Matrix for Storage of Biofluid Specimens and Biological Drugs at Room Temperature (20130180, Dr. Alpetkin Aksan)

This technology is a novel biopreservation sponge for storage of biofluid specimens and biological drugs at room temperature that prevents degradation and aggregation of biomolecules.

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The high cost of biological sample and drug storage

Cryogenic storage is the predominant method of storing biological samples in healthcare and scientific research. However, a single -80°C freezer uses the same amount of energy as an average US household and is prone to power failure that could destroy the samples. This exorbitant cost is prohibitive in resource-limited regions making specimen collection and storage unfeasible. Furthermore, the harsh freeze-thaw processing of samples leads to degradation of numerous proteinaceous biomolecules. This preservation technique is also problematic for increasingly prevalent biological drugs that require stabilization. Currently, this class of drugs is often freeze dried, a process that can cause aggregation, formulation of insoluble aggregates or crystallization of the drug. The new room temperature stabilization technology provides solutions to both of these problems using a novel matrix of modified polysaccharides that stabilize biofluid specimens at non-cryogenic temperatures (4°C to room temperature) in a dried state for long-term storage.

A "sweet" alternative to freezing samples

University of Minnesota researchers developed a technology that employs an electrospun fibrous matrix of polysaccharides onto which a biofluid specimen or biological drug can be applied, and subsequently dried/vitrified under vacuum. This process creates a mixture of polysaccharides and biological materials in a glass solid that entraps and stabilizes macromolecules for long term-storage at non-cryogenic temperatures. In the formulation, for increased biomolecular preservation, the end-groups of the polysaccharide sugar dextran was

reduced (from an aldehyde to a relatively inert alcohol), forming dextranol and eliminating the creation of protein-dextran conjugates. This method has been shown to effectively preserve samples, minimizing sample aggregation often observed during cryopreservation and leading to 90-100% recovery of biomarkers assayed (including those that are refractory to freezing). This technology represents the first-ever alternative to cryogenic preservation of a broad range of proteinaceous biomarkers and serum metabolites and facilitates research and medicine in underdeveloped and rural environments.

Facilitates Biomarker Discovery and Validation

Identifying cancer biomarkers may allow early disease detection, monitoring of disease progression and/or therapeutic response, and could one day reduce mortality, improve quality of life and minimize healthcare costs. However, this discovery and validation process has been slow to progress, and of the thousands of molecular signatures being evaluated, less than two dozen have been approved by the FDA, due in part to poor stability and less than-optimal biospecimen storage conditions. The considerably less stringent storage requirements afforded by this technology will be valuable in keeping samples viable for future research, facilitating the process of biomarker discovery and validation.

Phase of Development

• Formulation development. Researchers have a formulation with published results showing that the electrospun matrix preserves protein quantity and activity while minimizing aggregation as compared to cryopreservation.

Benefits

- **Maintains sample integrity:** Circumvents sample degradation from freezing and the associated chemicals. Avoids glycation of sample proteins by using reduced dextran (dextrol).
- **Reduces costs:** Bypasses the need for maintaining costly sub-zero temperatures for storage and/or shipping of biological specimens.
- **Saves space:** Vitrification reduces sample volume, accommodating more samples in the same amount of space, leading to further shipping and storage savings.
- Facilitates research and medicine in rural settings: Makes it possible to collect, store and ship biological samples or drugs in locations where it's not physically or economically possible to maintain a freezer.

Applications

Biological sample storage

- Sample shipping
- Excipient for preservation of biomolecular drugs
- Biomarker discovery and validation
- Analytical standard storage
- Non-reactive matrix for chromatography and other research use

Researchers

Alpetkin Aksan, PhD

Professor, Department of Mechanical Engineering

External Link (www.me.umn.edu)

Publications

Adsorbing/dissolving lyoprotectant matrix technology for non-cryogenic storage of archival human sera

Nature Scientific Reports, 6:24186. 2016

Dextranol: A better lyoprotectant

bioRxiv

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