

[White Paper]

**Next-Generation Lyophilized Bead Technology:
Achieving Stability, Precision, and Scalability in IVD Reagents**

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Executive Summary

In the rapidly evolving field of In Vitro Diagnostics (IVD), the transition from liquid reagents to lyophilized (freeze-dried) formats is reshaping supply chains and Point-of-Care Testing (POCT). **LYOBEAD** is at the forefront of this transformation, offering a comprehensive Contract Development and Manufacturing Organization (CDMO) solution.

This white paper outlines LYOBEAD's proprietary approach to manufacturing lyophilized reagent beads ("Lyo-beads"). By integrating **optimized formulation science, precision liquid dispensing, strict environmental controls, and validated packaging systems**, we deliver a product that ensures the long-term stability of traditional qPCR reagents for **over two years** at ambient temperature. With a projected annual capacity of **300 million beads**, LYOBEAD is engineered to meet global industrial demands.

1. The Challenge: Liquid vs. Solid State

Traditional liquid reagents face significant logistical hurdles:

- **Cold Chain Dependency:** High costs associated with shipping on dry ice or gel packs.
- **Shelf-Life Limitations:** Rapid degradation at room temperature.
- **Handling Errors:** Manual pipetting in laboratories introduces variability.

The Solution: Lyo-beads. These are single-dose, pre-mixed, and freeze-dried spheres that reconstitute instantly. However, manufacturing them requires overcoming technical barriers in bead shape consistency, enzyme activity retention, and moisture protection.



2. The LYOBEAD Methodology

LYOBEAD adopts a "Quality by Design" (QbD) approach, focusing on four critical pillars to ensure product excellence while respecting intellectual property boundaries.

2.1 Formulation Optimization (The Core)

The stability of a Lyo-bead is defined by its chemical matrix. LYOBEAD does not rely on a "one-size-fits-all" recipe. Instead, we utilize a screening platform to customize the excipient mix for each specific reagent (e.g., PCR enzymes, antibodies, primers).

- **Glass Transition Temperature (T_g) Management:** We optimize the formulation to maximize the T_g, ensuring the bead remains physically stable and does not collapse

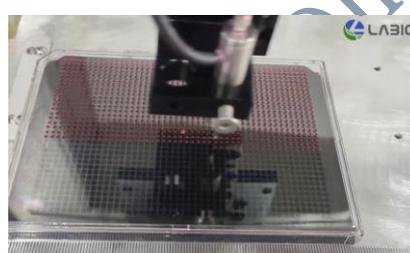
even under thermal stress.

- **Activity Retention:** Specialized cryoprotectants are selected to protect the tertiary structure of enzymes during the freezing and drying phases.

2.2 Precision Liquid Dispensing

Uniformity is the hallmark of LYOBEAD. We utilize advanced automated dispensing systems designed for micro-volume accuracy.

- **Volume Range:** Precise dispensing from 1 μ L to 50 μ L. Some special needs, LYOBEAD can offer from nL grade dispensing.
- **Consistency:** Our process achieves a Coefficient of Variation (CV) of **21%** for weight and diameter.
- **Morphology Control:** Through optimized surface tension control, we ensure every bead forms a perfect sphere, facilitating smooth automated packaging and rapid reconstitution.



2.3 Strict Environmental Control (Low Humidity)

Lyophilized products are highly hygroscopic. Re-absorbing moisture is the primary cause of product failure.

- **Dry Room Manufacturing:** All dispensing and packaging occur in ISO-certified cleanrooms with strictly controlled humidity levels (Dew Point < -40°C).
- **Static Elimination:** We implement rigorous anti-static protocols to prevent bead flight or sticking during the manufacturing process.

2.4 Validated Packaging Systems

A robust bead requires a robust barrier. LYOBEAD employs a fully validated packaging process.

- **Material Selection:** High-barrier packaging materials (e.g., aluminized foil, specialized plastic cartridges) are tested for Moisture Vapor Transmission Rate (MVTR).
- **Seal Integrity:** Automated heat-sealing and rigorous leak testing ensure that the low-humidity environment inside the package is maintained throughout the product's shelf life.

3. Performance & Stability Data

LYOBEAD has conducted extensive accelerated aging and real-time stability studies on standard qPCR reagents transformed into Lyo-beads.

- **Long-Term Stability:** Data indicates that our Lyo-beads maintain functional integrity (Ct values consistent with liquid controls) for **over 2 years** when stored at ambient temperature (20°C - 25°C).
- **Thermal Stress Resistance:** The beads demonstrate resilience to temporary

temperature excursions (e.g., up to 45°C during shipping), eliminating the need for cold chain logistics.

- **Instant Reconstitution:** Upon adding buffer, beads dissolve completely within seconds, leaving no residue or turbidity.

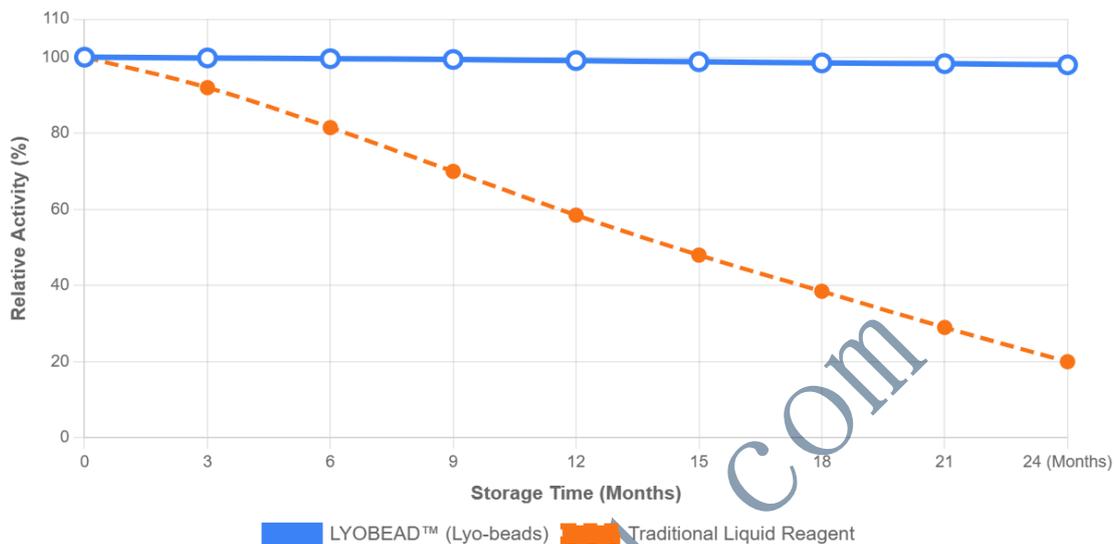


Figure 1.

Stability comparison over 24 months. LYOBEAD™ (Blue) maintains >98% activity at ambient temperature, while traditional liquid reagents (Orange) show significant degradation.

4. Scalability: Ready for Mass Production

Transitioning from the lab to the market requires scale. LYOBEAD has invested in high-throughput automation to support global IVD partners.

- **Annual Capacity:** Our current facility layout and automated lines are projected to support an output of **300 million beads per year**.
- **Flexible Batch Sizes:** From pilot batches for R&D validation to mass production for commercial launch.
- **Quality Compliance:** Manufacturing is conducted under strict adherence to ISO 13485 quality management systems.

5. Conclusion

LYOBEAD is not just a manufacturer; we are a strategic partner in reagent stabilization. By mastering the delicate balance of formulation, precision dispensing, and environmental control, we turn sensitive biological reagents into robust, easy-to-use Lyo-beads.

Our technology empowers IVD companies to reduce logistics costs, expand into remote markets, and improve the end-user experience.

Contact Us

Ready to transform your reagents?

LYOBEAD Technologies

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(Disclaimer: This white paper is for informational purposes only. Specific stability data varies based on the unique properties of the customer's raw materials.)

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