WHITE PAPER

Key Considerations for Biobanks



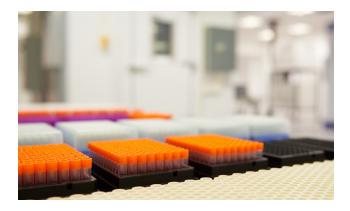
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Introduction

Biobanking — the process of collecting, maintaining, and sharing biological samples — is a central part of modern biomedical research. Biopharmaceutical research relies on high-quality biological samples to produce robust data¹. Over the past few decades, there has been a proliferation of biobanks. Now well over 1 billion samples are stored in over 1000 biobanks around the world ²⁻⁵. The main goal of every biobank is to preserve sample quality and integrity.

Biobanking is a complex endeavor due to the wide variety of biological sample types used in research². Sample handling and storage methods must be optimized for each sample type. Regardless of the type or number of samples stored, all successful working biobanks must address three key considerations:

- Protecting sample integrity
- Ease of sample access and traceability
- Turnaround of order fulfillment: sample retrieval, packaging and dispatch



Sample Integrity

Sample integrity is the foremost concern of every biobank. Sample quality can be maintained by implementing best practices for sample collection, processing, transport, storage and retrieval. The International Society of Biological and Environmental Repositories (ISBER) uses a scientific approach to develop industry-wide standards and best practices for biobanks and biorepositories⁶. These standards help biobanks meet the criteria required to be accredited or certified by accreditation bodies.

Storage Method

The preferred storage temperature for DNA is +4°C to -20°C with -80°C to -150°C for biological samples as it prevents sample degradation from enzymatic reactions⁷. Biologic storage at -80°C is often the pragmatic choice based on cost and practicality with -150°C cryopreservation used for more sensitive or backup samples. Transient warming events during storage, sample retrieval and transport can impair sample integrity and biological function⁸.

ISBER Best Practice: Minimize and document the number of freeze/thaw cycles for each sample.

Freezer Choice

Liquid nitrogen (LN2) vapor phase freezers store samples below -180°C, thus protecting all biomarkers, nucleic acids and cellular structures from degradation. BioStore[™] -190°C LN2-Based Automated Storage System is an automated cryogenic storage system that maintains samples at -190°C. The BioStore integrates with inventory management systems, tracks the temperature of all samples, protects innocent samples from warming during retrieval, restricts sample access to predefined users and provides complete inventory tracking and audit trail.

BioStore space efficient automated -80°C storage system from Azenta Life Sciences provides complete sample tracking; compact, flexible, high density sample storage; and efficient sample retrieval for fast turnaround and order fulfillment.

ISBER Best Practice: Maintain and document cold chain continuity throughout the sample lifecycle.

Storage Tube Choice

Plastic tubes are used in labs around the world to store samples. However, many of these tubes contain bioactive compounds that can contaminate samples and interfere with experimental results. Research has shown that these compounds called "leachables" or "extractables" can inhibit enzyme activity, interfere with nucleic acid quantification and inhibit cell growth⁹. Furthermore, inadequate tube sealing can lead to sample evaporation or contamination.



The Azenta range of tubes has been designed and independently tested to be free of leachables and extractables. Azenta tubes are barcoded

and seamlessly integrate with automated sample handling instruments including tube readers, tube capper/decappers and inventory management systems. The Azenta IntelliXcap™ Capper/ Decapper provides optimal and consistent sealing of up to 96 tubes in as little as 20 seconds. Biobanks can use these tools to create complete integrated workflows that minimize sample handling and maintain sample quality.

ISBER Best Practice: Use barcodes to ensure accurate tracking of samples.

Sample Access and Traceability

Over 25% of biobanks cite sample access as their biggest current challenge¹⁰. Access to samples is a key concern for biobanks because sample handling delays can extend research study timelines. There are two sides to sample access within biobanks. Firstly, biobanks must restrict access to authorized users in order to maintain sample security. Secondly, biobanks must build an integrated tracking system so that sample identity and location are known at all times. The system should facilitate quick and easy sample retrieval using methods that avoid damaging warming events.

Inventory Management

Inventory management systems such as FreezerPro[®] track samples, ensure samples are stored at the correct temperature and restrict sample access to registered users. FreezerPro maintains a complete audit trail, chain of custody and chain of condition for all samples. This is essential for regulatory compliance. FreezerPro also securely stores all linked data.

ISBER Best Practice: Inventory systems should link samples with associated data.



Workflow Optimization

Biobanks can integrate inventory management systems with automated sample handling instruments to create a streamlined work flow that protects sample integrity. The Azenta Direct Tube Marker uses thermal pixel technology to directly print text and barcodes onto tubes. Azenta tube readers and scanners can extract information from barcoded tubes and automatically update inventory management software. SBS Rack De-Icing System uses air to keep samples frozen while removing frost from tubes so they can be read manually or by a tube reader. The Azenta IntelliXcap Capper/ Decapper caps and decaps up to 96 tubes within the



time it takes to manually decap one tube. These tools minimize manual steps and improve data and sample tracking within biobanks.

ISBER Best Practice: Biobanked samples should be labelled with both a barcode and a sample ID.

Retrieval, Dispatch and Delivery

Clients expect quick turnaround times for requested samples. This can be one of the biggest challenges faced by biobanks. There is more pressure than ever for biobanks to deliver samples that are in a better condition, with superior annotation and faster turnaround time. Fortunately, retrieval and dispatch can be streamlined using inventory management systems and automated retrieval systems. Over 50% of biobanks use, or plan on using, automated storage and retrieval systems¹¹.

Automated Sample Retrieval

Automated sample retrieval systems protect samples by providing faster retrieval times and minimizing temperature excursions¹². BioStore is a complete automated storage and retrieval system that holds retrieved samples in an insulated column to prevent transient warming events. The system also alerts users when stocks or samples are low.

ISBER Best Practice: Implement a policy for when sample retrieval results in stocks reaching a critical level.

Portable Cryogenic Carriers and Benchtop Cooling Systems

Portable cryogenic carriers such as the Cryopod™ Carrier can maintain sample temperature below -150°C while packing and dispatching. The temperature is displayed with audible and visual alarms.

Ice-Free Cooling Workstations are compact, portable workstations to cool or snap-freeze samples. Ice-Free Cooling Workstations is a flexible, modular system that works with microfuge tubes, cryogenic vials, PCR tubes and plates, assay plates and many other sample containers. Ice-Free Cooling Workstations can maintain samples on the bench at temperatures between 4°C and -20°C. ISBER Best Practice: Cold chain management should include all temperature measurements, equipment qualifications, validation, and corresponding documentation.

Conclusion

Biobanks require complex infrastructure to protect sample integrity and security while maintaining easy access to samples and facilitating quick sample retrieval and dispatch times. Azenta Life Sciences offers complete, integrated sample management solutions to assist biobanks of all sizes achieve these goals.

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The fourth edition of the ISBER Best Practices can be downloaded at $\mbox{https://www.isber.org/page/BPR}$

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