

# Behind the Scenes with **Scripps Laboratories**... The Future of Diagnostics

*Many behind-the-scenes complexities affect the flow of crucial inputs for the diagnostic tests that our healthcare systems depend on*

**P**atients rely on diagnostic tests to monitor their health efficiently and effectively. There is a lot of background work that takes place to reliably produce the components of these indispensable products. GEN recently spoke with Shana Khoury, President of Scripps Laboratories, to learn more about the in vitro Diagnostic Industry (IVD) and the challenges that suppliers face.

**GEN: What are the major areas of focus for your business/laboratory?**

**Khoury:** We manufacture antigens and antibodies as well as buffers and reagents for the IVD market. Diagnostics are the first line of defense in healthcare to help direct treatment. Patients need to have a diagnosis, such as from a blood test, before they can be treated. Our products are key components in the test kits used at centralized testing facilities, hospitals, medical offices, clinics, and other laboratory settings that specialize in diagnostic testing. Although we do not manufacture infectious disease-specific products, during the height of the COVID pandemic, we ramped up production to meet the increased demand for our reagents that are used in some of the most widely distributed COVID home tests. Aside from infectious disease testing, developing reagents for point-of-care devices and the home test market for pregnancy, fertility, and ovulation monitoring are big areas of focus for us.

**GEN: What are the main challenges affecting your industry?**

**Khoury:** Our major challenges are the scarcity of resources and raw materials. Human tissues that are donated to science have diminished in quantity and quality over the last several years. Glands and organs have never been abundant; supply has always fluctuated. Over the last few decades, we made it a priority to stockpile excess supply when available. The recent COVID pandemic brought our supply chains to a screeching halt. It is still incredibly difficult to get these raw materials, regardless of the energy and resources spent trying to obtain them. Our stockpiles allowed us to continue manufacturing at maximum capacity throughout the pandemic. We began developing a mirror recombinant catalog to mitigate the impact of future tissue scarcity and to continue to supply our customers with the products they need to meet their manufacturing schedules.

Additional challenges have also presented themselves which have required us to get creative and adapt with the changing times. As a result, we find ourselves utilizing our domestic resources more and sourcing locally when possible.

**GEN: What is Scripps doing to combat the challenges?**

**Khoury:** The supply of native tissues is not coming back. We foresaw this scarcity and have been replacing our native catalog with recombinants that are reliable, available, and cost-efficient. As technology has advanced, we have been able to shift our focus and produce recombinants that are comparable to their native counterparts. We are proud of our results. Maintaining a consistent, reliable supply of these products is absolutely critical to our IVD customers. It is imperative for us to always meet our manufacturing deadlines, so our customers' schedules stay on track.

**GEN: What would you say to customers who are reluctant to switch from native to recombinants?**

**Khoury:** There is no other option. There is no foreseeable solution to the diminishing supply and quality issues we have been seeing over the last few decades. It is a good time to start validating recombinants and replace native-sourced proteins wherever possible. Our recombinants are different from those produced a decade ago; they perform better in IVD assays. We never release a recombinant product until we get the same, comparable results as with our native proteins. It has taken time, but customers are becoming more receptive. They realize that the short-term inconvenience of validating a recombinant gives them long-term guaranteed supply, stability, and security.

**GEN: Discuss the importance of a quality system and its role in your business/industry?**

**Khoury:** Our quality management system holds us accountable and evolves with our needs. It also helps us continually improve. It encompasses every function in our business, including manufacturing processes, training, and communications. We are ISO certified and we welcome customers to visit us to see how seriously we take quality. Our quality system ensures that we repeatedly produce products the same way and with the same performance, so we meet all expectations. If we need to make a modification, for example, due to a discontinued reagent, we inform our customers far in advance. Then we do everything possible to ensure the products we produce perform comparably or better than their predecessors.



Visit our website to see how you can benefit from Scripps Laboratories' world-class recombinants.  
[scripslabs.com](https://scripslabs.com)

