Kick Cold-Chain Dependency: The Future of Antibody Storage Is Here

Accelerating science and discovery with shelf-stable reagents

The ideal assay kit is easy-to-use and can be stored and distributed globally at ambient temperatures. These kits require minimal training, resulting in improved and more efficient technology transfer between labs and collaborators. Such kits have extended shelf lives, improved batch-to-batch consistency, and reduced lot replacement frequency. Assay kits like these simplify not only scientists' day-to-day work in the lab, but also generate higher quality data faster, leading to quicker and better business decisions.

Everyday obstacles need better solutions

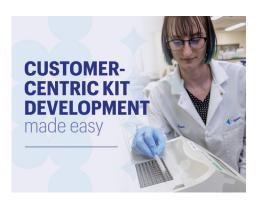
Antibodies are vulnerable to degradation, aggregation, and loss of activity during storage. The current antibody storage paradigm requiring temperature control generates several issues: increased assay complexity and reagent waste, limited reagent shelf and lot life, energy-intensive cold-chain infrastructure and shipping, and increased costs due to temperature excursions and product loss. This status quo hurts the profitability of reagent and kit manufacturers of all scales and limits their access to global markets.

Freeze-drying, or lyophilization, is a common method used to reduce cold storage use. Reagents are stabilized by first freezing and then removing moisture under vacuum. The freezing step necessary to prevent vacuuminduced boiling can result in crystallization that can significantly reduce product yield. Additionally, freeze-drying is capital intensive, requires deep subject matter expertise, and frequently only reduces, not eliminates, cold storage requirements. These limitations make lyophilization untenable for stabilizing complex assay mixtures, and access to the technology is limited to larger organizations that can support the necessary infrastructure.

Changing the paradigm with a novel biomolecule stabilization method

A novel, alternative method called capillarymediated vitrification (CMV) achieves stabilization without freezing, eliminating the negative aspects observed with lyophilization. Leveraging capillary evaporation, CMV locks molecules into a stabilized state via accelerated drying using porous microstructured scaffolds. The result is an amorphous dried product with no activity loss. CMV-stabilized biomolecules can be stored and shipped at ambient temperatures, eliminating the risk of product loss due to temperature excursions. The process cycle time is one hour or less, compared to freezedrying which requires 12–27 hours, and the stabilized reagents can be incorporated into structures that seamlessly integrate with standard laboratory consumables.

CMV was developed by Upkara and recently brought to market under the name BioFix™. The BioFix™ technology can be integrated into manufacturing lines and leverage existing freeze-drying infrastructure when available. Upkara partners with reagent and assay kit manufacturers via licensing the technology or can provide custom contract manufacturing services.



Win-win: customer-centric products without the cold chain

Customer-Focused Designs

BioFix[™] technology enables the development of easy-to-use kits that reduce training, eliminate errors, and simplify assay transfers all advantages for customers. Reagents are formulated based on assay requirements and can be multiplexed to meet customer needs.

Equivalent Performance

CMV stabilization maintains reagent performance, even after extended storage at elevated temperatures. Antibody-based reagents stabilized using the Upkara platform include monoclonal and polyclonal antibodies, HRP- and ALP-conjugated antibodies, fluorophore-conjugated antibodies, and antibodies conjugated to beads.

Minimal Optimization

CMV stabilizes most antibodies and bioconjugates with minimal to no formulation or process optimization, unlike moleculespecific freeze-drying methods. It's a practical solution for ambient storage at any scale.

Efficient Processing

Mix, dispense, and dry—you'll have stabilized reagents in about an hour, compared to the 12–72 hours required for lyophilization.

Simplified Storage

Kits and reagents maintain stability long-term at room temperature with no cold-chain. This reduces logistical requirements, enables global distribution, and achieves sustainability goals. CMV is a key tool to develop more accessible and sustainable reagents and assay kits.

It's time to shelve antiquated storage

Current biomolecule storage methods rely on decades-old technologies, but today's scientists need innovative solutions for state-of-the-art molecules and conjugates. BioFix[™] delivers ambient temperature-stable products that make science easier for you and your customers. This manufacturing-ready technology provides convenience, profitability and sustainability. Upkara is seeking fellow pioneers to partner with to change the future of biomolecule storage. Learn more about bringing the next generation of stabilization manufacturing technology to your organization with a free consultation at <u>www.</u> <u>upkara.com/partnership</u>.



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