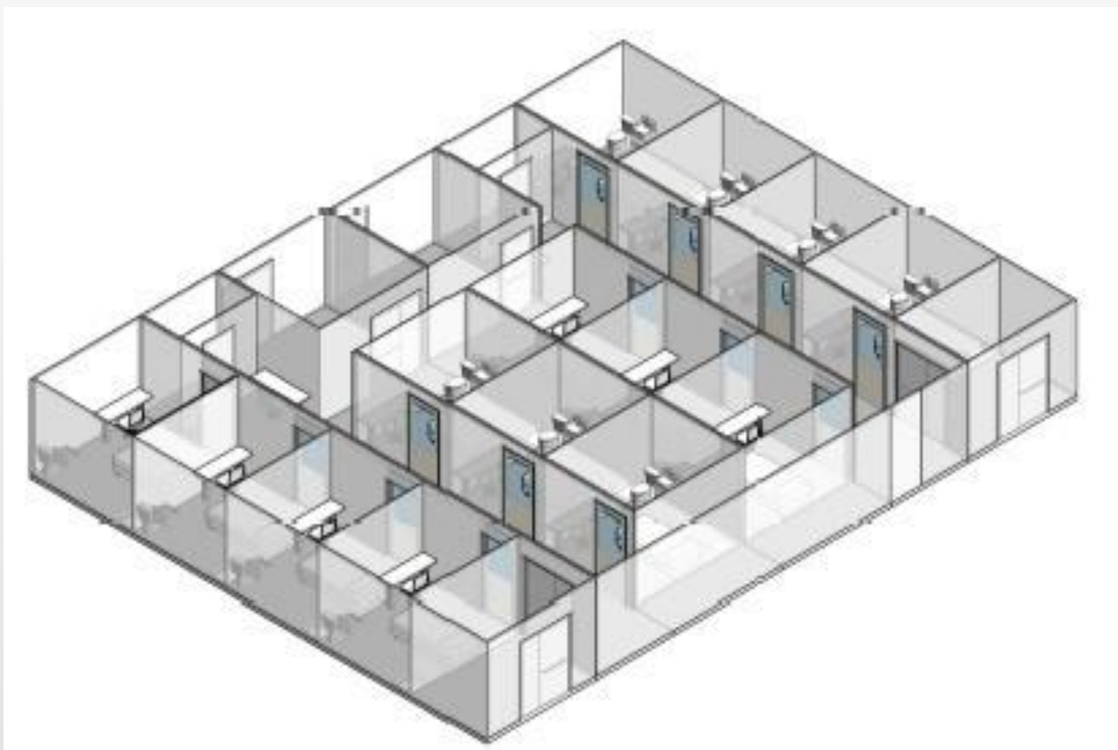
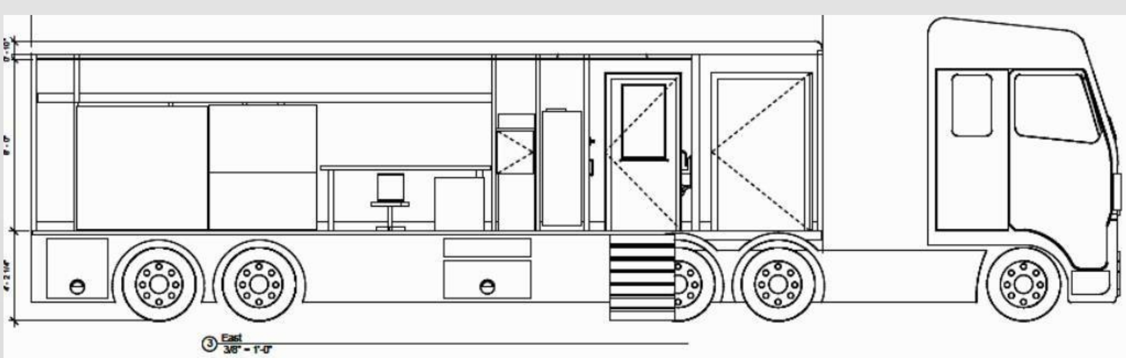
G-CON
MANUFACTURING Inc.

WHITE PAPER 2020

Transmissible Disease Defense Units

The Use of Flexible Mobile Biocontainment and Test Units to Prevent the Spread of Transmissible Diseases





INTRODUCTION

Transmissible diseases are no longer scarce and geographically limited to a location, but are becoming a more frequent occurrence, spreading rapidly due to rising populations and modern travel capability. Additionally, infectious diseases are now thriving in regions previously unsuitable for spread due to unfavorable climate and environmental conditions. Both types of diseases, therefore, have become a real threat for the entire global population.

The list of transmissible diseases is long. Most are either difficult to treat or untreatable. A few examples are listed in the table below:

Viral Transmissible Agents	Microbial Transmissible Organisms
* Flu (H7N9, H1N1, H5N1…) * Pneumonia * HIV * SARS/MERS/COVID-19 * Lassa * Ebola * Dengue * Hanta	* Anthrax * Pneumonia * MRSA * Typhoid

These transmissible diseases are no longer localized diseases but can easily be transferred to surrounding regions or globally. For example, the 1918 Spanish Flu was transmitted mainly via troop transports at the end of World War I. Today, such diseases can be transported easily via business travelers or tourists. Hence, the world of new, unfamiliar diseases is not thousands of miles away, but is literally at every doorstep, as the 2020 COVID-19 pandemic has demonstrated.

To prevent the spread of disease outbreaks, detection and containment is the first line of defense. However, events like the 2013/14 Ebola hemorrhagic fever outbreak in West Africa and the 2020 COVID-19 pandemic, have revealed that current containment defenses are insufficient.

Weaknesses are:

* Testing and test result acquisition: samples are taken in drive-through sampling points, which is efficient. However, samples are not tested at the sampling location, which means the results will be delayed and the sampled person may still spread the virus.
* Patient treatment centers: patient treatment centers must be designed to handle the transmissible disease effectively. For example, Ebola patient wards require much stricter containment designs than the COVID-19 treatment areas. In any case, both treatment centers have to be supplied rapidly and efficiently to the locations where such treatment centers are needed. These systems must be mobile and potentially stock-piled and deployed at a moment's notice. The treatment spaces must be flexible to be able to treat a different disease in the same units and the air handling system must be designed to handle any severity of containment.

THE CURRENT STATE

Currently our hospitals are underprepared for any transmissible disease outbreak, as COVID-19 shows. Standard operating procedures (SOPs) are activated, but hospitals have no overflow plans or capacities, nor are they able to handle hemorrhagic patients with the necessary segregation. Hospitals are designed to handle a certain volume of patients and visitors, all being typically noninfectious. As soon as an infectious disease or spreadable organism is involved, hospitals are likely not able to handle it.

Even special hospital wards are not optimal for containment. The 2011 *Klebsiella pneumonia* outbreak at the National Institutes of Health's very own clinical center shows that even the highest levels of traditional containment do not provide a reliable option. Radical measures had to be taken including erecting walls to separate areas, demolishing plumbing and sanitizing rooms with vaporized disinfectants. These radical measures were only successful after a 6-month battle, during which the organism continued to spread.

The radical measures taken by the hospital in that case could have been avoided entirely if an environment that allowed for strict patient segregation and easily cleanable surfaces (floor to ceiling UPVC walls or epoxy coating), (smooth surfaces and no or minimal obstructions on the wall and floor). Furthermore, sanitization with vaporized hydrogen peroxide (VHP) should be employed, so that the entire room can be sanitized at once. The containment area needs to run at negative air pressure to retain any transmissible agent (Biosafety Level 2—2+). Air locks upon entry and exit are also recommended. Since a typical hospital is not outfitted with such special containment rooms, another area (e.g. parking lot) should be used and be segregated, close to the base of doctors and nurses.

LEARNING FROM THE LIVE VIRUS VACCINE INDUSTRY

There are three key elements for controlling serious outbreaks of transmissible diseases: therapeutic countermeasures (i.e. vaccines, antivirals or antibody boosters), infection detection, and transmission control through isolation and containment. For some of the transmissible diseases there are no vaccines. Therefore, only immediate detection, containment and measures to address the patients' health and symptoms are available. In such instances, detection and containment are key.

The live virus vaccine industry provides the best example of containment and protection of personnel. The vaccine industry utilizes strict environmental and area control and segregation. Vaccines are produced in biosafety level classification (BSL) from 1 to 2+. Strict gowning and degowning procedures, air lock designs, pressure cascades and sanitization cycles assure that none of the infectious agents escape the containment area.

These containment options must be sophisticated and robust. These BSL cleanroom structures should be designed with enhanced, autonomous air handling and include redundant air filters and bag in/bag equipment out to avoid contact (Figure 1). Segregation of the air handling and HVAC systems greatly reduce the risk of excursions or secondary contaminations. In addition, these designs utilize a controlled environment that is easily cleaned and decontaminated using various methods, such as vaporized hydrogen peroxide and chlorine dioxide. Full isolation, as described, can be achieved with new autonomous, prefabricated cleanroom structures, which contain their own air handling system in its own mechanical space. These units are widely available for vaccine production purposes but can be modified to achieve patient containment options.

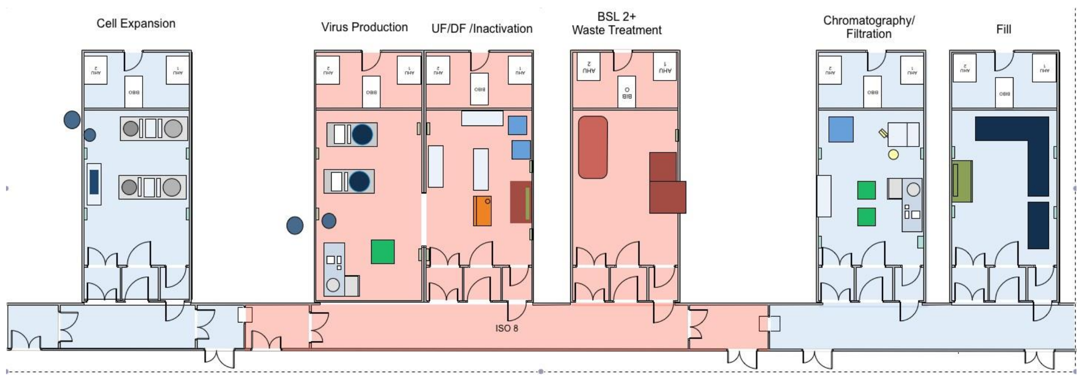


Figure 1: Example of a vaccine processing flow with cleanroom POD containment

Solutions as depicted in Figure 1. are in place for the production of either vaccines or antibody boosters. These systems are well proven within the biodefense spectrum and in routine biopharmaceutical manufacturing. The clear advantages of the flexible cleanroom infrastructures have been embraced by the industry as new manufacturing facilities must be:

⇒ Readily deployable

⇒ Reliable in costing and delivery time

⇒ Robust in its structure, design and quality

⇒ Repurposable and long lasting

⇒ Flexible—able to be used in a variety of applications

⇒ Scalable without interrupting existing processes

⇒ Off-site built to leverage the advantages of the same workforce

⇒ Mobile to move the structure after use or when capacities are required elsewhere

DIFFERENT NEEDS AND VARIOUS SOLUTIONS

Testing and Detection

The first line of defense in any contamination or infection event are sampling, testing and detection. It is crucial to get test results as fast as possible, in order to contain a contamination or infectious disease. Drive-through sampling of potentially infected people has been shown as effective as testers avoid close contact with the affected person.

However, when the samples taken are not immediately processed at the sampling location, but are collected and then driven in bulk to a laboratory to process the samples, logistic problems, possible mix-ups, delays in receiving the results all lead to a major risk of spread. Typically, one would expect a sampled person to move into self-quarantine, but this does not always occur. Therefore, tested persons have the ability to infect other people for 3-5 days if not longer. The results of this testing weaknesses are obvious in the spread of the COVID-19 virus throughout the U.S.

Testing must be as fast as the sampling is. This can only be done within a mobile controlled environment.

To meet this need, G-CON has designed two mobile test lab (MTL POD) trailers, which can be outfitted with any test equipment, including PCR and other rapid testing methods.. The MTL PODs are 37' (Figure 2) and 53' (Figure 3) in length. The units can be transferred to any sample point via truck and when not needed any longer, cleaned and sanitized (alcohol, detergent, VHP routine) and brought to a central storage or used for other microbial testing overflow capacity needs. The mobile test lab units have a typical airlock to transfer personnel and material into the controlled space. The patient samples are then transferred into the test space via a transfer port, as is typically used in the biopharmaceutical industry. The MTL POD is equipped with air conditioning, can run the test space at negative pressure, has a generator on board for electrical power and includes water/waste water tanks. All units have smooth cleanroom surfaces for ease of cleaning and sanitization. Lab benches and storage are included in the test space. Gowning and personnel supplies are stored in the airlock. Configurations of the MTL POD are possible, but standard delivery times may extend with any customization request.

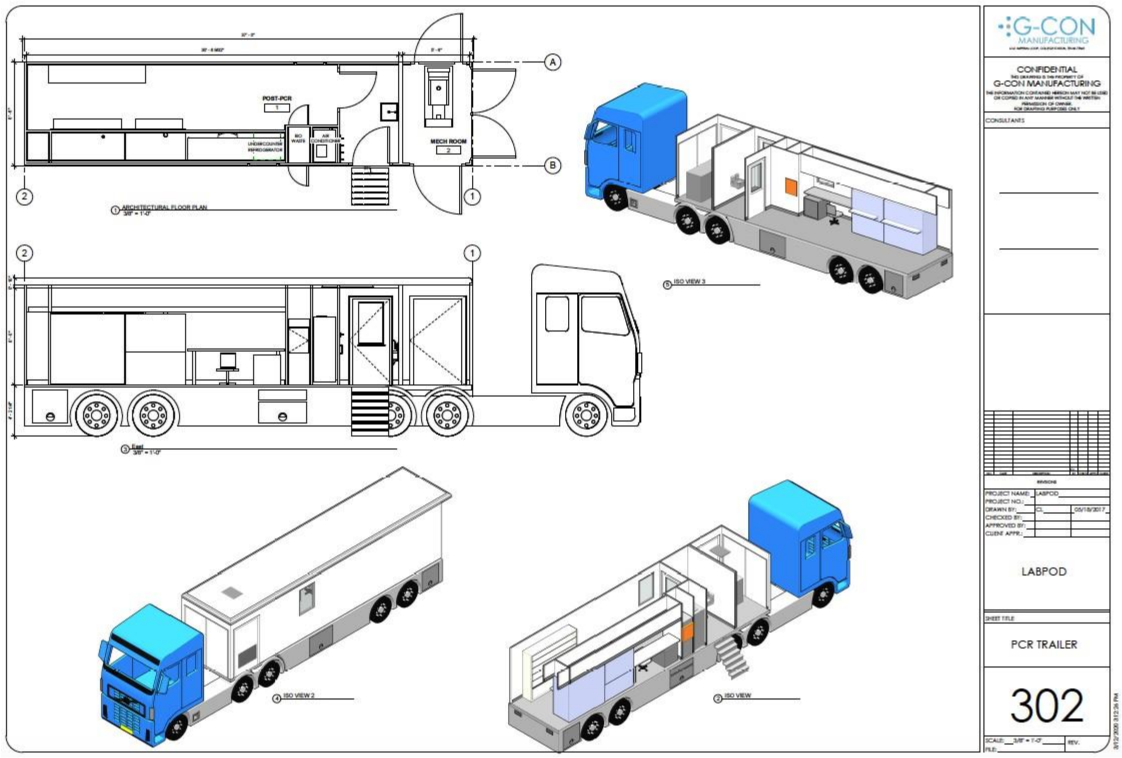


Figure 2: MTL POD 37' version

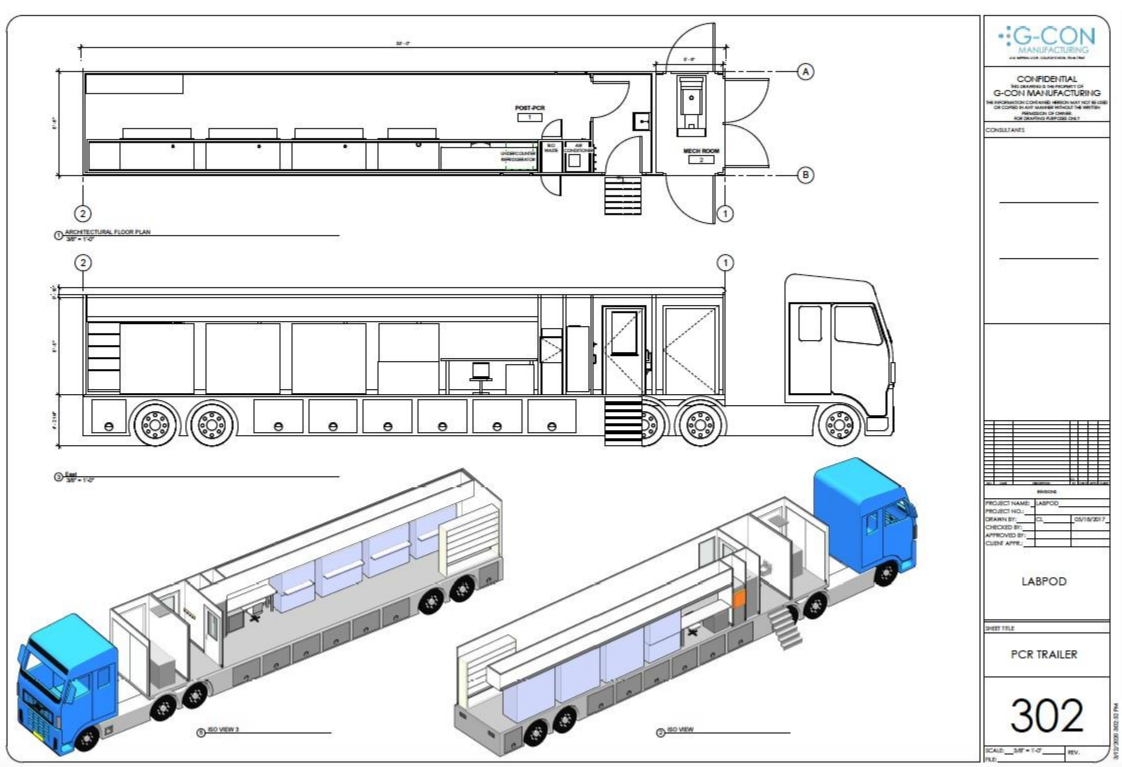


Figure 3: MTL POD 53' version

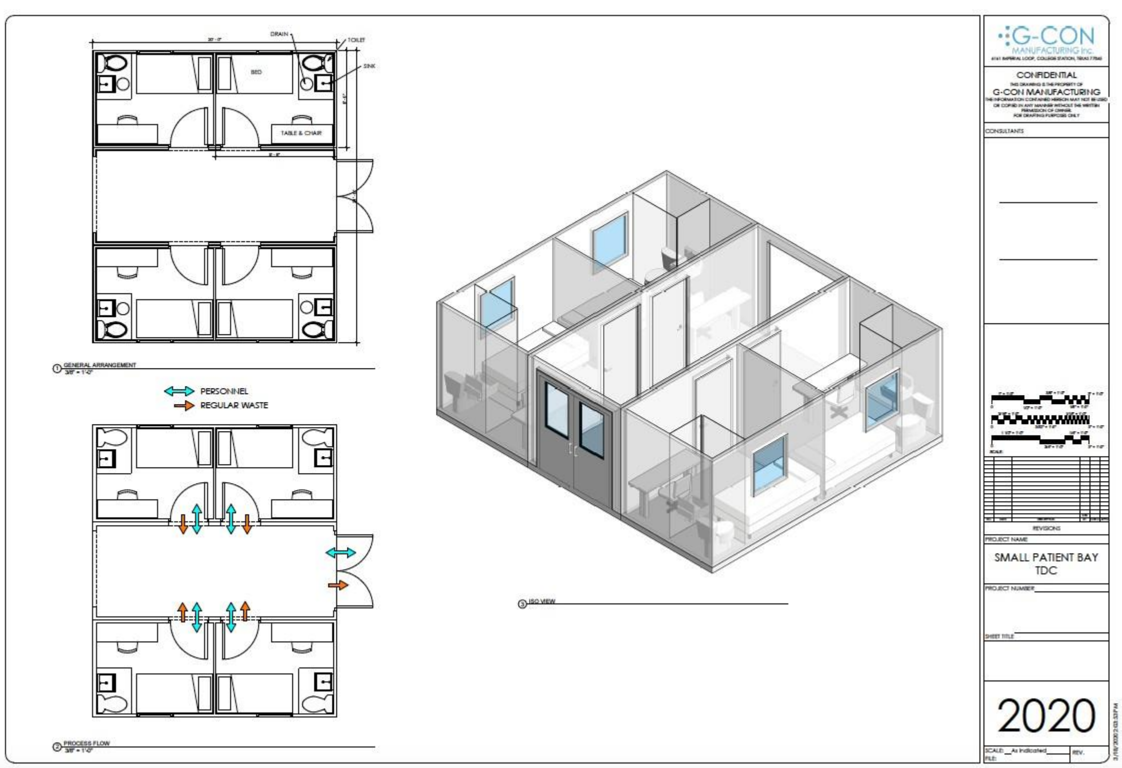
Patient Containment

The second line of defense is patient containment. The grade of containment depends upon the contaminants or infectious agent. For example, an Ebola patient would be placed in a very different containment area than a COVID-19 patient. An Ebola patient must be placed in an environment where the outside environment is protected from the patient and the viral agent. That should also be the case with COVID-19, however the viral agent does not have the same mortality rate, and has a different path of infectivity. The number of patients with COVID-19 is higher and therefore the patient containment system will be different than in patients with hemorrhagic fever.

In any case, such rooms are typically not found in hospitals, but typical patient rooms are either rapidly converted to isolation or containment wards. So far, we have not seen a major success in using this approach. Therefore, rapidly deployable, mobile patient containment units may be the better option. G-CON and Asgard have developed different patient treatment center options, with a high degree of containment or isolation wards where the healthcare workers are gowned sufficiently to handle the patient within a more open ward.

Figure 4 and 5 show containment units (TDC PODs), which can run as BSL 2-2+ environments and would hold patients with highly infectious diseases.

Figure 4: Small transmissible disease containment unit with sink and toilet (optional without)



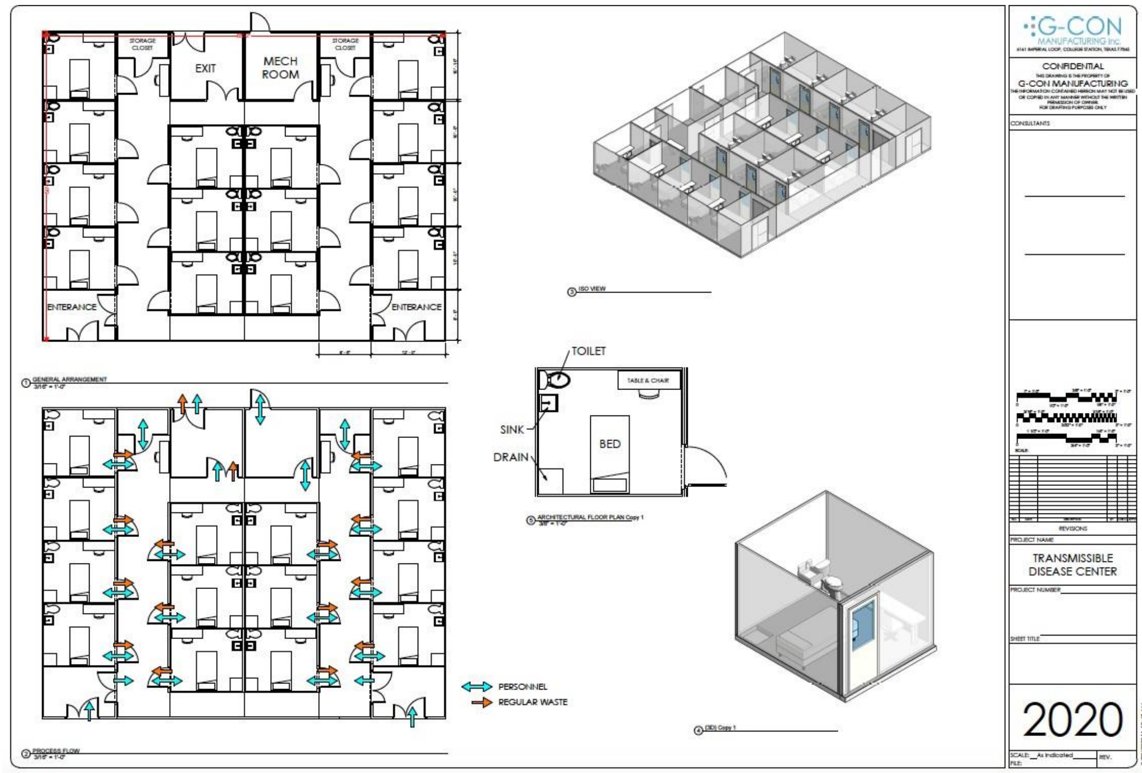


Figure 5: Large transmissible disease containment unit with sink and toilet (optional without)

These two TDC POD systems are off-site prefabricated, shipped to the required location by truck and interconnected. The small TDC POD unit consists of 3 x 8’ x 20’ sub- PODs and the large TDC POD unit consists of 2 x 8.5’ x 50’ and 4 x 12’ x 50’ units.

The units can be either positioned outside or in a shell building like a warehouse. The TDC PODs can be outfitted with fully functional BSL 2-2+ air handling systems, with redundantly filtered return air to protect the environment around the patient units. All units have smooth, cleanroom interior finishes and laminate floor for the ease of cleaning and sanitization. As the patients within these units are typically highly contagious and displacing fluids, the rooms can be hosed down and the fluids collected in kill tanks to neutralize the agent.

Once the units are not required any longer, they can be cleaned, sanitized, dissembled and shipped for storage or other purposes.

Patient Overflow and Isolation

As mentioned, the other option for patient treatments are isolation units. These are required to bring patient into a hospital-controlled environment to supply the appropriate care to the patient. Since hospitals can quickly run out of space in a pandemic, readily deployable, mobile isolation wards to handle overflow situations are required.

Figure 6 depicts a 20 bed isolation ward, which can be expanded as needed. This unit is assembled using multiple building blocks, interconnected at the point of need. This system has been designed as needed overflow unit with storage and typical curtain drawn treatment bays. The unit can be designed as a BSL 2 unit with fixed walls to isolate individual patients.

The entire unit, as with the TDC PODs, are off-site prefabricated and shipped via truck. At the point of care, the individual blocks are assembled to the 20-bed isolation unit. If more beds are needed an additional block of 2 beds can be added in a continuous fashion.

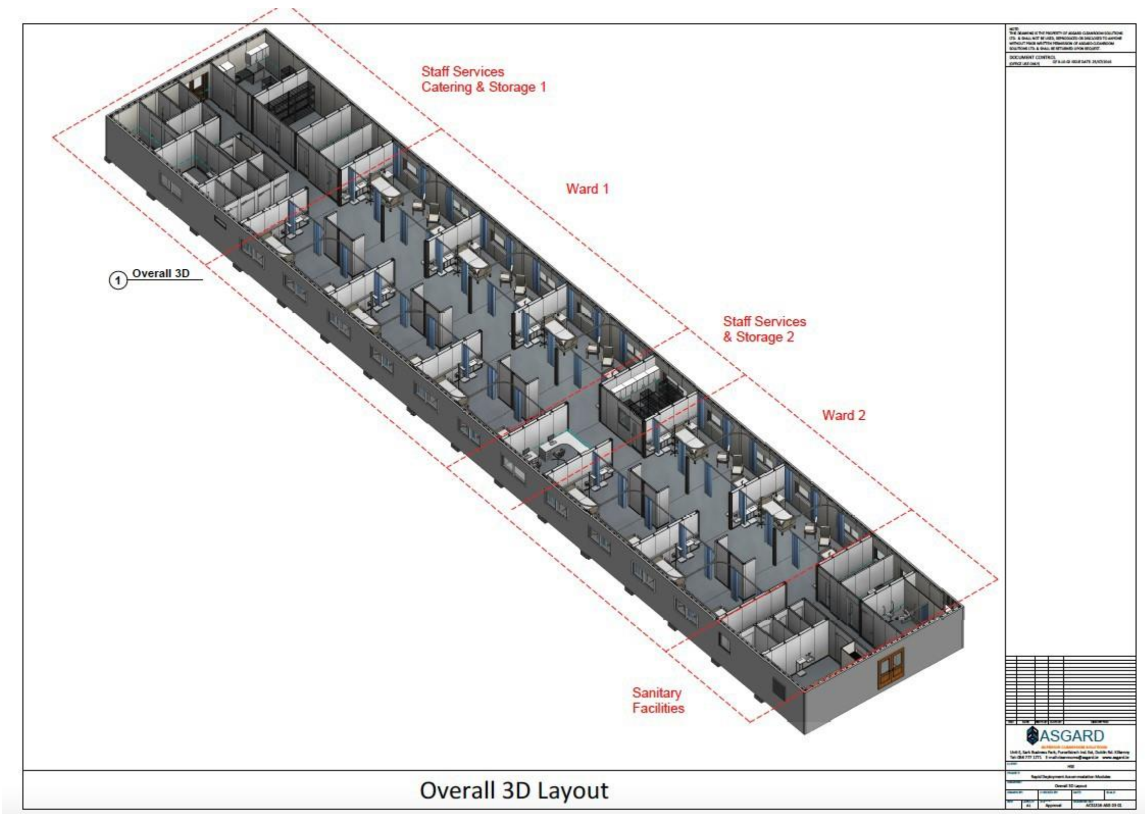


Figure 6: 20 bed isolation unit

ADVANTAGES TO USING FLEXIBLE MOBILE TEST AND CONTAINMENT UNITS

The need in case of an infectious disease outbreak or crisis is speed and flexibility. Test labs and/or patient isolation units require to be deployable immediately or at least in a fast timeframe. Immediate deployment can only happen when such units are stored within a central location and deployed for the event. This also means that these units must be mobile. This white paper shows examples of such mobile, flexible and fast deployable test lab and patient care units.

Advantages of flexible, mobile containment facilities that are deployable for use for testing, biosafety and containment purposes include:

- ⇒ Fabrication and delivery in 12—15 weeks (faster with repeats)
- ⇒ Close monitoring and separation of patients, either in BSL 2-2+ environment or isolation wards
- ⇒ Easy scalability of the containment options without interruptions of existing systems
- ⇒ Biosafety level cleanrooms can be decontaminated and properly sanitized for repeated uses and redeployment (including the use of vaporized hydrogen peroxide)
- ⇒ Easily deployable due to a robust yet light aluminum structure
- ⇒ Optimal containment flexibility by appropriate air handling designs and air locks, depending on the needs
- ⇒ Mobile test labs can be deployed to any sampling point to gain fast test results and improve containment
- ⇒ Flexible and configurable designs to meet variable space needs

CONCLUSION

The first line of defense against transmissible diseases is testing and containment. However, the COVID-19 scenario has shown that drive-through sampling station works well, but the testing lagged sometimes taking days to receive the results. With the delay of the results, containment of positive tested patients was delayed and additional spread likely occurred. Ideally, the testing should take place at the same location as patient sampling, which can be done with mobile test lab units. These units have the right environment and utilities to be used wherever required.

In addition, patient containment options experienced may not be sufficient. Different infectious diseases require different types of segregation robustness. Some containment require a strict BSL 2-2+ environment with the need to clean and sanitize the entire area. Other may be isolation wards without the need for a negative pressure environment, but the appropriate air conditioning systems to create patient and healthcare staff comfort.

Durable aluminum-based containment POD facilities, with optimal surface finishes for cleaning and sanitization represent the paradigm shift for containment. Depending on the severity, these negative pressure systems or isolation units can be constructed in weeks and are mobile once onsite. Redundant air filtration systems assure that the disease agents remain retained. The cleaning and repurposing of autonomous cleanroom spaces make them an ideal containment option to enforce the measures required to control the spread of transmissible diseases. Ultimately, flexible containment systems, such as G-CON's TDC PODs are the optimal choice of containment or as trailer base system for the use as test lab.

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