

# Longhorn Vaccines

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## Scaling up inactivated transport media for diagnostic samples for SARS-CoV-2 testing crisis

Longhorn Vaccines and Diagnostics LLC, a family-owned US company that aims to improve global health through innovative infectious disease testing and vaccination, massively scaled up as the FDA requested its help at the start of the COVID-19 pandemic.

When it appeared the world might be heading for a pandemic in early 2020, the US Food and Drug Administration (FDA) approached Longhorn Vaccines for assistance with collecting and transporting millions of SARS-CoV-2 samples for laboratory testing.

Two years earlier, the FDA had created an entirely new category for Longhorn's inactivating collection and transport media, PrimeStore MTM. Recognized as a major breakthrough in safe transport of disease samples for laboratory testing, it became the original device in a new FDA category: nucleic acid storage and transportation device.

PrimeStore MTM contains a patented, proprietary chemical mix in sample tubes that safely deactivates pathogens at the point of collection, keeping only the nucleic acid portion of the sample that is used for molecular testing. It enables ambient temperature transport with no need for special containment facilities to process the high-quality, highly sensitive samples (Fig. 1).

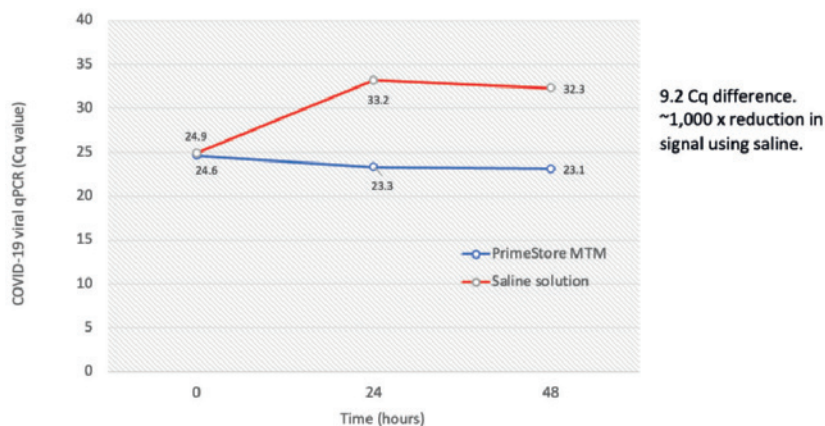
"Previously, the standard transport was viral transport media," said Jeff Fischer, Longhorn's President. "That kept the sample entirely intact, required cold chain transport and put people at risk from pathogenic organisms throughout the logistics chain. Once in the laboratory you needed high-level containment facilities to handle it, but, in some cases, especially in the developing world, people took the risk and just handled it outside of containment."

### Two million tubes per week

After the FDA's approach, Longhorn's 11 personnel massively scaled up from 30,000 sample tubes per month to 2 million tubes per week. Batches of PrimeStore chemicals were increased from 30 liters to 800 liters, the US Department of Health and Human Services stepped in to help find new suppliers for collection tubes, and the company's two fill-finish partners were increased to 15 sites around the United States.

Longhorn also worked closely with major diagnostic firms, as PrimeStore MTM and the newer PrimeStore ATM are compatible with their platforms, including Thermo Fisher, Roche and Avid; with point-of-care technologies such as Cepheid GeneXpert and Roche; as well as the syndromic platforms of BioFire and GenMark.

"This was important, because these testing centers realized they can use existing equipment with our product," Fischer said. Longhorn delivered sample collection kits worldwide and donated 1



**Fig. 1 | PrimeStore MTM.** This transport media provides greater sensitivity in qPCR testing compared with other sample collection solutions.

million PrimeStore MTM tubes to the International Organization for Migration.

PrimeStore ATM, which was launched early in 2021, differs from PrimeStore MTM in that it does not destroy proteins or enzymes. "This allows it to be used in many more testing situations including rapid antigen testing. It also allows us to remove a step in the molecular testing process where the sample is extracted from the solution. It speeds up testing and reduces some of the key components required, so really cuts both the time and cost," Fischer said.

Longhorn's scientific expertise originated with Fischer's father, Gerald Fischer, a pediatric infectious disease specialist for the US Army for 23 years. Jeff Fischer, a former member of the Marine Corps, shared his father's interest in diseases that impact the military and the two launched Longhorn in 2006. Luke Daum, the primary inventor of PrimeStore, joined the company in 2006.

### PrimeStore MTM used for tuberculosis testing

As many diseases originate in the developing world, the company began working in South Africa and Asian regions. PrimeStore MTM has already been used for diagnosing tuberculosis, can be applied to diseases including HIV, influenza and cancer screening, and can be used to transport samples of blood and urine as well as swabs.

COVID-19 has raised the company's profile globally, and there is a better understanding of the benefit of sample quality and safe transport even in very hot climates.

"There's really such a great need and such a great opportunity to help. We are a science-first company and have always focused on peer-reviewed quality science to sell the product. We have put our own money into developing this company and we've never put profit first," Fischer said.

"That's allowed us to focus on products for the developing world that other investors mightn't have a lot of focus on. We've found those diseases come into the developed world, and one of the lessons we've learned from this pandemic is that you can't shut down borders and stop disease. Infectious disease testing, screening and surveillance is something that's going to be crucial—the next SARS-CoV-2 is probably already out there. We need to be identifying disease earlier, treating it earlier and giving government and health experts the ability to move faster so we don't have the health and economic impact we've seen from this pandemic," Fischer explained.

Longhorn has continued its work on a universal influenza vaccine throughout the COVID-19 pandemic and is now aiming for a universal vaccine for both influenza and COVID-19. It is keen to form partnerships with companies that want to improve the speed, accuracy and sample quality for disease testing around the world.

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