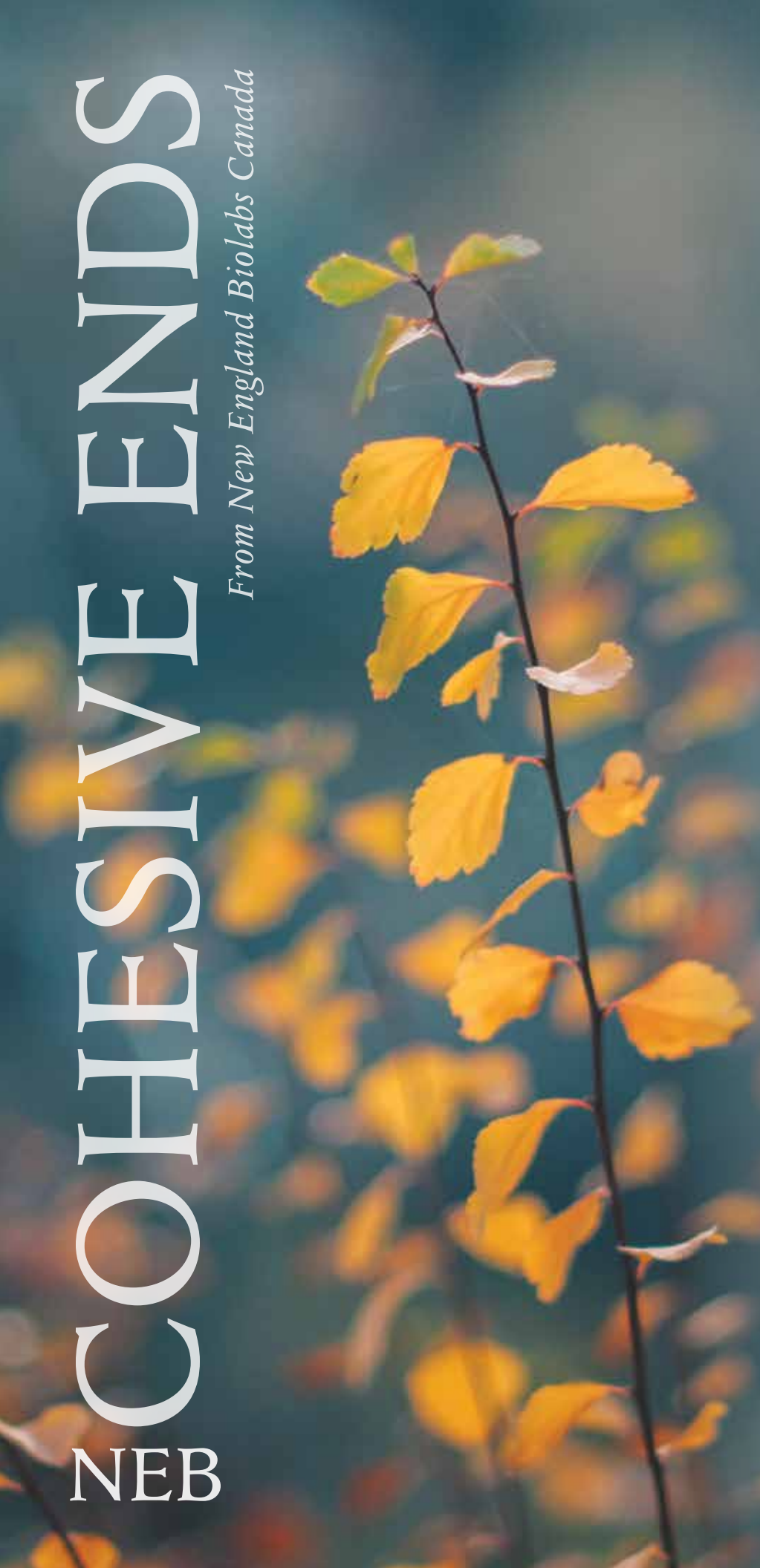
COHESIVE ENDS

From New England Biolabs Canada



Issue III • 2024

IN THIS ISSUE

SCIENCE

INNOVATION

NEW ENGLAND Biolabs® 50 YEARS

BEYOND THE NEB CATALOG

Over 40 years of supporting customers with customized solutions

Since 1974, NEB has proudly supported scientists with high-quality reagents to advance their molecular biology research. We have had the opportunity to support many of our customers as early as graduate school, and have been able to build relationships throughout their successful careers. We have done so with an expanding catalog portfolio that supports both existing and emerging applications and workflows, coupled with outstanding service and technical support.

We recognized long ago that our customers' needs sometimes extend beyond the traditional list of products found in our catalog. For over 40 years, we have employed a collaborative approach to discover, plan, and ultimately deliver custom products that fit these customers' unique requirements. From larger quantities of existing products, to custom packaging and labeling, or even custom formulations and formats, we are here to help.

LARGE FORMATS FOR NEB PRODUCTS

The most frequent request we receive is for larger quantities of our catalog products. Over the years, we have expanded our production capabilities and can easily support these requests. In fact, this capability became even more important during the COVID-19 pandemic, during which we were able to support customers developing diagnostics and vaccines. Large volume requests can be fulfilled in a single vial, bottle or plate for high-throughput applications, or dispensed into pre-determined aliquot sizes to meet your specific need.

CUSTOM FORMULATIONS AND PRODUCT QUALITY

A common question we receive from customers is whether we can supply an alternative formulation of an enzyme or product to better meet their needs. The answer is often yes – in fact, we have extensive experience successfully modifying enzyme or product formulations. Some modifications are relatively easy to make, such as providing an enzyme at a higher concentration. Others, such as removing glycerol, detergents, or other components from a formulation can also be done, but require more time to asses stability and ensure we can provide a robust product with complete confidence. In all instances, our team will work with you to understand your needs and provide honest feedback regarding technical feasibility and timelines to develop and optimize a custom product formulation.

In addition to formulation changes, some customers have alternative quality requirements. While our products undergo extensive quality control testing, these customers require additional testing and/or documentation. In this case, we would transition you from our research products to our GMP-grade* formulations, which are discussed below.

In today's global regulatory landscape, compliance and risk tolerance are central themes for customers who source critical materials from us. For example, the ability to modify formulations to be compliant with local regulations (e.g., EU REACH Regulations) has become increasingly important. We understand the scrutiny you face and will work with you to identify alternate product formulations and/or documentation to reduce, or mitigate risk, when using our products.

As with any product that you purchase from us, the reagents and products that we supply through our Customized Solutions Team are manufactured in compliance with our Quality Management System. Our Quality team utilizes a two-tiered approach to ensure product quality. Tier one is a focus on compliance, specifically our ISO 9001 and ISO 13485 certificates. The second tier incorporates a variety of cutting-edge quality controls which assess a product's physical attributes, performance and purity. We are committed to achieving the highest level of product quality regardless of whether you purchase a product from our catalog or through our Customized Solutions Team.

In all of these situations, our Customized Solutions Team is ready to help, and serves as a bridge to the support and resources you

** "GMP-grade" is a branding term NEB uses to describe products manufactured or finished at NEB's Rowley facility. The Rowley facility was designed to manufacture products under more rigorous infrastructure and process controls to achieve more stringent product specifications and customer requirements. Products manufactured at NEB's Rowley facility are manufactured in compliance with ISO 9001 and ISO 13485 quality management system standards. However, at this time, NEB does not manufacture or sell products known as Active Pharmaceutical Ingredients (APIs), nor does NEB manufacture its products in compliance with all of the Current Good Manufacturing Practice regulations.*

need to ensure your success. We will work with you to understand your formulation and performance requirements, as well as your packaging needs. In doing so, we may put together a cross-functional team that includes our scientific staff, to work collaboratively with you and to help troubleshoot problems that may arise during development. You can be sure that we will work with you to develop a solution that fits your needs both now and in the future.

PRIVATE LABELING AND KITTING

Our Customized Solutions Team also supports customers who are looking to include our reagents as drop-in components in their own kits and solutions. In this situation, we offer private labeling and options to build custom kits, all of which would be included as part of an OEM contract. This conversation begins with a member of our Customized Solutions Team, who will assemble the appropriate cross-functional team to swiftly address your needs. As with all of our services, we will work closely with you and provide the best option that fits your requirements.

EXPANDED CAPABILITIES AND DISTRIBUTION NETWORK

Since NEB was founded 50 years ago, we have consistently invested in our capabilities to meet specific needs of our customers. This includes expansion of our Research and Applications and Product Development teams, as well as our manufacturing capabilities, quality control testing, and global distribution. In 2004, NEB moved its headquarters to Ipswich MA, USA, and built a LEED®-certified, state-of-the-art research and production facility. Since then, NEB has expanded its footprint to several locations nearby its main campus. Approximately 15 minutes away, our production facility in Rowley, MA, is designed to serve the needs of customers in regulated markets and is used for manufacture of GMP-grade products. Also in Rowley, our packaging facility is responsible for kitting and packaging a selection of NEB products. We also have two locations in Beverly, MA which are approximately 20 minutes from our main campus. Our Beverly Organic Synthesis Facility is an ISO compliant laboratory responsible for synthesis and manufacture of oligonucleotides, modified nucleotides, and affinity beads/resins. Our R&D facility, also in Beverly, houses many of our Research and Application & Product Development groups. Most recently, we have completed a state-of-the-art expansion on our headquarters in Ipswich that expands our manufacturing capabilities and quality control labs. All of these facilities are ISO 9001- and 13485-certified and take into account sustainable building design.

All of these updates have been made with the end users in mind – we want to be able to support you both now and in the future, but we want to do this in a sustainable way that is best for our customers and for the environment. For our customized solutions customers, this means our level of support has improved to include expanded fermentation capabilities, improved quality control testing, faster turnaround, and more comprehensive documentation – all in an environment you can feel good about.

We have 10 subsidiaries worldwide, making shipping and warehousing product across the globe seamless. We are expanding our operational capabilities outside of the U.S. with planned 2024 openings of a new Experience Center in Suzhou, China, which has dedicated space for formulating and kitting, a QC laboratory, and local warehousing. Additionally, we have a dedicated lyophilization development and manufacturing facility in Oxford, UK.

LYOPHILIZATION AND AMBIENT SHIPPING

More recently, the market has experienced an increase in demand for ambient-stored, lyophilized enzymes and reagents. We are excited to support these needs with our new, dedicated 30,000 sq. ft. lyophilization development and production facility in Oxford, UK. This site allows us to transition key wet enzyme and reagent formulations to ambient-stable, lyophilized products in multiple formats (beads and cakes). Ambient storage and shipping reduces shipping costs, the need for cold-chain access, and importation difficulties. We have the unique ability to match our innovative enzymology experts with our lyophilization experts, and can work with you to develop an optimized lyophilized product that meets your requirements and performance specifications. Contact our dedicated Customized Solutions Team today to discuss your project and how we can help bridge your project gaps.

For 50 years, we have researched, developed and manufactured innovative enzymes and reagents for the scientific community and has served as a bridge that connects scientific innovations and workflows. Our Customized Solution Team is privileged to support incredible customers like you and our mission is to equip you with products and support that will shorten your path to success. Our global network of OEM Business Development Managers are excited to meet and discuss how our custom products can support your goals.

To learn more about NEB's custom capabilities or contact our Custom Solutions Team visit:

www.neb.com/customized-solutions

Your bridge to successful innovation.

NEB's Customized Solutions Team is here to help, and serves as a bridge to the support and resources you need to ensure your success.

Creating the right partnership is essential when pioneering a new life science product. Every aspect of development – technical expertise, reagent optimization, manufacturing scale, turnaround time, reagent quality, and comprehensive logistical support – is vital for achieving your objectives. And in the regulated markets landscape, these challenges magnify, demanding an even more specialized approach.

Your Bridge to Successful Innovation

- Leverage NEB's 50 years of experience in enzymology and reagent manufacturing
- As an extension of your team, we prioritize a deep understanding of your objectives, work with you on an optimal solution, and help to anticipate your future needs
- Benefit from our ISO 9001- and 13485-certified processes and commitment to quality, as well as our GMP-grade* production facility, and specialized lyophilization facility for the highest quality production standards
- Access unparalleled support from our dedicated account managers, program managers, technical scientists and production teams, all through a single point of contact
- We work closely with you on inventory management and global distribution through our network of NEB-owned subsidiaries, to ensure successful commercialization

NEB's Customized Solutions Team will help you access novel products, meet quality specifications, speed time to market, and streamline your supply chain, allowing you to focus more on what matters most — innovation.

Ready to start the discussion? Learn more at
www.neb.com/customizedsolutions.

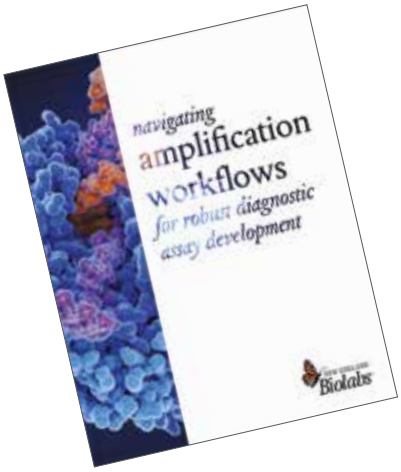
** "GMP-grade" is a branding term NEB uses to describe products manufactured or finished at NEB's Rowley facility. The Rowley facility was designed to manufacture products under more rigorous infrastructure and process controls to achieve more stringent product specifications and customer requirements. Products manufactured at NEB's Rowley facility are manufactured in compliance with ISO 9001 and ISO 13485 quality management system standards. However, at this time, NEB does not manufacture or sell products known as Active Pharmaceutical Ingredients (APIs), nor does NEB manufacture its products in compliance with all of the Current Good Manufacturing Practice regulations.*

Navigating amplification workflows *for robust diagnostic assay development*

Knowledge of amplification techniques and optimization tactics is crucial to driving innovation in molecular diagnostics (MDx). During the COVID-19 pandemic, the number of molecular diagnostic assays incorporating amplification technologies increased significantly to meet public health needs. This expansion was enabled by years of workflow optimization, broader access to enhanced reagents and design tools, and the deployment of common equipment and automation worldwide. Molecular diagnostic workflow improvements led to substantial time savings and critical quality metrics – from the point of sample collection to the result. With diligent planning, the accuracy, sensitivity and specificity of an assay can be effectively established for the successful implementation of any molecular diagnostic.

The pandemic also broadened the scope of amplification methods validated for sensitive and robust molecular diagnostic tests, putting isothermal protocols into use alongside qPCR (the 'gold standard'). Isothermal amplification methods, such as Loop-mediated isothermal Amplification (LAMP) were adopted for their simplicity and speed, which permitted at-home testing. The ability to collect a sample, perform a molecular assay, and read the results at home offered many advantages over traditional testing scenarios. The standard testing paradigm required a visit to a hospital or clinic for sample collection, after which the test itself was performed in a central laboratory. Subsequently, a healthcare provider would contact the patient with the results. This process could take several hours, or even days, before the results were available for clinical decision-making. If instead tests and results could be provided at the point-of-care or even at home, this timeline could be accelerated significantly. These efforts have necessitated a shift to supply reagents as lyophilized or dry versions of the assays. These efforts are leading to an increased demand for lyophilized formats.

Despite these advances, many goals remain the same for MDx assay developers: determining the appropriate amplification method, optimizing assay components, and selecting a reliable supply partner who will provide support from early development all the way through to large-scale manufacturing.



Download our latest ebook, featuring:

- Comparison of PCR and isothermal amplification technologies
- Examination of assay design optimization parameters
- Considerations for assay lyophilization
- Testimonial from Anne Wyllie, Ph.D., *Research Scientist in Epidemiology of Microbial Disease, Yale School of Public Health*

Register here to receive your copy of the eBook

How can NEB support your diagnostics development efforts?

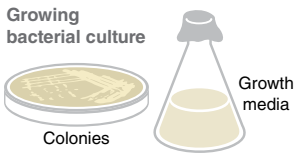
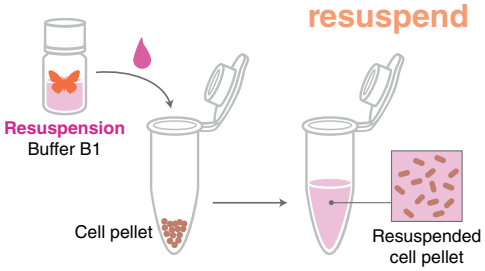
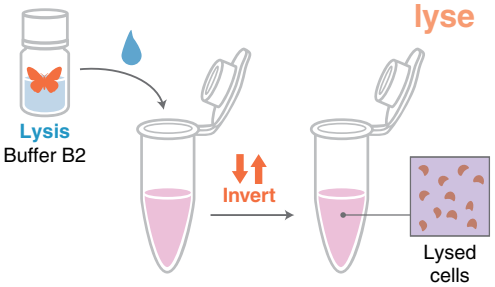
Integrating scientific expertise with a global presence, NEB can support your amplification reagent needs for small-scale research projects through to large scale manufacturing and commercialization. Setting the standard for an effective partner, we provide personalized technical and commercial support throughout a project's entire life cycle. We are committed to your success.

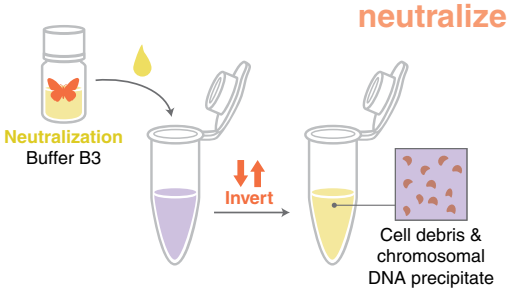
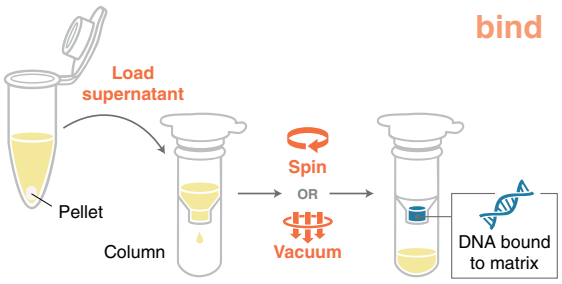
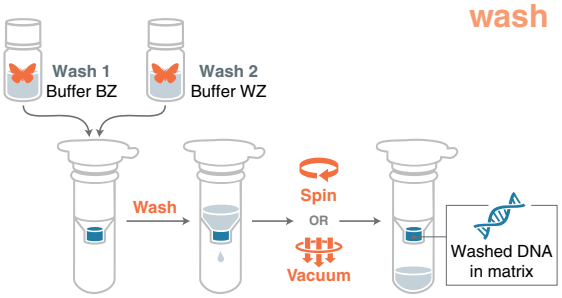
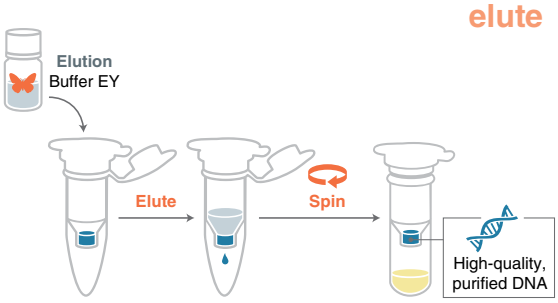
Contact our Customized Solutions Team today to find out how we can support your next MDx development project at **www.neb.com/customized-solutions**

Expert Tips & Tricks for Plasmid DNA Purification Using Miniprep Kits

Purifying DNA plasmids using a miniprep kit may seem like a straightforward task, but what happens when things don't go according to plan? Unexpected issues can arise, from low yields to impure samples. We have asked our scientists what some of the most essential tips and tricks are to help you face any plasmid purification challenges that can occur. By troubleshooting common problems, you can ensure your plasmid purification process is as efficient and reliable as possible. Read on for expert insights and practical advice for mastering DNA plasmid purification with miniprep kits.

Miniprep kits, such as the Monarch® Spin Plasmid Miniprep Kit (NEB #T1110), generally follow a similar set of steps: Sample Preparation (Growing bacterial culture), Resuspend, Lyse, Neutralize, Bind, Wash, and Elute.

STEP	DO ✓	DON'T ✗
sample preparation 	Use fresh media plate and antibiotic for growing colonies. Inoculate from a single colony. Use the correct antibiotic concentration to maintain selection during growth. Harvest during the transition from logarithmic to stationary phase (12–16 hours in LB medium).	Don't select satellite colonies when inoculating the culture; they may not contain the desired plasmid. Avoid sub-culturing ampicillin-maintained cultures to prevent depletion of antibiotics by secreted β-lactamase. Don't grow the culture beyond the recommended time to avoid cell lysis and low DNA yield. Avoid using *E. coli* strains like HB101 and the JM series due to high levels of endogenous endonucleases that degrade plasmid DNA.
resuspend 	For low-copy plasmids, process more cells and scale up buffers accordingly. Fully resuspend the cell pellet before adding Lysis Buffer. When using the Monarch Spin Plasmid Miniprep Kit, add RNase A to Buffer B1 to avoid RNA contamination.	Don't exceed the recommended cell amount (up to 5 ml or 15 OD units) to avoid inefficient lysis and matrix clogging, which lowers DNA yield.
lyse 	Confirm the lysis color change from light pink to dark pink and transparent. Proceed quickly to neutralization after lysis to prevent plasmid denaturation Mix by inversion after lysis to avoid contaminating with host chromosomal DNA.	Limit incubation in the presence of sodium hydroxide (in Monarch Buffer B2) to 2 minutes to prevent irreversible plasmid denaturation. Avoid vigorous mixing or vortexing after lysis and before pelleting cell debris to prevent host DNA shearing and contamination. Contaminating genomic DNA may appear as a high-molecular-weight band on an agarose gel.

STEP	DO	DON'T
neutralize 	If RNase A was added, mix well and incubate as recommended for RNA degradation. For the Monarch Spin Plasmid Miniprep Kit, incubate for 2 minutes. Gently invert the tube to ensure a complete color change to yellow during neutralization. Ensure cell debris is abundant and fully compacted after centrifugation.	
bind 	Transfer only the supernatant to the column, ensuring it is free of cellular debris to avoid clogging. Use the recommended lysate volume for optimal plasmid DNA binding.	Do not overload the column. For the Monarch Spin Plasmid Miniprep kit, load a maximum of 800 µl at a time. If the supernatant is >800 µl, load, spin, discard flow-through, and reload. Ensure sufficient contact time during the binding step to avoid poor DNA recovery.
wash 	Ensure a final wash spin of 1 minute to completely remove the wash buffer. Strains like HB101 and the JM series have high endogenous carbohydrates that interfere with enzymatic DNA manipulations. Include the first wash with Monarch Buffer BZ to reduce plasmid degradation, and keep samples on ice during preparation.	For the Monarch Spin Plasmid Miniprep Kit, don't skip any wash steps in the protocol to help remove any residual RNA, protein and other contaminants
elute 	Use recommended elution volumes and times for plasmids <15 kb. Larger volumes and longer times increase yield but result in a more dilute sample and longer processing. For larger plasmids, incubate the column at room temperature for 5 minutes or heat the elution buffer to 50°C. Add elution buffer to the center of the matrix to ensure even wetting. If eluting in water, use nuclease-free water with pH 7-8.5. Adjust pH if using Milli-Q™ water. For long-term storage, use the supplied DNA elution buffer with 0.1 mM EDTA to inhibit nucleases. Store DNA at -20°C for stability. Consider using Exonuclease V (RecBCD) (NEB #M0345) to remove contaminating genomic DNA.	Avoid smaller elution volumes or shorter incubation times; it may yield concentrated DNA but result in incomplete elution and low yield. Don't store DNA in magnesium-containing solutions to prevent degradation. Prevent the column tip from touching the flow-through when transferring to a new tube. If unsure about ethanol carryover, re-spin the column for 1 minute.

For more information on the Monarch Spin Plasmid Miniprep kit, visit:
www.neb.com/T1110

Migrate to the better choice

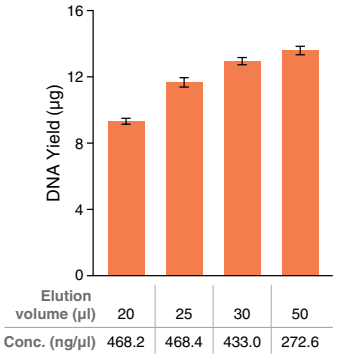
Introducing new versions of some of our most popular Monarch® nucleic acid purification kits. All three kits feature upgraded spin columns, precision-engineered to minimize buffer retention and salt carryover, deliver higher purity and yield, and reduce hands-on time with faster protocols and less spin time. Significantly less plastic is used in the columns and kit compared to leading suppliers.

Monarch Spin Plasmid Miniprep Kit (NEB #T1110)

Advantages:

- Elute in as little as 30 µl for highly concentrated DNA, with yields up to 20 µg
- Easy to follow workflow with colored buffer system to indicate completion of key steps

Monarch Spin Plasmid Miniprep Kit can elute in as low as 30 µl for high yield



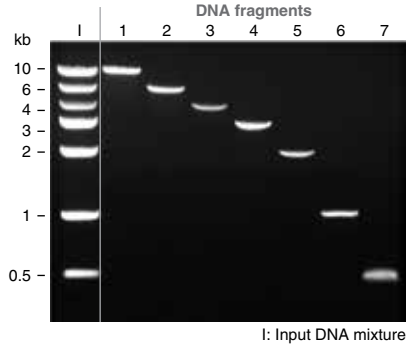
Various elution volumes used in Monarch Spin Plasmid Miniprep Kit can generate high yield, highly concentrated DNA. 2 ml of NEB 10-beta Competent E. coli (NEB #C3019) transformed with pUC19 plasmid (NEB #N3041) was used. Monarch Buffer EY was used to elute the plasmid with the volumes indicated. Concentrations of plasmid were measured using a Trinean DropSense 16.

Monarch Spin DNA Gel Extraction Kit (NEB #T1120)

Advantages:

- Elute in as little as 5 µl for highly concentrated DNA, with yields up to 5 µg
- No need to monitor pH or add isopropanol

Monarch Spin DNA Gel Extraction Kit is effective for a wide range of DNA sizes



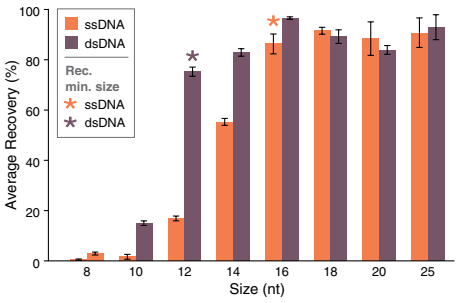
A mixture of 7 DNA fragments (lane I) ranging from 0.5 kb to 10 kb was prepared and resolved on a 1.2% (w/v) TBE agarose gel. Each fragment was manually excised from the agarose gel and processed using the Monarch Spin DNA Gel Extraction Kit. The elution of each fragment was resolved on a new gel with the original mixture for comparison.

Monarch Spin PCR & DNA Cleanup Kit (5 µg) (NEB #T1130)

Advantages:

- Elute in as little as 5 µl for highly concentrated DNA, with yields up to 5 µg
- No need to monitor buffer pH
- Protocol modification for oligo cleanup is provided, allowing purification of ssDNA, oligos and other small DNA fragments

Monarch Spin PCR & DNA Cleanup Kit (5 µg) effectively cleans up oligonucleotide DNA using the oligonucleotide cleanup protocol.

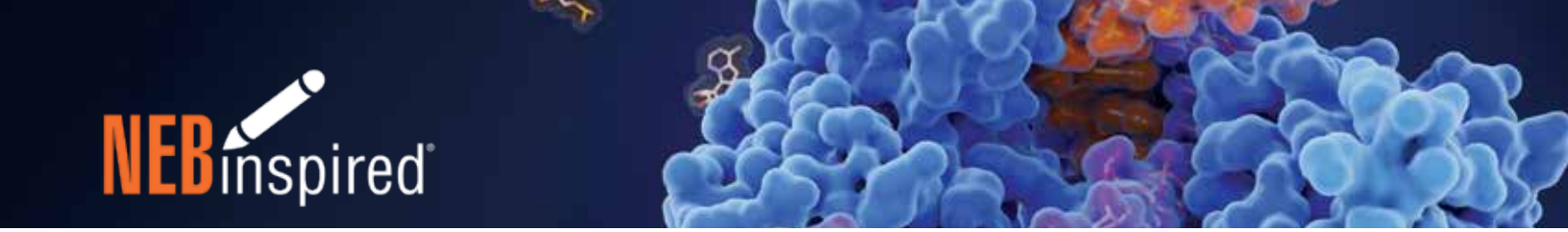


Synthesized ssDNA (≥16 nt) and dsDNA (≥12 bp) oligonucleotides can be effectively purified and recovered using Monarch Spin PCR & DNA Cleanup Kit (5 µg). The provided oligonucleotide cleanup protocol was followed using 1 µg of oligonucleotides of varying lengths (8–25 nt/ bp) as an input. DNA was eluted in 20 µl of Monarch Buffer EY. Concentrations of DNA were measured using a Trinean DropSense 16 and percent recovery calculations are based on the eluted DNA concentration and elution volume used. The minimum sized ss- and ds-oligonucleotides that can be used are marked with a star (*).

Ordering Information

PRODUCT	NEB #	SIZE
Monarch Spin Plasmid Miniprep Kit	T1110S/L	50/250 rxns
Monarch Spin DNA Gel Extraction Kit	T1120S/L	50/250 rxns
Monarch Spin PCR & DNA Cleanup Kit (5 µg)	T1130S/L	50/250 rxns

For more information on Monarch kits, visit **NEBmonarch.com**



Why Glycerol-free Reagents Matter in Molecular Diagnostics

By Joanne Gibson, Ph.D, New England Biolabs

Precision and reproducibility are paramount in molecular testing. Even minor components in reagent formulations can significantly impact diagnostic assay development and testing outcomes. Glycerol, a common cryoprotectant in many enzyme formulations, is valued for its protective properties when storing liquid reagents in a freezer, as it prevents ice crystal formation. However, the limitations of glycerol—such as its potential to complicate lyophilization (freeze-drying) workflows and challenge automated processes—have become increasingly apparent. To navigate these challenges, our eBook "Navigating Amplification Workflows for Robust Diagnostic Assay Development" offers in-depth insights and practical solutions.

Transitioning to glycerol-free reagents offers a way to overcome these obstacles, paving the way for more accessible and accurate diagnostic workflows. Read on to learn how glycerol-free alternatives are transforming the landscape of molecular biology.

Benefits of glycerol-free reagents for molecular diagnostics

Lyophilization compatibility, long-term stability, and global reach

Glycerol is incompatible with the lyophilization process, which is crucial for creating stable, dry reagents that do not require refrigeration. The drying process in lyophilization requires the sublimation of water (converting solid to vapor without passing through the liquid phase). The presence of glycerol can hinder this process because it retains moisture, making complete drying challenging. Consequently, formulations intended for lyophilization should be glycerol-free to ensure successful drying and long-term stability.

Lyophilized formulations can be stored at room temperature, eliminating the need for cold-chain shipping and cold storage. This is particularly beneficial for point-of-care or field diagnostics, especially in regions with limited access to cold-chain logistics.

By simplifying distribution and ensuring reliable performance across diverse climates and conditions, glycerol-free, lyophilized reagents in molecular diagnostic assays support global health equity in regions that typically lack sufficient healthcare resources.

Automation accuracy

Glycerol's high viscosity can pose challenges in automated systems commonly used in diagnostic laboratories. These systems rely on precise and reproducible pipetting, and the viscous nature of glycerol-containing solutions leads to slower flow rates during pipetting. While several best practices are typically used when pipetting viscous liquids (e.g., reverse pipetting, liquid class development), glycerol can still cause inaccuracies in volume dispensing, clogging of pipettes, and difficulty achieving reproducible results. The slower aspiration and dispensing rates necessitate adjustments to protocol parameters to minimize liquid loss, ensure accurate pipetting, and provide adequate mixing, which complicates the automation workflow.

However, glycerol-free reagents effectively overcome these pitfalls by reducing solution viscosity, allowing for faster, more precise pipetting. This improvement enhances the accuracy and reliability of automated high-throughput systems while shortening the overall turnaround time. This makes glycerol-free formulations helpful for maintaining the reproducibility required in molecular diagnostics.

Making an assay reagent glycerol-free

Making a product glycerol-free involves several key steps to ensure the reagent remains stable, functional and compatible with various applications, particularly in molecular diagnostics. The process begins with evaluating and selecting alternative stabilizers that can provide the necessary protective effects without the drawbacks of glycerol. Following this, the product is carefully reformulated, and concentrations and conditions are fine-tuned to ensure the glycerol-free version performs as effectively as the original. Rigorous testing, including shelf-life assessments and freeze-thaw cycle stability, is conducted to confirm the product's robustness. Finally, any necessary adjustments to the manufacturing process are made to accommodate the new formulation, ensuring consistent quality, even at larger production scales.

Offering comprehensive support for glycerol-free products

NEB offers extensive support for scientists transitioning to glycerol-free reagents, including those developing molecular diagnostic assays. We provide a range of glycerol-free enzyme formulations specifically designed to meet the demands of advanced diagnostic assays, including PCR and isothermal amplification.

Our glycerol-free products are available in various concentrations and formats, tailored to fit your workflow. For those requiring further customization, our Customized Solutions Team is ready to assist in developing glycerol-free reagents to meet your unique requirements. These options are especially beneficial for those looking to improve the compatibility of their reagents with lyophilization processes, enhance automation in high-throughput systems, and ensure reliable performance across diverse conditions.

We also offer technical support and consultation to help labs validate and optimize their protocols when switching to glycerol-free formulations, ensuring a smooth and effective transition.

View list of glycerol-free reagents available

Afrigen's Mission to Empower Developing Countries with mRNA Vaccine Production

Addressing global and regional health inequalities through local manufacturing initiatives

– Joanne Gibson, Ph.D., New England Biolabs

The global disparity in vaccine distribution was brought into sharp focus by the COVID-19 pandemic. While affluent nations quickly secured and distributed life-saving vaccines, lower-income countries faced severe shortages, exacerbating health inequities and prolonging the crisis. To address this issue, Afrigen Biologics & Vaccines (www.afrigen.co.za), supported by the World Health Organization (WHO) (www.who.int), was given a bold mission to bridge the vaccine gap and empower regions traditionally left behind by global healthcare advancements.

Afrigen is at the forefront of advancing vaccine innovation and manufacturing in Africa- a continent that uses 25-30% of global vaccine supplies but is only able to produce 1% of its needs. They sit at the center of a program born from the COVAX initiative (www.who.int/initiatives/act-accelerator/covax) and jointly run by the WHO and the Medicines Patent Pool (MMP) (medicinespatentpool.org). The program aims to address vaccine inequity by creating a hub for technology transfer and training that could be passed to lower-middle-income countries, which in turn would become regional manufacturers of mRNA vaccines.

Overcoming Initial Obstacles

The WHO/MPP program envisioned Afrigen as a central hub for mRNA vaccine production technology, aiming to transfer this technology to 15 global partners in low-middle-income countries across four continents. However, initial expectations of a technology transfer during the recent COVID-19 pandemic from major manufacturers fell through. By September 2021, Afrigen realized they would need to develop the mRNA technology from scratch. With a team of only 20 people, none of whom had prior mRNA experience, Afrigen embarked on a journey to learn, innovate, and collaborate. They partnered with universities in South Africa, expert advisors, and suppliers, including New England Biolabs, to gain the necessary knowledge and resources. Over nearly three years, Afrigen has grown its staff by 150 people, built an end-to-end research, development and GMP manufacturing facility, and developed the technology to a point where it is ready for phase 1-2 clinical trials.

> *"The realization that we had to start from scratch was daunting, but it also gave us the unique opportunity to truly embed the know-how and create a robust foundation for future developments."*
>
> – Dr. Caryn Fenner, Executive Director: mRNA Hub, Afrigen Biologics

While these collaborations allowed Afrigen to fast-track the development of mRNA vaccines, it was also realized that in terms of the timeline, they would not be able to participate in the manufacture of the COVID-19 vaccine. However, the program included medium- to long-term sustainability goals, with each partner using the technology to address specific regional health needs while also contributing to global health security. For example, in South Africa, Afrigen is prioritizing vaccines relevant to the burden of disease in Africa in a quest to address unmet needs. The current product development pipeline includes HIV, TB, Rift Valley Fever virus, gonorrhea, and RSV.

The 15 partners include six countries in Africa (South Africa, Senegal, Tunisia, Nigeria, Kenya, Egypt), two in Eastern Europe (Serbia, Ukraine), five in Southeast Asia (Pakistan, Vietnam, India, Indonesia, Bangladesh), and two in South America (Brazil, Argentina). These partners have varying levels of bio-manufacturing maturity. Some lack an R&D component and collaborate with research institutes, while others, without manufacturing capabilities, partner with commercial companies. Afrigen partners with Biovac, a South African vaccine producer and the first manufacturing partner in this network. Given these differences in bio-manufacturing maturity, a phased approach to technology transfer has been implemented between Afrigen and its partner countries, tailored to each country's specific needs and existing capabilities. Many partners who were previously unfamiliar with mRNA technology have received training at Afrigen's facility at the laboratory scale. This diverse consortium ensures that countries with different bio-manufacturing capabilities can effectively contribute to and benefit from the global vaccine initiative.

In addition to these international partnerships, Afrigen is part of a local R&D consortium managed and funded by the South African Medical Research Council. Supported by the South African Department of Science and Innovation, the consortium focuses on specific disease priorities for South Africa, such as TB and HIV. Afrigen also fosters partnerships around the globe to address specific priorities for the long-term sustainable introduction of mRNA vaccines into public health systems. The focus of these innovation partnerships is to improve manufacturing processes to reduce costs as well as improve thermostability to address supply and logistic challenges of the current mRNA vaccines.

Current Progress and Global Impact

Afrigen has completed the scale-up process and is preparing for GMP certification. They will host another round of on-site training for their 15 global partners. The company's comprehensive approach involves extensive training and capacity-building efforts, ensuring that each partner is equipped to handle mRNA technology.

Afrigen's story is one of determination and ingenuity. From its inception as a small adjuvant formulation vaccine development company, it is now poised to significantly impact global health using mRNA technology addressing immediate health needs and building a foundation for sustainable vaccine manufacturing in Africa and beyond. Their journey demonstrates the power of collaboration, innovation, and resilience. With continued global support and commitment to equity, Afrigen is well-positioned to achieve its mission and contribute to a healthier future for all.

> *"The essential ingredients of Afrigen's progress and success are diverse partnerships, suppliers such as NEB who walked the extra mile for us, innovative collaborations, a dedicated 'can do' attitude team, and society believing in us – all inspired by the vision of equitable health for all universe. Afrigen says: Thank you"*
>
> – Professor Petro Terblanche, CEO Afrigen Biologics

2024 PASSION IN SCIENCE AWARDS® RECIPIENTS

In October, twelve scientists were recognized for their inspiring achievements in science mentorship, environmental stewardship, humanitarian efforts and the arts.

More information on the winners can be found at **www.neb.com/passioninscience**

We are excited to announce the winners of our fourth Passion in Science Awards, which acknowledge scientists for their innovative work that goes above and beyond the boundaries of pure science to make a profound impact on other fields, including the arts, humanitarian service, environmental stewardship, and science mentorship.

On October 9th and 10th, 2024, we hosted award recipients from around the world at our headquarters in Ipswich, MA. In a truly inspiring event, the award recipients received their awards, shared their personal stories of success, and participated in group discussions and creative brainstorming sessions with the NEB community.

As part of our 50th anniversary celebrations., winners of our recent Golden Butterfly Grand Prize competition, which involved researchers from around the world seeking out golden butterfly icons hidden on our website and product literature, also attended the festivities.

The full list of Passion in Science Awardees is as follows:

CATEGORY: SCIENCE MENTORSHIP AND ADVOCACY AWARD™

• Rogelio Hernández López
(Stanford University, Stanford, CA, USA): Co-founder of the Clubes de Ciencia Program, which hosts hands-on STEM workshops for high school and college students in Latin America. To date, the program has hosted 19,000 students in nine countries.

• Anne Madden
(The Microbe Institute, Yarmouth, ME, USA): Founder of the Microbe Institute, a nonprofit dedicated to fostering microbial discovery for a better tomorrow through participatory art, research and education projects.

• Samuel Ogunsola
(University of Manitoba, Winnipeg, Canada): Founder of Shaping African Women in STEM (SWIS Africa), an initiative aimed to celebrate, promote and shape women in STEM in Africa. To date, the program has organized 10 training programs with over 1,000 women participating.

• Alyssa Paparella
(Howard Hughes Medical Institute Inc., Chevy Chase, MD, USA): Launched DisabledinSTEM, a program that connects individuals with disabilities across STEM fields with mentors. To date, the program has connected 380 individuals.

• Don Spratt
(Clark University, Worcester, MA, USA): Launched the ClarkU STEM Outreach Program, which provides an opportunity for underrepresented groups to be exposed and inspired to pursue careers in STEM.

CATEGORY: ENVIRONMENTAL STEWARDSHIP AWARD™

• Jim Chadwick
(University of Oxford, Oxford, UK): Conducted a grassroots study to raise awareness among scientists about their energy usage and its impact. He also established a community allotment and wildflower garden at the institute to improve the mental health of graduate students.

• Martin Farley
(Sustainable Science Leader and LEAF founder, London, UK): Founder of the LEAF (Laboratory Efficiency Assessment Framework) program - which helps laboratories conserve plastics, water, energy and other resources - and a lifelong advocate of sustainability.

CATEGORY: HUMANITARIAN DUTY AWARD™

Adewunmi Akingbola
(King's College, Cambridge, UK): Founder of HealthDrive Nigeria, which combats viral hepatitis in Nigeria through awareness, free hepatitis B surface antigen and HCV antibody tests, and subsidized vaccinations for underserved communities. The program has screened >15,000 and vaccinated >10,000 individuals.

• Dylan Pillai
(University of Calgary, Alberta, Canada): Founder of the LAMPREG project, which has screened >2,500 women in Ethiopia for malaria using LAMP, to determine whether asymptomatic detection improves pregnancy outcomes.

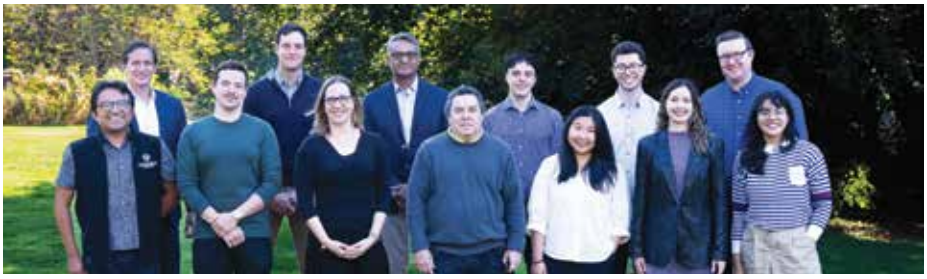
CATEGORY: ARTS AND CREATIVITY AWARD™

• Ji Hyun (Sally) Kong
(Rockstar Games, Brooklyn, NY, USA): Creator of Mitos – Handweaving My Ancestral DNA, a data physicalization project of handwoven patterns generated from the artist's own mitochondrial DNA sequence.

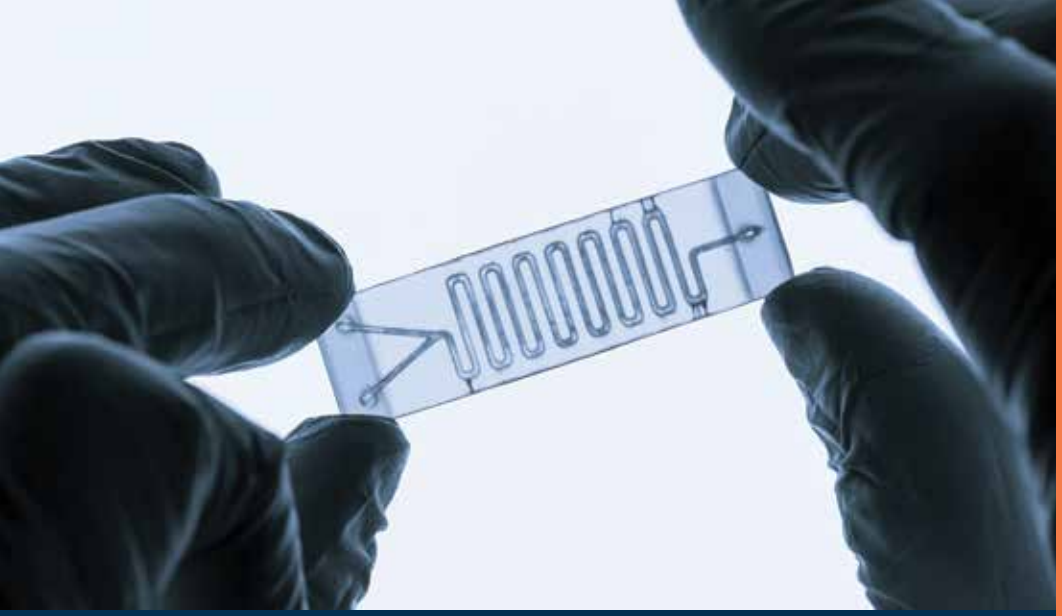
• Sam Siljee
(Gillies McIndoe Research Institute, Wellington, New Zealand): Created the "The Sound of Science", an innovative method of engaging with mass spectrometry data by generating a unique tone for every spectrum in the raw data.

• Michael Weiner
(*Abbratech, Branford, CT, USA)*: Creates art from recycled lab consumables, including a DNA sculpture made from microtiter plates and portraits using pipette tips.

> *"Our 2024 Passion in Science Awards recipients truly embody the values which have been embraced by NEB for the past five decades – passion, humility, and being genuine."*
>
> – Salvatore Russello, Chief Executive Officer at NEB



2024 Passion in Science and Golden Butterfly grand prize winners.



Glycerol-free & Lyo-compatible Reagents to Support Molecular Diagnostic Assay Developers

NEB® has been developing innovative enzymes used in molecular biology research for 50 years. To meet the demands of today's assays, which include functional, performance and environmental requirements, scientists rely on the most innovative and specialized enzyme formulations. NEB's glycerol-free and lyo-compatible enzyme formulations meet these demands, and can be customized to meet your concentration, volume and format requirements. This can include ambient shipping and storage through lyophilization, automation and HPLC compatibility and improved fluid dynamic properties.

Learn more about how NEB can support support scientists developing molecular diagnostic assays

Supporting Scientists Developing Molecular Diagnostics
www.neb.com/supporting-molecular-diagnostics

NEB Customized Solutions
www.neb.com/customized-solutions

NEB Lyophilization Sciences®
www.neb.com/lyosciences

Ordering & inquiries

To learn more, or if you require other enzymes in a glycerol-free format, contact our Customized Solutions Team.

www.neb.ca/ContactUs

Howard Cukier, Ph.D.
Regional Manager,
Ontario and Manitoba
Cell: (416) 527-2352
hcukier@neb.com

Nicholas Prevedel, MSc.
Associate Field Sales Representative,
Ontario and Manitoba
Cell: (437) 431-8820
nprevedel@neb.com

Alexandre Rochette, Ph.D.
Territory Manager,
Eastern Canada
Cell: (514) 233-4557
arochette@neb.com

Martin Chenal, Ph.D.
Associate Field Sales Representative,
Eastern Canada
Cell: (438) 466-2884
mchenal@neb.com

Julie Wong, Ph.D.
Territory Manager,
Western Canada
Cell: (604) 767-5078
jwong@neb.com

New England Biolabs Ltd.
Telephone (905) 665-4632
Toll Free 1-800-387-1095
email: info.ca@neb.com

Products and content are covered by one or more patents, trademarks and/or copyrights owned or controlled by New England Biolabs, Inc (NEB). The use of trademark symbols does not necessarily indicate that the name is trademarked in the country where it is being read; it indicates where the content was originally developed. See www.neb.com/trademarks. The use of these products may require you to obtain additional third-party intellectual property rights for certain applications. For more information, please email busdev@neb.com.

Your purchase, acceptance, and/or payment of and for NEB's products is pursuant to NEB's Terms of Sale at neb.com/support/terms-of-sale. NEB does not agree to and is not bound by any other terms or conditions, unless those terms and conditions have been expressly agreed to in writing by a duly authorized officer of NEB.

New England Biolabs is an ISO 9001, ISO 14001 and ISO 13485 certified facility.

LEED® is a registered trademark of U.S. Green Building Counsel
Milli-Q™ is a trademark of Merck KGaA
B CORPORATION® is a registered trademark of B Lab IP, LLC, Inc.
iPhone® and iPad® are trademarks of Apple Inc., ANDROID™ is a trademark of Google LLC

© Copyright 2024, New England Biolabs, Inc.; all rights reserved.