions or techniques, and ingredients that encourage growth of microorganisms can all contribute to products becoming contaminated.[6]

Cleaning and disinfection of the clean room environment is a core requirement for maintaining sterile conditions in compounding facilities.

In 2004, the United States Pharmacopeial Convention (USP) Chapter <797> emphasized the "need for routine cleaning and disinfection of the clean room environment as a core requirement for maintaining sterile conditions in compounding facilities." Unfortunately, the level of adherence has not always been where it needs to be. A study in 2013 indicated that only 73% of practitioners were in full compliance with the cleaning-related aspects of USP <797>.[7]

Lack of compliance can lead to severe consequences as products are at risk for contamination. It is for this reason that the USP has recommended routine testing of products for pathogens, including Salmonella, *E. coli, P. aeruginosa* and *S. aureus*, all of which can yield serious health consequences if they go undetected.

With the legalization of marijuana in many states, similar oversight in cannabis production and extraction labs is likely to be the standard going forward. Cannabis extraction requires both analytical methods and real lab equipment to produce products safely and correctly. However, early studies of samples from dispensaries found concerning levels of bacteria and fungi known to cause serious infections. In California, nearly 20% of products evaluated failed tests for potency and purity during the first two months of safety tests.[8] These pathogens are especially dangerous to immunocompromised patients, many of the early adopters of medical marijuana.

When charged with the formulation and manufacturing of pharmaceuticals designed to improve health outcomes in patients or consumers, it is critical that these types of laboratories ensure that harmful pathogens do not contaminate their working environments and ultimately the products they produce.

## RESEARCH LABORATORIES

There are also a variety of research laboratories where a clean, controlled environment is critical. Contaminants on surfaces or in the air may cause issues with mold or bacteria accumulating on equipment, in flow hoods, or in materials or substances involved in experiments.

Some research laboratories may have even higher stakes, such as NASA Clean Rooms used for assembling spacecraft, where contaminated surfaces have not just global implications, but planetary ones.

In spite of an extensive series of decontamination steps, including air filtration systems, fully outfitted staff with masks and hooded coveralls, and stringent cleaning and disinfecting protocols, studies have revealed that especially virulent strains of *Acinetobacter* (a bacteria known to cause serious infections, including pneumonia) have figured out a way to survive all of these conditions. According to Lisa Pratt, NASA's Planetary-Protection Officer, "disinfectant chemicals intended to kill bacteria are feeding, sustaining, and increasing the sterilization tolerance for some microorganisms."[9]

While this may be an extreme situation of resistance in microbes, particularly in a species already known for being tough to kill, it does highlight the importance of understanding the need for effective disinfection and the challenges that laboratories must overcome through the introduction of new technologies and new processes to keep staff, consumers, and the broader world safe.

For pharmaceuticals manufacturers, it is critical to ensure that harmful pathogens do not contaminate their working environments.

Image credit: NASA/JPL-Caltech

# Considerations for Effective Disinfection

Regardless of the specific type of facility, laboratories must create a plan for how they will disinfect the air and surfaces throughout their spaces to minimize the risk of exposure to employees or contamination of products/samples produced. There are a series of critical questions that one must ask and answer to develop effective protocols.

What is the difference between disinfection and sterilization?
While disinfection procedures may often be enough to dramatically reduce the transmission of infections from the environment, it is still often the general practice of medical or clinical laboratories to use sterilization methods to completely remove the potential for infection transmission.

According to the CDC, "a sterilization procedure is one that kills all microorganisms, including high numbers of bacterial endospores." After completion, the probability of a microorganism surviving on an item that has been sterilized is less than one in a million.[5]

The challenge with sterilization is, however, multi-fold, including much higher cost, residual impact on equipment from heat and/or highly toxic chemicals, and the inability to scale designs to really keep large spaces truly "sterile."

Disinfection can have a wide range of effective levels from just shy of sterilization to a basic reduction in the number of microorganisms on a surface or item. The difference between high-level disinfection and sterilization is typically based on the ability to kill bacterial spores.

Ultimately, what level of protection is needed depends on the space, but a key piece of advice is this: Don't let the "perfect" become the enemy of the "good."

What types of pathogens are likely to be encountered?
The specific protocols recommended for a laboratory depend on the type of setting and the types of pathogens a laboratory may typically encounter. However, laboratories, particularly those in health care facilities often do not know the infectious nature of the specimens with which they are dealing.

Given this ambiguity, the initial processing of clinical specimens are typically handled with protocols for Biosafety Level 2 facilities, a rating given to laboratories working with a "broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity." In these facilities, workers should "decontaminate

Chlorine used in disinfectants is corrosive to metals if the residue is not removed.

work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectants."[5]

What is considered an "appropriate disinfectant"?

The answer to this question is not simple, nor are the other considerations or factors that will influence the efficacy of any chemical disinfectant, revealing the many challenges of traditional disinfection. The nature and number of microorganisms; level of organic matter present; type of surfaces or instruments to be disinfected, and temperature can all impact the effectiveness of disinfectants.

Most of the 'high-level' disinfectants are designed for use on instruments and medical devices, not on environmental surfaces that staff will come into contact with during the course of their work. However, low-level and intermediate disinfectants that are designed for use on environmental surfaces don't have the potency of high-level disinfectants necessary to effectively kill bacteria and inactivate viruses.

Bacterial spores have proven to be the most resistant to germicidal chemicals, followed by mycobacteria, non-lipid or small viruses, fungi, vegetative bacteria and medium-size viruses. For example, 70% isopropyl alcohol is widely accepted as a disinfectant and used to help remove residue, but is not effective against bacterial spores and limited in its effectiveness against non-enveloped viruses.[7]

There is no "one size fits all" chemical disinfectant, so laboratories need to match their choice with the specific issues they face.

Are all disinfectants safe to use?

In addition to selecting a disinfectant based on effectiveness against target pathogens, one must also consider the impact using those disinfectants may have on the health of employees. Many common disinfectants are harmful to people, causing skin, eye and respiratory irritations. Additionally, they may also have negative effects on surfaces and equipment. For example, chlorine is corrosive to metals if the residue is not removed.

Phenolics, an EPA-approved disinfectant for healthcare surfaces, may not only cause skin or eye irritation, they may also damage the finishes on floors and surfaces.[7]

Many pharmaceutical manufacturers may have a back-up disinfectant they use when there is significant build up, which appears to be resistant to routine disinfectants. These are disinfectants for which routine use is "restricted because of likely damage to the equipment and premises."[10]

> "This approach is messy and with some of the disinfectants used represents a toxic hazard to laboratory staff."
>
> Centers for Disease Control and Prevention (on traditional surface decontamination methods in laboratories)

What is the contact time required for this disinfectant?
The presence of any organic matter on surfaces will result in longer contact times for decontamination methods to be effective. This can be a challenge when high-level disinfectants are already prescribed to have contact times (the length of time the surface remains visibly wet) of as long as 10-30 minutes. Sterilization may require even further extended contact times of 6-10 hours.

For laboratories that require more stringent protocols, they may require even more extreme measures. Biosafety level 3 laboratories have to be designed to be water resistant for surface decontamination. However, the typical approach for surface decontamination is to "flood the area with disinfectant for periods up to several hours." This can be both a messy and a toxic approach for laboratory staff.[5]

Are there any other challenges with manual disinfection?
Another well-researched factor in disinfection approaches that rely on manual processes is the likelihood that not all areas, items, or surfaces will be cleaned or disinfected properly due to human error. Studies in health care settings have frequently found less than 50% of surfaces being cleaned properly, even when current protocols were supposedly followed.[11]

Furthermore, not changing cleaning rags or mops frequently enough can lead to poor cleaning outcomes, as germs begin to get moved from place to place, rather than removed.

So, what else can be done?
Given all of these issues, various types of facilities, including healthcare, have begun to incorporate enhanced disinfection methods, including the use of ultraviolet light, to improve disinfection outcomes and subsequently reduce infection rates.

# Benefits of UV Disinfection

As a result of the growing concerns of the resistance of microorganisms to chemical disinfectants, continually evolving antibiotic resistant strains, and new threats of bioterrorism, it is essential that new methods and protocols be explored to help ensure that laboratories can be quickly and effectively disinfected to help protect both workers and the public at large.

While not a "new" disinfecting technology, UV light has rapidly been growing in use in hospital settings as it is a proven disinfectant for surfaces, instruments, and air. With over 140 years of research behind it, UV light has been proven effective at killing bacteria, viruses, mold, and fungi.

Ultraviolet light attacks microorganisms at the DNA and RNA level. Microbes are not able to develop resistance to ultraviolet light, compared to their ability to form resistance to certain types of chemical disinfectants and antibiotics.

Ultraviolet light has been repeatedly proven effective against pathogens, including *C. diff*, MRSA, *E. coli*, Salmonella, Norovirus, and many more. The ability of UV light to kill microorganisms is directly related to the energy dosage produced by the UV source as a function of spectrum, time and distance to the target (see table 1).[12,13]

| | Pathogen | UV Dosage (mJ/cm²)* |
|---|---|---|
| Bacteria | *E. coli* | 6-11 |
| | Staphylococcus aureus | 10.4 |
| | Clostridium tetani (*C. diff*) | 22 |
| | Salmonella typhimurium | 7.1-15.2 (2-log) |
| | Vibrio cholerae | 2.9-6.5 (2-log) |
| | Pseudomonas | 6.6-10.5 |
| | Legionella | 6.4-7.7 |
| | Shigella | 3-8.2 |
| | Campylobacter | 4.6 |
| Viruses | Adenovirus | 165 |
| | Rotavirus | 200 (36 for SA-11) |
| | Norovirus | 30 (based on Calicivirus feline) |
| | Hepatovirus | 16.4-29.6 |
| | Calicivirus | 30 |
| | Influenza | 6.6 (2-log) |
| Protozoa | Cryptosporidium | 22 (EPA Requirement); 9.5 (Parvum study) |
| | Giardia | 22 (EPA Requirement) |

Table 1 — Ultraviolet Exposure Dosages[12,13]
*4-log reduction unless otherwise noted

UV light, particularly UV-C, has been successfully used to disinfect surfaces and to kill fungal, bacterial, and viral pathogens that may be transmitted via the air. UV light has also been shown to have great benefits when combined with other cleaning methods for optimal results.

Researchers at Duke University and the UNC Schools of Medicine found an additional 94% reduction in epidemiological-important pathogens when UV was added to the standard use of quaternary compound disinfectants.[14]

Furthermore, UV light has the potential to help against potential bioterrorism agents, such as anthrax, smallpox, drug-resistant tuberculosis, Ebola, and more.[15]

# Conclusion

Ultraviolet light has an extensive history of effectively killing microbes in the air and on surfaces, which has been proven to reduce the infection rates of MRSA, *C. diff*, VRE, coronaviruses and other harmful pathogens.

As a result of the miniaturization of the technology deployment, it is now possible to incorporate UV disinfectant technology in dramatically more settings than ever before, thereby creating cost-effective solutions to fight off harmful germs in all kinds of environments, particularly when used in combination with existing cleaning protocols.

Given the risk that laboratories face in dealing with infectious agents whose origins are often unknown, along with the potential for transmitting illness-causing pathogens to patients or consumers, ultraviolet light should be seriously considered as an addition to standard cleaning protocols in any lab setting for an added layer of protection.

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## ABOUT PURO UV DISINFECTION LIGHTING

Launched in 2019 in Lakewood, Colorado, PURO™ Lighting products, powered by Violet Defense™ technology, have set out to take proven UV light disinfection technology to the next level by making it more powerful, more affordable and most importantly, smaller and easier to utilize. PURO Lighting products can rapidly disinfect any room of any size and at any time using the proprietary miniaturized, pulsed Xenon Light Engine System. Our high intensity broad-spectrum UV disinfection units rapidly kill up to 99.9% of viruses and bacteria and can significantly reduce the growth of fungi such as yeasts and molds. All in remarkably small, yet powerful fixed or mobile units designed for any sized space. For more information, visit www.purolighting.com.

## ABOUT VIOLET DEFENSE

Founded in 2012, Violet Defense is on a journey to find new ways to protect people from harmful germs that have grown resistant to traditional forms of cleaning and disinfecting. Its patented technology is the only known Pulsed Xenon UV solution that can be installed into a room full-time, creating continuous way to address disinfection needs of all types of settings, including healthcare and non-healthcare alike. Designed to bring hospital-grade disinfection to everyday spaces, Violet Defense has cost-effective solutions to kill up to 99.9% of bacteria and viruses, including *E. coli*, Salmonella, MRSA, Norovirus and *C. diff.* For more information, visit www.violetdefense.com.

PURO™
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