WHITE PAPER

ENTITLED

"LABELING OF BIOLOGICAL SPECIMENS"

(BASED ON PRESENTATIONS & DISCUSSIONS FROM THE JUNE 13, 2003 SAIC-FREDERICK LABEL WORKSHOP)

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SECTION TITLE

I. Purpose: To provide necessary technical and product-related information to be able to standardize labels used on various types of biological specimens collected by the National Cancer Institute (NCI) and their collaborators for NCI-directed studies.

II. Scope: This White Paper presents information for optimized label configuration, supplies and equipment needed for the following four specimen storage vessels or devices at different temperatures commonly used by the NCI: 1.) Small vials that hold volumes <1.0 ml, 2.) Cryovials that hold volumes between 1.0 – 2.0 mls, 3.) Microscope slides and 4.) Paraffin tissue blocks.

III. Historical Overview: Necessity for a White Paper on NCI specimen labeling arose from the need to provide Investigators, Study Managers, and Repositories associated with NCI-directed studies a convenient, centralized location for label relevant information in an effort to standardize all specimen labels, with regard to size, eye read-able information, two-dimensional barcode encryption, supplies and equipment.

IV. Relevant Technical Information:

A. Labels – Labels recommended in this White Paper are of a type made up of five layers of material attached to a two-layer carrier (the paper-like surface a label is attached to when purchased) as depicted in Figure 1 below. Materials used for each layer of a label are specifically chosen to properly interact with each adjacent layer in order to achieve maximum performance specifications. Overall successful application and user satisfaction with label performance is related to the type of specimen being labeled and its corresponding storage temperature. The label (and its composite materials) must be chosen based upon its intended use and the conditions to which it will be exposed. Likewise, the label must be appropriately matched to a carrier so that the label is securely attached to the carrier, but can easily be released for application to a specimen container.

A brief overview of the function of each layer of label and carrier is provided as follows: 1.) The Topcoat is the outermost layer of the label that accepts the print. It can be smooth, rough, hard, or soft depending on the intended use. 2.) The First Primer is the layer of the label that contains the adhesive that holds the Topcoat to the Substrate. 3.) The Substrate is the layer of the label that consists of the material, which was selected to withstand environmental exposures that will be encountered during the life of the label. Typical types of Substrates that are used are: polyester, vinyl, paper, polypropylene and nylon. 4.) The Second Primer is the layer of the label unites the Substrate to the Adhesive. 5.) The Adhesive is the layer of the label that contains the adhesive, which attaches the label to the carrier until it is ultimately applied to the specimen's storage container. 6.) The Release Coat is the first layer of the Carrier and it interacts with the label's Adhesive so that the label sticks to the Carrier but allows the label to easily be removed for its permanent application on the specimen or its container. 7.) The Liner is the second layer of the Carrier. It is composed of paper or polyester and covered with a Release Coat, which allows the label to adhere to the Liner after the label is manufactured so that the label can be delivered to the customer.

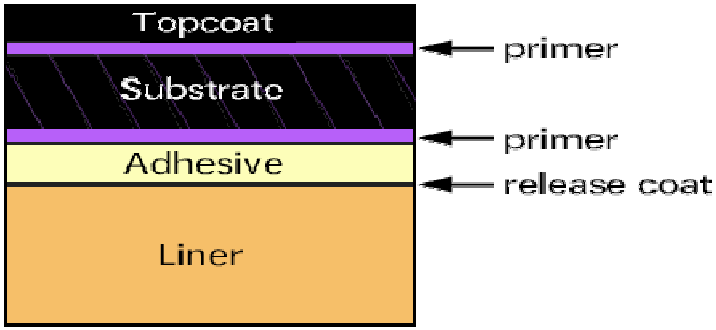

Figure 1: Construction of a Typical Label

B. Barcodes – Barcodes were invented in the early 1950s and have greatly facilitated the exchange of information. Two basic kinds of barcodes that are discussed in this White Paper, i.e., one-dimensional (linear) and two-dimensional. Each barcode, regardless of kind, is based on a particular symbology or rule that describes how a character, e.g., letter, number or punctuation, is defined and therefore presented for scanning. For example, a one-dimensional/linear barcode is comprised of a series of varying width and height vertical lines (bars) and spaces, which when scanned equate to a letter or symbol. Different combinations of the bars and spaces represent different characters that when decoded translates to a unique series of numerics or alpha and numerics, which are used to identify a particular specimen or vial, e.g., specimen ID. It is also important to have at least a ¼" of clear space (Quiet Zone) on each end of a one-dimensional barcode. This space defines the beginning and end of a barcode. Most retail stores use this type of barcode, which is limited to between 15-to-50 character capacities depending on the symbology that is used. Typically, barcodes include a check digit at the end of the encrypted information to validate that all of the preceding characters were decoded correctly. They also include an "interpretation line," i.e., encoded information printed in human readable characters printed directly below the barcode. An example of a one-dimensional barcode with Code 128 symbology is presented in Figure 2 below. It is important to note that choosing to place one-dimensional barcodes on small vials may result in labels that are difficult or even impossible to scan (depending on the orientation of the label, i.e. vertical or horizontal to the axis of the container, respectively). Additionally it can result in ergonomic problems for staff required to inventory a large number of vials. For this reason a one-dimensional barcode is not the recommended barcode for NCI.

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Figure 2. Example of a One-Dimensional (Linear) Barcode using Code128 symbology

However, a two-dimensional barcode is recommended for NCI studies. It has a higher "data density" than any one-dimensional symbology and permits a smaller and more flexible barcode. In fact, it can encode 20 times the information in the same amount of space as compared to a one-dimensional barcode. This is especially important for small diameter vials used by NCI, e.g., robot tubes. A single two-dimensional barcode is able to encode up to 3,116 numeric or 2,335 alphanumeric characters. Basically, a two-dimensional barcode has improved scanning accuracy because it consists of four quadrants. Each quadrant can encrypt the same information to provide up to four-fold redundancy. The amount of redundancy in a barcode, typically termed Error Correction, is expressed as a percentage. This White Paper recommends that the label printer be set for a 200% Error Correction (Click here for more information on ECC). Up to 60% of the barcode is damaged; a scanner will still be able to read the encrypted information on the label using the remaining half of the label. This is due to data redundancy. A two-dimensional barcode is also able to encode photographs, fingerprints, signatures, etc. and can be used in any language or combination of languages. An example of a two-dimensional barcode using Data Matrix symbology is presented in Figure 3 below. The focal nature of a two-dimensional barcode enables the staff to scan large collections of labeled vials or specimens with minimum ergonomic impact.

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Figure 3. Example of a Two-Dimensional Barcode using Data Matrix symbology

V. Label Materials and Formats for Specimen ID:

This section presents in table format, each of the four types of NCI commonly used specimen storage vessels or devices their corresponding recommended Brady Product information. The table includes: Brady B# (Product Number), Laboratory Application, Special Properties, Recommended Environments/Temperature and Surfaces Recommended. Linked to each Table is a Figure that contains an illustration and description of recommended label type and configuration associated with a particular application. The Label/Format Details include the Label Size Configurations, Recommended Printing Font, Data Matrix Size (used to size the bar code relative to the label size and the quantity of information that needs to be encrypted), Error Correction (the percent redundancy of encrypted information, 200 is the maximum amount that is referred to as ECC200 [and suitable for NCI] which means over half of the label can be destroyed and it should still be decodable), and Quiet Zone (amount of clear space around a bar code needed to ensure a clean scan) of approximately 1 cell or greater.

A. **Small Vials – <1.0 ml (PCR and microfuge tubes, robot tubes, and Eppendorf vials):** The materials below are suggested for smaller vials that need to house <1.0 ml of liquid, which typically are used in molecular applications or with various types of robotics. Each material will resist mechanical freezer (-80°C) temperature and many will resist liquid nitrogen temperature (-196°C) exposures, as well as warmer temperatures (80°C to 121°C) used during polymerase chain reaction (PCR)-formatted testing. To identify the best material for a particular application, please review Table 1 below, which provides unique performance characteristics. Once the label material has been chosen, select the proper size and design of the label so that it fits the vial that is to be used for the study. We encourage you to verify performance by testing labels in your specific application. Suggested labeling configurations are presented below (Figure 4 and 5). The labels in Figure 4 (Option A, B and C) is a single application, which is applied around the body of the vial; whereas, the label in Figure 5, is designed as two parts. In the latter case, there is a rectangular label, which is applied to the body of the vial and a round label that can be adhered to the cap. This two-piece label can be used either together (Option A) or separately (Options B and C). An advantage to the label pair configuration is the ability to identify a vial from two different vantage points, thus reducing the amount that a vial is handled. The disadvantage is that one can mix up the label parts during application, which can result in a vial that is labeled with two different identifiers.

   Frequently, vials stored at extreme temperatures need to be labeled or relabeled. For these cases, included in Table 1, there are two products identified as B490 and B492, which can directly label or relabel a specimen stored at temperatures ranging from 121°C to –196°C. Of these 2 products, B492 does not need to wrap onto itself. A second type of product option is B427 or B461 that can also be applied to a frozen vial, but only adheres by having the label tightly wrapped onto itself rather than attaching directly to the vial or specimen, i.e., it has a clear wrap-around adhesive tail which overlaps the printed label. These are referred to as self laminating labels.

Table 1. A summary of various types of labels and their appropriate applications for <1.0 ml vials.

Brady B#	Laboratory Application	Recommended Ribbon(s)	Special Properties	Recommended Environments	Surfaces Recommended	Temp. Range
B499	Vials, tubes, conical, boxes and other general laboratory applications	B4300 series	Permanent adhesive, easy to handle, conformable, excellent contrast	Freezer, liquid nitrogen (liquid/vapor)	Glass, polypropylene, other plastics, metal	-196℃ to 80℃
B461	Vials, tubes, straws conical, slides	R4300 series	Permanent adhesive, self laminating, conformable, low profile, excellent solvent resistance	Freezer, liquid nitrogen (liquid/vapor), ice baths, autoclave, water baths	Glass, polypropylene, other plastics, metal	-196℃ to 121℃
B490	Vials, tubes, conical and bottles	R4300 series	Permanent adhesive, conformable, low profile, excellent contrast, write-on capabilities, ability to adhere to frozen samples	Freezer, autoclave, liquid nitrogen (liquid/vapor), hot water baths, ice baths	Glass, polypropylene, other plastics, metal, easily adheres to frozen samples if only slightly wrapped around itself	-196℃ to 121℃
B492	Slides, vials, tubes, conical and bottles	R6400 series suggested (R4300 accepted for limited solvent exposure)	Permanent adhesive, conformable, low profile, excellent contrast and material very opaque, ability to easily adhere to frozen samples	Freezer, autoclave, liquid nitrogen (liquid/vapor), hot water baths, ice baths	Glass, polypropylene, other plastics, metal, easily adheres to frozen samples	-196℃ to 121℃

Figure 4. Label options for <1.0 ml PCR, microfuge, and robot tubes

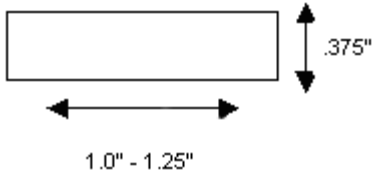
Option A  	Recommended Label Size /Part Numbers Label /Format Detail Option A - 0.375" x 1.8", Brady Stock Part Number THT-123-461-3 THT-123-461-1.5-SC Materials: B461 Ribbon: Brady R4300, R4313 Recommended Font: Triumvirate Condensed Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater
Option B  	Option B - 0.375" x 1.0", Brady Stock Part Number THT-152-499-3, THT-152-499-1.5-SC 0.375" x 1.25", Brady Stock Part Number THT-154-490-3 THT-154-490-1.5-SC 0.375" x 1.0", Brady Stock Part Number THT-152-492-3 THT-152-492-2.5-SC Materials: B499, B490, B492 are all acceptable Ribbon: Brady R4300 (B461, B427, B490, B499), R6400 (B492), R4313, R6413 Recommended Font: Triumvirate Condensed Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater

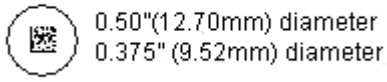
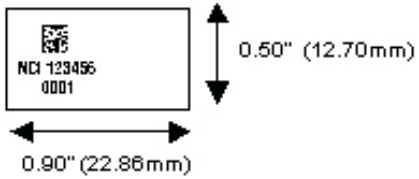
Figure 5.

Option A

Label /Format Detail

Recommended Label Size/Part Numbers:

Option A -	0.90" x 0.50" (vial side label) with 0.50" x 0.50" (top of vial label), Brady Part Number THT-126-499-3
	1.0" x 0.50" (vial side label) with 0.375" x 0.375" (top of vial label), Brady Part Number THT-163-499-3
	1.0" x 0.375" (vial side label with 0.375" x 0.375" (top of vial label) *Brady* THT-163-492-3*, sticks to already frozen vials*
Material:	B499 for new vials, B492 for new or, frozen vials
Ribbon:	Brady R4300 (B499), B6400 (B492 only)
Recommended Font:	Triumvirate Condensed Preferred, Minimum 6 Point Font (note option B format uses 5 pt. font)
Data Matrix Size:	8.3 Minimum Narrow Bar
Error Correction:	Level 200
Quiet Zone:	1 Cell or Greater

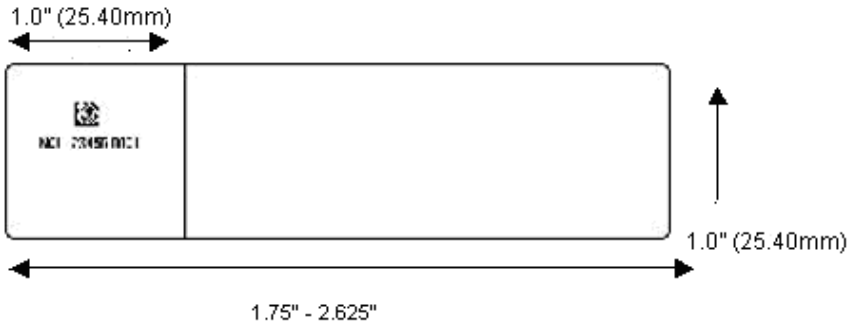
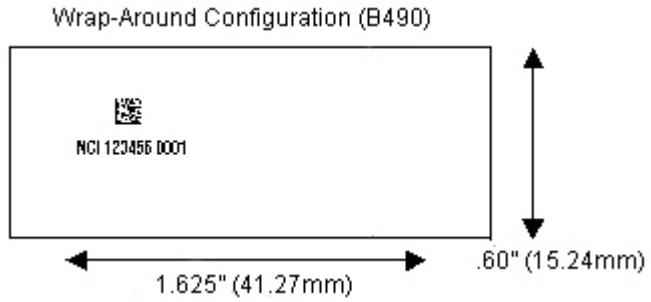
Option B Vial Top Label  0.50"(12.70mm) diameter 0.375" (9.52mm) diameter	Label /Format Detail Recommended Label Size/Part Numbers: Option B - 0.50" x 0.50" (top of vial labels), Part Number THT-144-499-3 THT-144-499-1.5-SC 0.375" x 0.375" (top of vial labels), Part Number THT-143-499-3 0.375" x 0.375" (top of vial labels), Part Number THT-143-492-3 THT-143-492-1.5-SC *Note that this material label option adheres to frozen vials* 0.50" x 0.50" (top of vial labels), Part Number THT-144-492-3 THT-144-492-1.5-SC *Note that this material label option adheres to frozen vials* Material: B499 for new vials, B492 for new or, frozen vials Ribbon: Brady R4300 (B499), R6400 (B492 only), R6013, R6413 Recommended Font: Triumvirate Condensed , Preferred, Minimum 5 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater
Option C: Vial Side Label Only Vial Side Label Only  	Option C - 0.90" x .50" – vial side only label – Brady Part Number THT-125-499-3, THT-125-499-1.5-SC 1.0" x .50" – vial side only label – Brady Part Number THT-59-492-10, THT-59-492-2.5-SC *Note that this material label option adheres to frozen vials* Material: B499 for new vials, B492 for new or, frozen vials Ribbon: Brady R4300 (B499), R6400 (B492 only), R4313 Recommended Font: Triumvirate Condensed , Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater

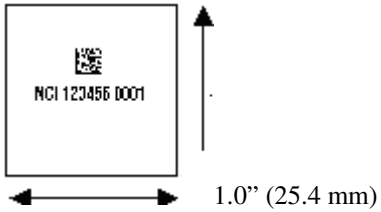
B. **Standard Vials - 1.0 – 2.0 ml (Cryovial)**: The materials below are suggested for use on a standard size cryovial that can house ≥1.0 ml but ≤2.0 mls of fluid. Each listed material will withstand exposure to mechanical freezer (-80°C) and liquid nitrogen (-196°C) freezer temperatures. Typically, this size cryovial is used to store serum, plasma or cryopreserved peripheral blood mononuclear cells. This is probably the most widely used vial size, especially for long-term specimen storage. Review the unique performance characteristics in Table 2 below in order to choose the best material for both storage and testing applications for this container type. Due to the similarities in vial usage, the same type of labels is recommended for the Standard Vial as for the Small Vial or Centrifuge tubes. We encourage you to verify performance by testing labels in your specific application. Once the label material has been chosen, then select the proper size and design of the label to fit the vial that is to be used in the study. Figure 6 contains an Illustration and Label/Format Detail for different label options, e.g., Self-Laminating and Wrap-Around Configurations. The main difference between the options occurs when a frozen vial needs to be relabeled. The Self Laminating Configuration label (B427 and B461) uses a clear adhesive tail that wraps over the entire label and adheres to itself rather than directly to the frozen vial. Whereas, the Wrap-Around Configuration (B490) adheres directly to a frozen vial as long as the label slightly wraps onto itself by 1/10". There is another material for the labeling of frozen vials that is the B492. This material does not need to wrap upon itself. It can be adhered to the frozen vial, leaving a "window" to view contents of the vial.

Table 2. A summary of various types of labels and their appropriate applications for 1.0 – 2.0 ml vials.

Brady B#	Laboratory Application	Recommended Ribbon(s)	Special Properties	Recommended Environments	Surfaces Recommended	Temp. Range
B499	Vials, tubes, conical, boxes and other general laboratory applications	B4300 series	Permanent adhesive, easy to handle, conformable, excellent contrast	Freezer, liquid nitrogen (liquid/vapor)	Glass, polypropylene, other plastics, metal	-196℃ to 80℃
B461	Vials, tubes, straws conical, slides	R4300 series	Permanent adhesive, self laminating, conformable, low profile, excellent solvent resistance	Freezer, liquid nitrogen (liquid/vapor), ice baths, autoclave, water baths, and flash freeze	Glass, polypropylene, other plastics, metal	-196℃ to 121℃
B490	Vials, tubes, conical and bottles	R4300 series	Permanent adhesive, conformable, low profile, excellent contrast, write-on capabilities, ability to adhere to frozen samples	Freezer, autoclave, liquid nitrogen (liquid/vapor), hot water baths, ice baths, and flash freeze	Glass, polypropylene, other plastics, cardboard box, room temperature metal, easily adheres to frozen samples if only slightly wrapped around itself	-196℃ to 121℃
B492	Slides, vials, tubes, conical and bottles	R6400 series suggested (R4300 accepted for limited solvent exposure)	Permanent adhesive, conformable, low profile, excellent contrast and material very opaque, ability to easily adhere to frozen samples)	Freezer, autoclave, liquid nitrogen (liquid/vapor), hot water baths, ice baths, flash freeze	Glass, polypropylene, other plastics, room temp metai, easily adheres to frozen samples, (not recommended for frozen metal)	-196℃ to 121℃

Figure 6. Two label options for 1.0 – 2.0 ml cryovials.

Option A  	Label/Format Detail Recommended Label Size/Part Numbers: Option A - 1.0" x 2.625 "(Self-Laminating Configuration) Brady Part Number THT-131-427-3, THT-131-461-3, THT-131-427-1.5-SC, THT-131-461-1.5-SC OR THT-183-461-1 – 1" x 1" white area by 1.75" tail Material (s): B427, B461 for new vials and B490 or B492 for new or Frozen vials. Ribbon: Brady R4300, R4313 Recommended Font: Triumvirate Condensed Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater
Option B  	Label/Format Detail Recommended Label Size/Part Numbers: Option B - 0.60" x 1.625", Brady Part Number THT-155-490-3 THT-155-490-1.5-SC Material (s): B490 for new or frozen vials Ribbon: Brady R4300, R4313 Recommended Font: Triumvirate Condensed Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater

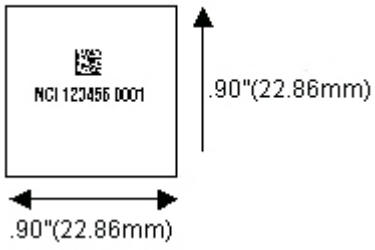
Option C	Label/Format Detail
	Recommended Label Size/Part Numbers: Option C - 1.0" x 1.0", Brady Part Number THT-179-492-3 THT-179-492-2.5-SC Material (s): B492 for new or frozen vials Ribbon: R6400, R6413 Recommended Font: Triumvirate Condensed Preferred, Minimum 6 Point Font Data Matrix Size: 8.3 Minimum Narrow Bar Error Correction: Level 200 Quiet Zone: 1 Cell or Greater

C. **Microscope Slides**: The material described below is suggested for labeling a microscope slide because it is best suited for a wide range of processing and testing applications. Review the unique performance characteristics given in Table 3 below especially they relate to solvent resistance required during staining and de-staining such as H&E and IHC. Once the label material has been chosen and is acceptable for processing at various temperatures needed, then select the proper size and design of the label to fit the microscope slide that is to be used. Note that B481 will have the highest level of performance. Please see Figure 7 for layout of label format, material and size information.

Table 3. A summary of label type and its appropriate application for microscope slides.

Brady B#	Laboratory Application	Recommended Ribbon(s)	Special Properties	Recommended Environments	Surfaces Recommended	Temp. Range
B488	slides, well plates, bottles, conical	R4300 series	permanent adhesive, good contrast, ideal for flat surfaces, write-on capabilities, smooth topcoat, excellent solvent resistance, white polyester	slide id - moderate solvent resistance, freezer	glass, polypropylene, other plastics	-80℃ to 100℃
B481	vials, tubes, straws conical	R6400 series	permanent adhesive, good contrast, ideal for flat surfaces, write-on capabilities, smooth topcoat, superior solvent resistance, white polyester, most suitable for wide variety of staining protocols.	slide id - moderate extreme resistance, freezer	glass, polypropylene, other plastics	-80℃ to 100℃

Figure 7. The recommended label option for microscope slides.



Label /Format Detail

Recommended Label Size/Part Numbers:

Label Size:	0.90" x 0.90". Brady Part Number THT-141-488-3, THT-141-481-1.5-SC 0.90" x 0.90". Brady Part Number THT-164-481-3, THT-164-481-2.5-SC
Material:	B488 or B481
Ribbon:	Brady R4300 (B488), R6400 (B481), R6413
Recommended Font:	Triumvirate Condensed Preferred, Minimum 6 Point Font
Data Matrix Size:	8.3 Minimum Narrow Bar
Error Correction:	Level 200
Quiet Zone:	1 Cell or Greater

* other sizes available on line

D. **Tissue Cassette Identification**

Pre-process Tissue Cassette labels are applied before fixation and embedding. Labels are secured to tissue cassette via the BSP31 Label Attachment System.

Post–process Tissue Cassette labels or Tissue Block De-identify and Re-identify Labels are recommended for ***after it has been embedded in paraffin***.

Please review the information presented in Table 4 below for unique performance characteristics of the material, especially as they are related to temperature since paraffin blocks tend to be stored at –80°C and can also be subjected to a heat block for needed sample processing. Please see Figure 8 for pertinent layout of Label/Format Detail. Note that after 60°C the paraffin wax can begin to melt.

Table 4.1. A summary of label type and its appropriate application for pre-process of paraffin tissue cassettes

Brady B#	Laboratory Application	Special Properties	Recommended Environments	Surfaces Recommended	Temp. Range
B482	Tissue Cassettes/Paraffin blocks	Use with BSP31™ Label Attachment System for label adherence permanence. Manually Print and Apply to face of tissue cassette. Label provides clear crisp alphanumeric text as well as barcodes	Up to 200 cassettes per day per BSP31 System. Tissue Processing, Fixation, Embedding	Acetal (plastic) Tissue Cassettes	TBD 35° C to 60° C

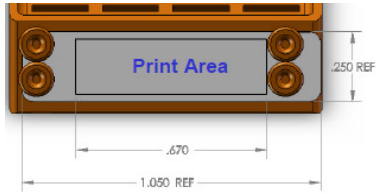
Table 4.2. A summary of label type and its appropriate application for reidentification of paraffin tissue blocks.

Brady B#	Laboratory Application	Special Properties	Recommended Environments	Surfaces Recommended	Temp. Range
B498	Slides, bottles, plates, boxes, conical tubes, and tissue cassettes/paraffin blocks. Reidentify Tissue Blocks	Removable from flat surfaces, good contrast, smooth topcoat, write-on capabilities, and white vinyl cloth. Adhere to waxy surface	Mechanical freezer storage and heat block treatment. Post Process Tissue Blocks	Glass, polypropylene, other plastics, and metal. Parrifin Wax Surface	-70°C to 80°C - TBD ◦C to 60◦C

Figure 8. The recommended label option for paraffin-embedded tissue blocks.

Recommended Label Size/Part Numbers:

Label Size:	0.984" x 0.192", Brady Part Number Y366419 (B498 Custom Label) *Note: this custom size exactly fits the front slope on cassette* *Note that other stock sizes are available if you have a larger surface to adhere to: Those Options are listed below:* 1.0" x 0.50" –Brady part Number THT-5-498-10 0.75" x 0.25" – Brady Part Number THT-1- 498-10 0.65" x 0.20" – Brady Part Number THT-14-498-10 1.0" x 0.375 – Brady Part Number THT-88-498-5
Material:	B498 Preferred
Ribbon:	Brady R4300
Recommended Font:	Triumvirate Condensed Preferred, Minimum 6 Point Font
Data Matrix Size:	8.3 Minimum Narrow Bar
Error Correction:	Level 200
Quiet Zone:	1 Cell or Greater



Recommended Label Size/Part Numbers:

Tissue Cassettes	Standard 35◦ and 45◦ degree angle
Label Size: Brady Part Number	1.050" W x 0.250" H THT-199-482-3 (3" core) THT-199-482-3-SC
Material: Complementary Product	B482 Tissue Cassette Label Affix label to cassette with Brady BSP31 Label Attachment System
Ribbon: Recommended Font:	Brady R6400, R6413 Triumvirate Condensed Preferred, Minimum 6 Point Font
Data Matrix Size: Error Correction: Quiet Zone:	8.3 Minimum Narrow Bar Level 200 1 Cell or Greater

For laboratory labeling applications or product not listed on this document, please see our Brady Laboratory Products Website or to view the video on slide and tissue cassette

VI. Suggested Printing Hardware

For each labeling project, there are several printing-related questions that need to be answered before a plan can be formulated to print the appropriate type, format(s) and quantity of needed labels. A few basic questions must be answered before beginning:

- Should printing of labels be out sourced to a commercial printing expert or done in-house?
- What are the associated costs for each, e.g., labor, materials/supplies and equipment?
- If labels are printed in-house, should the printing be centralized (repository or data-coordinating centers) or performed at multiple locations (study sites)?
- What type of Quality Assurance/Quality Control needs to be instituted for each situation, to ensure that so duplicated specimen identifiers are not used and/or poor quality labels are not generated?

In-house printing generally takes place at or near the point of use. The data encoded are usually variable, entered by an operator through a keyboard or downloaded from the host computer. The most common bar code print technologies for in-house use are:

- Dot Matrix — a moving print head, with one or more vertical rows of hammers, produces images by multiple passes over a ribbon. These passes create rows of overlapping dots on the substrate to form an image. Serial dot matrix printers produce images character by character; high-volume dot matrix line printers print an entire line in one pass. The advantage to this type of print is that it is inexpensive but the print tends to be of poor quality with very little flexibility. *Not Recommended*

- Ink Jet — this technology uses a fixed print head with a number of small orifices that project tiny droplets of ink onto a substrate to form an image made up of overlapping dots. Ink jet printers are used for in-line direct marking on products or containers. This type of print results in a label with poor contrast and durability. The print is not resistant to solvents and can smear if the ink does not dry completely. *Not Recommended*

- Laser (Xerographic) — the image is formed on an electrostatically charged, photoconductive drum using a controlled laser beam. The charged areas attract toner particles that are transferred and fused onto the substrate. The advantages of this type of printer are its wide equipment availability and excellent print quality. However, it has limited print permanence and generates a high number of waste labels since it cannot print a single label. It is not well suited for the wide range of temperatures to which biological samples are subjected. *Not Recommended*

- Direct Thermal — Heating elements in the print head are selectively heated to form an image made from overlapping dots on a heat-sensitive substrate. This type of printing is normally seen with paper applications and does not require a ribbon but causes increased wear on the print head resulting in its replacement. The limitations of this type of printing are limited substrate choice, questionable cleanliness of materials, and short life expectancy of the printed label. *Not Recommended for long term storage requirements*

- Thermal Transfer — Thermal Transfer technology uses much of the same type of print head as Direct Thermal, except that an intervening ribbon with resin-based or wax-based ink is heated and transfers the image from the ribbon to the substrate. Thermal Transfer produces the most stable image for a variety of environments and allows for variation in substrate and ribbon formulations to meet the needs of different applications. It offers crisp resolution with 200 – 600 dots per inch, high speed, excellent print quality and the highest read-rate in bar coding. Waste material is controllable. There is a higher cost associated with Thermal Transfer printing as a result of the need to match ribbon and substrate requirements and compatibility. Additional operator training is required with this type of printing. Preventative maintenance is critical to ensure print quality. ***Overall, Thermal Transfer is the method recommended by this White Paper***

Another issue that is often overlooked, in both outsourcing and in-house printing, is waste. Waste may occur through obsolescence of the data on the labels, degradation during storage (for a variety of reasons), application problems and other factors. Some figures suggest that as much as 10% should be added to the cost of printed labels for waste or obsolescence due to improvements in labeling technology. This figure may be either high or low depending on quantities, training of personnel, or the need to frequently rethread the printer when label stocks are changed. To avoid the latter problem and decrease waste, it is recommended that dedicated printers be used for each specific label design and label stock.

Suggested on-site printers for specimen container labeling are presented below, which is based on the number of labels needed in a single day, e.g., low, medium and high volumes. Associated web links are given to provide relevant product information. Note all recommendations are for Thermal Transfer Printers. The model and style of printer is related to the quantity of labels needed. At the bottom of this section is some valuable preventative maintenance information.

A. Low Volume Requirements – up to 100 labels/day

LabXpert™ Printer

1. Portable Printer – 2.5 lbs
2. USB
3. 300 DPI
4. Cartridge based material for ease of use
5. Click here for label choices specific to this printer

B. Low - Medium Volume Requirements – up to 2000 labels/day

BBP11™ Printer

1. Desktop Printer – 5.5 lbs, small footprint
2. USB, Ethernet 10/100
3. 300 DPI
4. 1' core materials and ½" core ribbon
    a. (material part numbers ending in "–sc")

C. Medium to High Volume Requirements – up to 5000 labels/day

IP™ 300 or IP™ 600 Printer

1. Desktop Printer – 16 lbs.
2. Small Footprint – opens from top
3. Serial, USB 2.0 and Ethernet 10/100
4. 300 or, 600 DPI
5. Uses Smart Cell Technology (RF ID) for minimal label waste and auto position printing, "load, click and print!"

D. Preventative Maintenance for all benchtop thermal transfer printers

1. Brady 360 Customer Care Solutions
2. Print head care and maintenance
3. Knowledge base

VII. Data Collection Hardware and Suggested Software

A. **Data Collection Hardware:** Below are suggested types of handheld imagers for scanning two-dimensional and/or one-dimensional or only one-dimensional barcodes. This hardware information is based on input from various contractors and is linked to their website for additional product information.

1. Suggested Hardware – CodeReader Imagers
   a. CR1200 Entry Level Imager
   b. Codereader 2500
   c. Codereader 3500 with data screen
   d. Codereader User Instruction Manuals

2. Background information
   a. Scanner and Barcoding Technology – Aim Global
   b. "Online" classroom training on Barcoding Related Topics – website that has on-line training courses about barcodes and their uses. The information is good for the novice and the experienced barcode user.
   c. Whitepapers on Bluetooth Technology - "Bluetooth" is the code name for a technology specification for small form factor, low-cost, short-range radio/wireless links between portable or desktop devices that allows for the transfer of information. The initiative for the standard belongs to the Bluetooth SIG (Bluetooth Special Interest Group). This website presents information on how to use this technology.
      i. Frequently asked questions
      ii. Case Studies, applications papers and whitepapers

VIII **Suggested Software:** Also provided in this section is an example of how Brady's software packages (listed below) can integrate with various Laboratory Information Management Systems (LIMS) to offer convenience in printing labels.

Envision the power of having a single integrated database system common throughout a large clinical trial that has the capability to develop, track, and print labels. Imagine having the ability to globally share clinical trial samples without the potential for duplicate sample numbers. Think of the time that can be saved by using a bar-coded label packed with all the pertinent information that eliminates the need for re-labeling, and provides a vial that can be seen because there aren't multiple labels stuck on it. These concepts are exactly what prompted BBI Biotech Research Laboratories (BBI Biotech, a government contractor who processes and stores NCI samples), Information Management Services (IMS, a government contractor who designed and maintains the Biological Specimen Inventory System version II [BSI-II] for NCI) and Brady Corporation (Brady) to collaborate. If you want to learn more about how these three companies integrated label printing with their LIMS, please contact them directly (www.bbii.com, www.imsweb.com, and www.bradyid.com/lab).

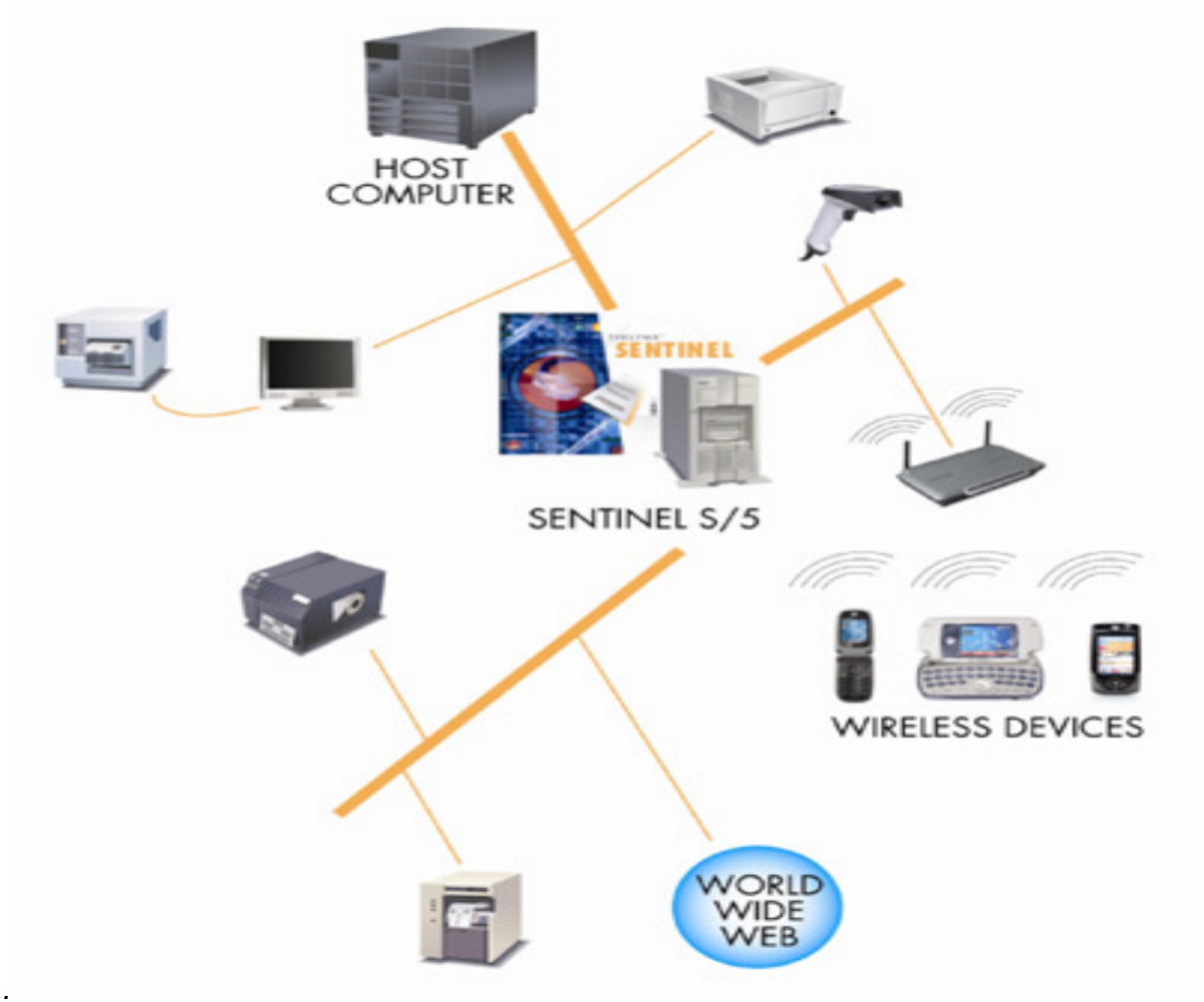
Many repositories and laboratories use BSI-II, not only to track samples from an inventory perspective, but also because BSI-II has a label/sample identification reserve. BSI-II has the capability to reserve blocks of printed numbers, so a duplicate number cannot be issued. This capability is critical, because when dealing with 50 or 100 studies that all need to develop labels at multiple locations, control of the process must be established. By providing a system that interfaces with labeling software and hardware, the user can design formats that utilize a variety of label materials for different applications and even harsh environments.

a. For this effort, Brady's **Codesoft ™ Label Design and Integration Software** was chosen because it includes such features as printing text, bar codes, two-dimensional bar codes and ODBC data linking importing to Excel, Access, SQL, or any windows compliant database product. Another important feature is that Codesoft™ can be integrated with a Laboratory Information Management System (LIMS) or Laboratory Information System (LIS) to print labels on demand. With three levels to choose from, Codesoft ™ can be the design and print foundation of any tracking solution.

b. In addition, Brady's Sentinel™ can be used as the distributive printing middleware to capture the needed data and to automate the printing of labels created with this label design software. This approach can be used on any LIMS, LIS/HIS system. Sentinel™ allows the user to send data from the host application into Codesoft™ label designs without leaving the host system. This is done by connecting the data from an application to the Codesoft™ printing functions through an ActiveX protocol between the two modules. Sentinel™ multithreaded architecture allows labels to be printed simultaneously throughout a facility to over 2000+ different thermal printers, any Windows®- or Macintosh-supported printer. Multiple applications can send transactions to the print server without compromising performance.

This information is presented to demonstrate how label making can be integrated into an inventory tracking system, LIMS or LIS. A similar configuration may be possible for your operations.

Figure 9. Diagram of how Brady Sentinel works.



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Below are Internet links to the specific label-relevant software.

1. Barcode/Labeling Software
   c. Codesoft ™
      1. Codesoft Features Comparison
      2. Related Information

2. Integration Software Package:
   a. Sentinel 5 ™
      a. Sentinel Overview
      b. Sentinel Users Manual & Guides
      c. Sentinel Whitepaper

If the products that are discussed in this White Paper are not used, an industry equivalent needs to be obtained for a comparable performance.

VIII. Additional Resources

National Cancer Institute Best Practices for Biospecimen Resources: https://cissecure.nci.nih.gov/ncipubs/detail.aspx?prodid=P103
Benefits of Barcoding - http://www.bradyid.com/bradyid/cms/contentView.do/8106/Laboratory.html
Lab Automation and Barcoding Efficiency webinar http://www.bradyid.com/bradyid/cms/contentView.do/8168/Laboratory.html
BSP31 and Tissue Cassette Video – www.bradyid.com/specimenlabeling
Software training on archiving, approval, history and security http://www.teklynx.com/top_pages/training.html
AIM Global Datamatrix Barcode Standards http://www.aimglobal.org/technologies/barcode/2d_symbologies_matrix.asp
Data capture information - Bioinformatics Support for Life Sciences http://www.saic.com/news/resources.asp#

For more information on labels, hardware or software included in this whitepaper,
Please visit www.bradyid.com/lab or contact Brady customer service by phone at 1-888-272-3946.