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ACCURATE BIOSPECIMEN IDENTIFICATION AND TRACKING FOR caBIG INITIATIVE

By: Nicole Nelson, Market Manager Lab Healthcare, Brady Corporation
Julie Schoenborn, Sr. Strategic Account Manager, Brady Corporation
Dana Ray, Lab Marketing Team Member, Brady Corporation

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Introduction

An estimated $1 billion has been invested in the biobanking industry within the last ten years. The first advances are expected to result in the improved treatment of cancer.[1] "The lack of standardized, high-quality biospecimens has been widely recognized as one of the most significant roadblocks to the progress of cancer research. Over the past several years, the National Cancer Institute (NCI) has undertaken an intensive due diligence process to understand the state of its funded biospecimen resources and the quality of biospecimens used in cancer research."[2] To step up to the needs of the community, a best practice under the cancer Biomedical Informatics Grid directive, or caBIG®[3], was created.

Globally, tissue repositories and population databases are also adding clinical annotation, genetic data, and increasingly genomic, proteomic, and other 'omics information. "The UK Biobank is one of the most ambitious of these projects, intending to collect, store, and study the genetic information of 500,000 people with the hope of finding correlations between disease and lifestyle, environment, and genes."[4]

This whitepaper provides an overview of caBIG, discusses the benefits and operation of barcoding, and highlights identification solutions for your lab labeling needs. Whether already moving forward with caBIG or perhaps just investigating, this document will provide you with practical information about how to implement a unique identification system, create and use the specimen unique identifiers, and leverage that data in the repository so that is useful to the industry.

caBIG®/caTISSUE Overview

The caBIG initiative aims to create a collaborative information network for all constituencies in the cancer research community. Overseen by the National Cancer Institute Center for Biomedical Informatics and Information Technology (CBIIT), the mission of caBIG is to easily share approaches to the detection, diagnosis, treatment and prevention of cancer to ultimately improve patient outcomes.

The goals of caBIG are:

- Provide a shared and (interoperable) infrastructure
- Develop standard rules and common languages for sharing information, and
- Provide (either new or adapted) tools for collecting, analyzing, integrating and disseminating information related to cancer research and care.[5]

Projects such as caBIG, biomarker discovery initiatives and large-scale genome projects are driving advances in molecular technologies and improved clinical trial design. As a result, biospecimen resource facilities have become more important in the collection, processing, storage and distribution of specimen samples to the research community. Accurate biospecimen inventory and tracking requirements are necessary for the success of those initiatives, as well as for improving patient safety and creating a lean lab environment. In order to comply with federal regulations and industry and accreditation requirements, biospecimen resource facilities, research and clinical labs, pathology departments and histology labs will need to find easy and cost-effective ways to identify, store and track biospecimen inventory.

1. http://www.fiercebiotech.com/research/future-biobanks-regulation-ethics-investment-and-humanization-drug-discovery#ixzz0ey6bGEHq
2. http://biospecimens.cancer.gov/practices/
3. caBIG® is a registered trademark of the cancer Biomedical Informatics Grid.
4. http://www.genomeweb.com/dxpgx/changing-face-biobanks
5. https://cabig.nci.nih.gov/overview

Biospecimen Informatics: Sharing and Using the Data

Research sharing programs like caBIG rely on informatics systems to ensure that the infrastructure is interoperable and can be shared easily. The NCI Best Practices for Biospecimen Resources 2007 is the recognized implementation guideline for the caBIG initiative. It states that biospecimen resources should implement informatics systems that are robust and reliable for data management and that support all aspects of biospecimen resource operations, including biospecimen collection, processing, storage and dissemination.[6]

The caTISSUE software tool was released as part of the Tissue Banks and Pathology Tools (TBPT) knowledge center within caBIG and is the network's tool for biospecimen inventory management, tracking and annotation. caTISSUE allows users to input and share data regarding the collection, storage, quality and distribution of biospecimens. This software can be used by any biospecimen repository or facility regardless of the type of specimens being collected. caTissue is a specific type of biospecimen management software exclusive to the caBIG initiative that can be used by pathology laboratories around the world.

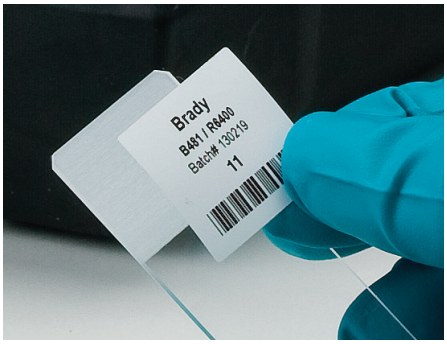
Using a unique specimen identifier allows a laboratory to adequately build a resource database and then easily update and track the specimens in that database. Implementation of a barcode identification system for biospecimens is inherent to laboratory information systems (LIS), laboratory information management systems (LIMS) and biospecimen management software, including caTISSUE.

Barcoding Biospecimens: Unique and Accurate Identification

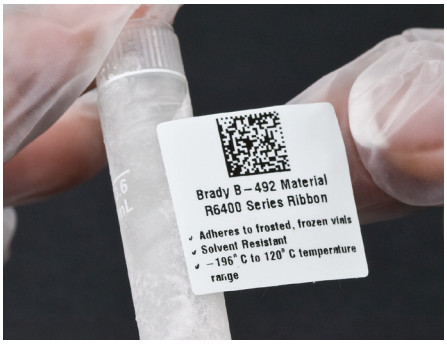
Labs that have the ability to barcode tissue specimens can be significantly more efficient while dramatically reducing errors. Barcode technology has been used since the early 1960s and is being adopted at high frequencies in laboratory environments for specimen identification and tracking.

Linear (or 1D) barcodes can be used effectively in a laboratory setting to assign a unique identifier, usually less than 15 characters, which represents a key to a database containing information about that specimen.

2D barcodes have become more popular in many industries. A 2D barcode can encode 20 times the amount of data in the same space as a typical linear barcode. This allows data, such as a patient's name, ID and biopsy reference, to be contained in a very small space with the actual specimen instead of in a separate database, helping to reduce pre-analysis errors.



Slide label showing ID barcode.



Tube label showing 2D barcode.

Industry information provides comparative error rates:
- Linear barcodes have an error rate of 1 in 2 million.
- 2D barcodes have an error rate of 1 in 10 million (due to data redundancy).
- Handwriting labels have an error rate of 1 in 200.

Barcode technology is an easy way for biospecimen repositories and labs to follow federal regulations and implement industry best practices while reducing errors and lowering costs. Barcode technology:
- Automates many manual processes
- Improves lab efficiencies
- Greatly reduces the chance of error
- Provides clear and reliable identification
- Allows scanning for instant, error-free identification and traceability
- Enables data to be automatically sent to the correct location

6. http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf

Labels Meeting Regulations

There are a number of industry standards and regulations that can be successfully met through the use of labels. Below are a few examples of how labels can be used to meet the industry's best practices.

College of American Pathologists (CAP)
In pathology and histology, tissue specimens must have a unique identifier that can be tracked, be firmly affixed to the specimen container, and endure harsh processing. The tissue must keep identification information intact for up to 20 years of storage,[7] as suggested by the College of American Pathologists (CAP) laboratory accreditation guidelines.

JCAHO 2006 National Patient Safety Goal
Use at least two patient identifiers (neither to be the patient's location) whenever collecting laboratory samples or administering medications or blood products, and use two identifiers to label sample collection containers in the presence of the patient. Processes are established to maintain samples' identity throughout the pre-analytical, analytical and post-analytical processes.[8]

ISBER Biorepository Best Practice: Where possible and appropriate, data should be electronically convertible into formats that can easily be shared among collaborating institutions. H2.100 Barcoding: Whenever possible, labels should be printed with a linear (one-dimensional or 1D) barcode that uniquely identifies the specimen. Under some circumstances, two-dimensional (2D) barcodes may be utilized. 2D barcodes have the advantage that scanning error rates may be lower and more information can be included on the label and may be optimal for use on smaller vials. Cost considerations may influence the systems selected for creating and reading barcodes.[9]

Implementing a Barcode System:

Thermal transfer technology provides superior printers, ribbon and label combinations that can withstand harsh processing environments. Here are the key components to a barcode system:

Printers

See how Washington University deployed the caBIG webservice with the Brady IP™ Printer. Brady's line of thermal transfer printers can print alphanumeric, symbols, graphics and linear and 2D barcodes, as well as crisp, indelible copy with multiple lines and characters. Thermal transfer technology uses heat to register an impression on material. A printhead containing many small resistive heating pins that contact, depending on the type of thermal transfer printer, melt wax-based ink onto ordinary paper or burn dots onto special coated material. This is a key feature that provides performance in harsh environments and solvents/chemicals. Entry-level printers such as the Brady BBP™11 Label Printer provide labs an economical and compact choice.

Software

Brady printers and software can be easily implemented with sample management programs, LIMS or LIS systems, such as Freezerworks, StarLIMS, LabWare, Co-Path or caTissue, as well as with caBIG designated SPP (support service providers) systems. There are three typical methods for outputting data onto a label:

- Set up format in LIS/LIMS and output to a printer with the windows driver provided with the printer. This will require a set format and will need updating with LIS provider for each change in design.
- PC Station middleware package that creates a 1-lane highway of information. Here the lab is able to pull data from their database to the label and has the flexibility to create label design and modify for each adjustment. An example of this software is Brady's Codesoft™ or LabelMark™ Software from MS Excel.
- Residing at server middleware package directly linked to LIS/LIMS system. This allows the lab the flexibility to create labels and also provides a 2-lane highway of information. An example of this is Brady's Sentinel™ Software package.

There are varying degrees of LIS or IT assistance depending upon the level of integration and labeling services that your LIS/LIMS company provides.

7. http://www.cap.org/apps/docs/education/lapaudio/pdf/111506_handout_format.pdf
8. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/06_npsg_lab.htm
9. http://www.isber.org/pubs/bestpractices2008.pdf, page 34.

Scanners

Data collection and barcode scanning provide the most effective form of tracking and transmitting the data directly to a database. The key to an effective scanner for laboratory applications is finding a scanner that can read small 2D barcodes on small reading surfaces. Scanners can be tethered with a wire or run Bluetooth for mobility. The optimal focus and field of view indicator on the Brady CR3500 scanner decodes a 2D barcode quickly to improve productivity.

Labels

The key to success for chain of custody, archive and retrieval of the specimen is the means to which it is identified. It is critical that the correct label material adheres to the collection and storage device to ensure that the material will survive the protocol, process and provide the longevity of the information.

Tissue Cassettes

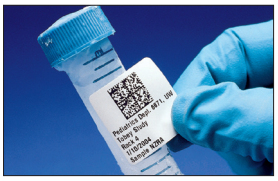
Brady's tissue cassette labels are designed to fit most tissue cassettes (45° and 35° angle) in any color. They work exclusively with the Brady Label Attachment System, the newest and most economical tissue cassette labeling solution in the industry. Brady's B482 Tissue Cassette Labels are printed and applied pre-process and will withstand the rigors of the tissue fixation and embedding process. The Brady BSP™31 Label Attachment System is unique in that it utilizes a heat staking process that forms rivets in the tissue cassette to ensure the label identification remains intact and the specimen or sample is identifiable throughout histology and anatomic pathology tissue protocols up to 20 years in storage.

Slide Labels

Brady's Stainerbondz™ B-481 Slide Labels can withstand harsh staining processing protocols and will stay adhered to slide surfaces even when soaked for an extended time in Xylene, or exposed to boiling water or the microwave. Automated serialization with Brady's solution, provides quick and easy unique identification.

Vial and Tube Labels

Brady's Freezerbondz™ thermal transfer printable labels perform well in common laboratory environments where a wide range of temperatures are used for processing, including liquid nitrogen and autoclaves. Freezerbondz labels can not only be applied at room temperature, but also on already frozen samples.



Conclusion

Brady solutions will help biospecimen repositories implement modern tracking systems to reduce pre-analysis errors and help to ensure data integrity. Labs are able to uniquely identify their specimens for input into the caBIG/caTissue repository database.

For more information, visit www.bradyid.com/lab.

Additional Resources:

http://cabig.cancer.gov/
https://cabig.nci.nih.gov/
http://biospecimens.cancer.gov/practices/
http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf
"NCI Best Practice Guidelines for Labeling Whitepaper" at http://www.bradyid.com/lab
CLIA standards, 42CFR493.1232
http://www.isber.org/pubs/bestpractices2008.pdf

Brady Worldwide, Inc.
6555 W. Good Hope Road
Milwaukee, WI 53223
1-888-272-3946
www.bradyid.com

Brady Canada
355 Apple Creek Blvd.
Markham, ON L3R 9X7
1-800-263-6179
www.bradycanada.com

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