Think differently about your molecular diagnostics supply chain


By Tom Evans, Ph.D. and Salvatore V. Russello, Ph.D., New England Biolabs, Inc.

New England Biolabs® (NEB®) partners with customers globally to address the challenges faced by innovators developing the molecular diagnostics (MDx) technologies required to address public health and pandemic preparedness.

The current COVID-19 pandemic has impacted nearly every aspect of daily life. It has elevated many of the challenges faced by clinical labs, and new and innovative solutions are required to address them. One strategy to help public health professionals understand and control the spread of SARS-CoV-2 is the widespread testing of millions of people around the world. Conventional RT-qPCR based tests performed in large, centralized testing facilities have been the backbone of testing to date. Despite the rapid development of these SARS-CoV-2 assays, dozens of new modalities are being introduced to help close the gap between the number of cumulative tests that can be performed daily and the desired testing capacity required to control and track the spread of the virus.

Numerous companies, diagnostic testing facilities, and academic institutes have introduced SARS-CoV-2 assays under the FDA's Emergency Use Authorization (EUAs). Based upon recent FDA guidance, the priority of new EUAs reviewed by FDA will be on tests that increase testing accessibility or significantly increase capacity. Additionally, new SARS-CoV-2 assays can be introduced by Clinical Laboratory Improvement Amendments (CLIA) laboratories without going through the EUA process. Still, such rapid progress has not been without challenges – it has exposed weaknesses in diagnostics supply chains and has belied the need for innovation and thinking differently about how diagnostics should be developed, manufactured, and deployed.

Many scientists know NEB as a trusted reagent provider to the life science community. What many do not know is that we also offer a portfolio of products that serve as critical components for a wide array of diagnostics products and services. Extensive molecular biology and enzymology experience provide NEB with the unique ability to help customers solve the challenges inherent in technology development and ultimately in scale-up and commercialization.

Leveraging NEB's research program to influence product development for SARS-CoV-2 testing

NEB's founder, Dr. Donald Comb, prioritized basic research ever since NEB was founded in the early 1970s, and this has influenced the product development direction of the company. Our research interests include finding new enzyme activities, engineering enzymes specifically for biotechnology applications, and understanding how enzymes behave. This level of expertise and knowledge is then harnessed by our development and production teams to create robust enzymes and optimized workflows for commercialization. For example, NEB's expertise in amplification has resulted in an extensive portfolio of reagents for RT-qPCR and isothermal amplification, two technologies essential in today's molecular testing landscape. In fact, many of NEB's products have been already cited in numerous publications and EUA protocols.

Currently, the gold standard for diagnostics testing is RT-qPCR, and most of today's testing infrastructure is based on this technology. It's highly sensitive and robust, and NEB offers a number of products in this area, as do many other suppliers. However, like any technology, it has strengths and weaknesses. For example, it requires use of expensive equipment (a thermal cycler with fluorescence detection) and, in some cases, has longer turnaround times.

At NEB, our emphasis on long-term research resulted in us evaluating and working with loop-mediated isothermal amplification (LAMP), an alternate approach originally developed at the Eiken Chemical Co., Ltd. Over the last decade we combined a number of breakthroughs to make the technology even more suitable for the molecular diagnostics community. This included novel engineered DNA polymerases, a new reverse transcriptase, the ability to set up reactions at room temperature using "WarmStart®" enzymes, multiplexing, and the ability to perform carryover prevention. We also introduced a version of this technology that enables the visual detection of products amplified by LAMP and RT-LAMP. We have also published extensively in this area (1).

Partnering with you from R&D to production

NEB is a company that scientists know and trust. We pride ourselves on being a resource – not just through our product offerings and production capabilities, but also through the support we provide to diagnostics assay development scientists – from R&D through to scale-up and commercialization. For this reason, NEB is an ideal partner as new testing technologies are moved from the bench into production.

Our support starts early in the R&D process, as customers obtain information about our products and technologies through our catalog, extensive web resources and support staff, and ultimately

obtain material to evaluate. As questions arise about how a product might be used in a given technology, customers can speak directly with scientists who have played a role in developing or producing these products. And in those instances where a customer wishes to optimize performance for a particular detection modality, modify a product, or request a customized packaging format, the OEM & Customized Solutions Team is brought in. We quickly assemble a cross-functional team of researchers, product developers, project managers, and logistics staff to assess and make recommendations as to how best to address our customers' needs.

Identifying the pain points involved in developing diagnostics

Our customers range from some of the largest molecular diagnostics organizations to early stage technology companies. Their challenges differ. In some cases they are looking to build out redundancy in their reagent supply chain, while in others they may need NEB to work collaboratively to further develop and help bring their technology to market.

That said, there are several common challenges that many customers have cited repeatedly over the past several months. These are scale, supply chain resilience, and product quality, performance, and consistency.

Regardless of what technology is ultimately incorporated into a molecular diagnostics product, a consistent and reliable supply chain is essential, especially in today's landscape. Product demand is higher than ever before, and dozens of organizations are pursuing similar approaches with the need for the same reagents and associated consumables. Further, the quality and consistency of reagents can vastly impact the performance of an assay.

Enabling your solution

Unlike other reagent providers of similar size and capacity, NEB has made the decision to enable science and not compete with our diagnostics customers in the markets that they serve. As one of the few privately held molecular biology tools providers, our goal is to establish partnerships that advance our customers' science and business objectives – 100% of our production capacity is earmarked for the customers we serve, and not for the manufacture of our own diagnostics products.

Over the past decade, NEB has made significant investment in its manufacturing scale-up and operations, as well as in its quality systems. Our ISO 13485 facilities in Ipswich, Rowley, and Beverly, Massachusetts, have the capacity to provide reagents to enable many millions of molecular assays, whether they be for RT-qPCR or isothermal amplification.

NEB was founded to serve the scientific community with humility, integrity and transparency – principles which we believe are more important now than ever. We look to our diagnostics customers as the real innovators. These customers engage with NEB scientists to understand what our products do and don't do, to make good decisions quickly about whether or not we are a fit for their technology platform. We also provide clarity about capacity, turn-around-times and, when possible, pass along cost savings to our customers in the event that scale can be achieved to reduce the price of our products.

In summary, we would like the molecular diagnostics community to think differently about NEB and consider us as their partner for future assay development and scale-up needs.

References

1. Anahtar, M.N. et al (2020) Open Forum Infectious Diseases, 2020;, ofaa631.

If you want to learn more about how NEB can support your Molecular Diagnostics needs, visit **www.neb.com/MDx** or **contact your local distributor**.

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NEW ENGLAND BioLabs® GmbH

New England Biolabs GmbH, Brüningstr. 50, Geb. B852, 65926 Frankfurt/Main, Germany

Tel: +49/(0)69/305-23140 Toll Free: (Germany) 0800/246-5227 Toll Free: (Austria) 00800/246-52277 Fax: +49/(0)69/305-23149 e-mail: info.de@neb.com