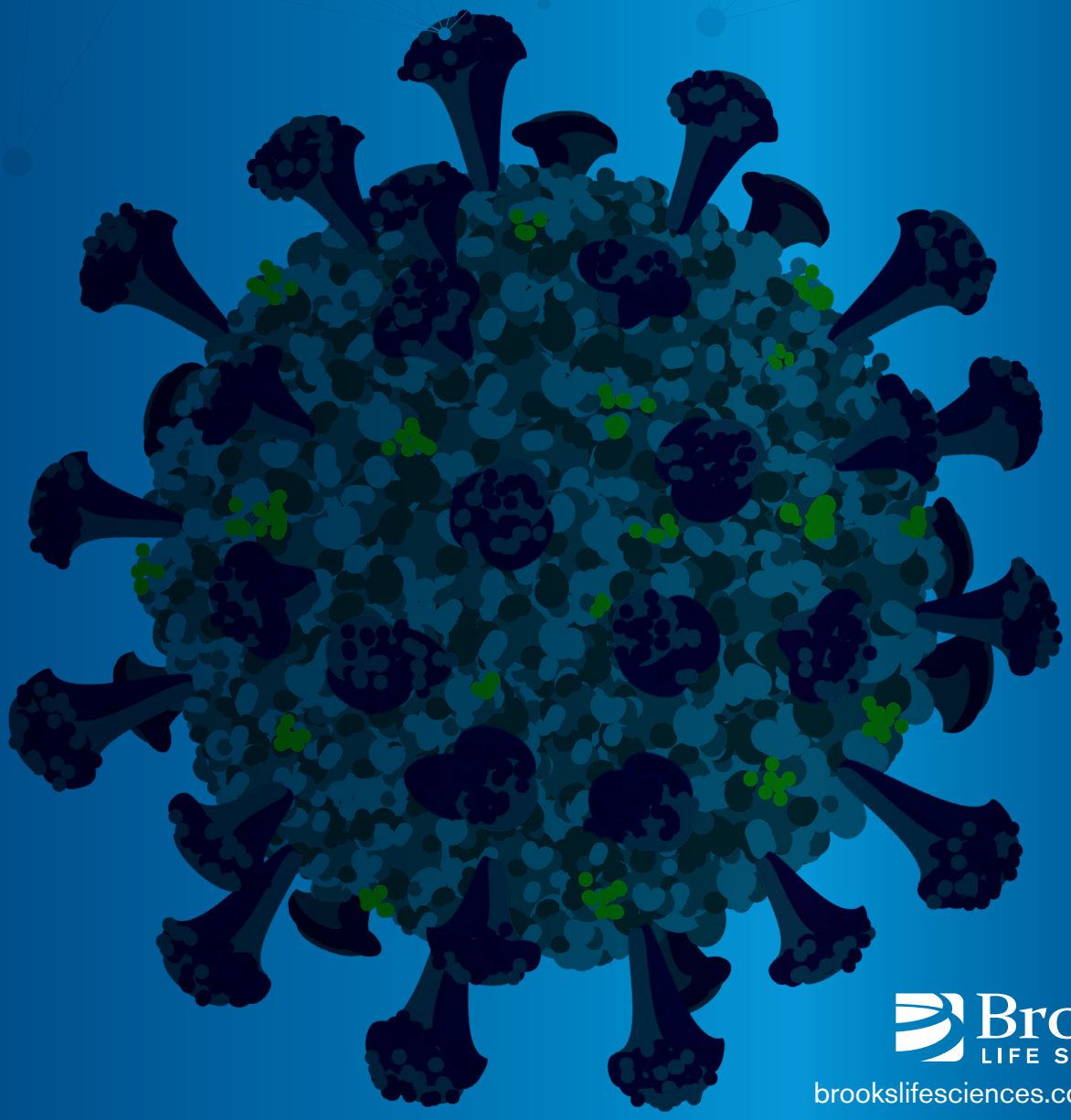
White Paper

COVID VACCINE DISCOVERY AND COLD CHAIN DISTRIBUTION REQUIREMENT:

PROCESS CONTROL



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INTRODUCTION

In the wave of COVID research and distribution, can the current cold chain infrastructure support what is coming? In a word: Yes. But only if scalable, consistent, repeatable, and documented processes are in place and ready to go.

According to FasterCures, a center of the Milken Institute[1], the COVID-19 Treatment and Vaccine Tracker cites 315 treatments and 202 vaccines currently in development. Industry's leading programs are being retooled based on the changes that COVID -19 brings to the industry. New focus areas include topics like supply chain strengthening, growth bioprocessing, regional scalability, staffing concerns and increased automation[2].

Unwavering processes are vital to the scientific community. But when it comes to vaccine development for COVID-19 amid the delicate framework of the world right now, having these processes in place means vaccines can get to market faster. This includes having the cold chain distribution infrastructure to help supercharge insight and collaboration, enabling scientists to have more time for discovery…including a COVID-19 vaccine.

This is where automated sample storage must be implemented. Process automation software should mimic human actions by interpreting and generating responses to perform time-consuming, repeatable tasks, including documentation, that can burden employees.

AUTOMATED SAMPLE STORAGE

Manual sample storage is not scalable, consistent or repeatable. In fact, before COVID-19, studies estimate that unreproducible research costs scientists in the US some $28 billion a year[3]. In the wake of the coronavirus, researchers are proceeding with special care, knowing they can't make mistakes that impact discovery. Specifically speaking, automated sample storage offers process control, data management, risk mitigation and efficiencies.

Unlike manual mechanical freezers, some of the new LN2 based automated storage provides a consistent temperature – even during sample access – with zero temperature recovery time and fully documented inventory. Process control aspects of automated storage include engineered design to limit ambient exposures of non-targeted samples, enable efficient inventory interactions, and provide data connectivity. Automated storage supports accurate inventory data access to provide extensive visibility and helps maintain SOP compliance. This accuracy and inventory visibility is necessary as high value advanced therapies scale. LN2 based automated storage systems like the BioStore™ IIIv, can hold samples longer in emergencies than mechanical freezers by a factor of 16x (96 hours versus 6 hours) while using up to 98 percent less energy than a mechanical freezer. Additionally, automation efficiencies can deliver samples in seconds versus minutes.

WHY AUTOMATED STORAGE IS IMPORTANT TO COVID-19 RESEARCH

Samples sourced from automated storage do not go through the potential shock of thermal cycling that those in a manual freezer would. During routine access from manual storage, which is part of the normal life cycle of the product, thousands of adjacent samples are exposed to ambient temperature for various, unmonitored durations. This exposure can create a wide swing in temperature between the freezer and the ambient environment. Temperature cycling is believed to decrease cell viability as it induces thermal cycling stresses on the cells[4].

Repeated interactions with freezer contents can take a toll. Wearing PPE and working diligently in cold conditions for long periods of time is not a job for everyone. From the perspective of environmental health and safety, automated storage implements practical aspects for protection and safety at work and the design directly relates to user safety. Easy sample access that minimizes the risk of repetitive or strain injuries is paramount.

AN UNINTERRUPTED COLD CHAIN

Compromising sample quality when adding or removing materials from storage is a real-world problem. The ability to provide visibility and availability of samples with an auditable chain of custody and a proven cold-chain lifecycle can significantly increase the value of irreplaceable samples. An unbroken cold chain and recorded storage temperature, along with associated equipment and logistics, keeps samples at the desired low-temperature range to support the highest quality and goals for their intended use. Automated systems give COVID-19 labs the means to maximize sample integrity, manage collections more efficiently – and improve turnaround times when sourcing materials from the freezers.

Figure 1. Brooks BioStore™ IIIv

ENHANCED CONTROLS AND DOCUMENTATION

Automated storage like the BioStore™ III comes with various monitoring systems, much like new cars come with computer modules that tell drivers what needs to be addressed. Temperature alarms are included on the system with full validation and qualification capabilities. The onboard, proprietary software controller can serve as the local LIMS or be integrated with a larger enterprise LIMS solution[5].

CONCLUSION

Automated storage users are more efficient and accurate in documenting all inventory interactions.

REFERENCES

1 *https://covid-19tracker.milkeninstitute.org/*

2 *https://www.bioprocessonline.com/doc/covid-s-impact-on-bioprocessing-insights-from-industry-leaders-0001*

3 *https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165*

4 *https://www.brookslifesciences.com/resources/8-8the-effects-common-transient-warming-events-post-thaw-recovery-and-viability*

5 *https://en.wikipedia.org/wiki/Laboratory_information_management_system*

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