Nationwide Children's Hospital Biospecimen Core Resource Training

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Team Science: A Collaboration in Medical Genomics

Sponsored by the National Cancer Institute, the National Institutes of Health

NATIONAL CANCER INSTITUTE

Nationwide Children's Hospital (NCH) Biospecimen Core Resource (BCR)

The BCR will oversee the acquisition of appropriately consented, standardized and meticulously collected biospecimens (patient tumor and /or normal control samples) and associated clinical data. They will also ensure quality transport and preservation of samples. An independent quality assurance check on these samples will occur prior to the isolation of analytes (DNA and RNA) to be distributed to the Sequencing and Characterization Centers. Samples will be de-identified with removal of protected health information (PHI) prior to distribution

Established Tissue Banks/Medical centers contracted through NCI/Leidos

leidos
Leidos Biomedical Research, Inc.

Genome Characterization and Sequencing Center (GCC and GSC)

Several characterization technologies may be used to analyze the copy number, methylation, miRNA and/or expression changes associated with cancer and high-throughput genome sequencing centers will identify the mutations in DNA associated with specific types of cancer.

Data Management, Bioinformatics and Computational Analysis at the Data Coordinating Center (DCC)/ Genomics Data Commons (GDC)

The information that is generated by genomics projects will be centrally managed and entered into public databases as it becomes available, allowing scientists to access the information during the course of a project.

Scientists will analyze the complete set of genetic and clinical data produced by the genomics projects to develop a comprehensive web-based resource which will be available to the scientific community. Researchers will use the information to accelerate advances in cancer diagnosis, treatment, and prevention.

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The role of the BCR

- The BCR acts as a centralized facility using uniform protocols to receive and process all tissues and clinical data
- The BCR collects all regulatory documents prior to shipping (Material Transfer Agreement and IRB approval documentation if applicable)
- The BCR is the liaison to all contributing sites from which it receives tissue samples and clinical data

Pathology Validation

- Tumor nuclei and percent necrosis are verified by BCR contracted pathologists for qualification using designated tumor metrics

Note: If a significant diagnostic discrepancy is found during the BCR review process, the Tissue Source Site (TSS) will be informed

Analyte Processing

- Samples are processed into molecular analytes using strict quality controls
- Molecular analytes (RNA and DNA) are distributed for genomic analysis to:
  - Genome Characterization Center (GCC)
  - Genome Sequencing Center (GSC)

Clinical Data Collection (If applicable)

- Clinical data elements associated with qualified cases are submitted to the BCR
- Quality Control is performed on submitted data
- Data are uploaded to the Data Coordinating Center (DCC)/Genomics Data Commons (GDC)

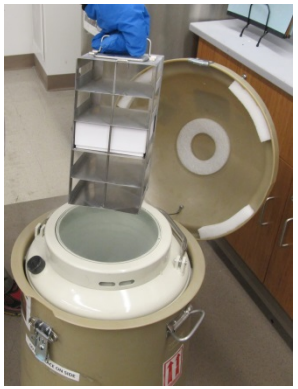
Clinical Assays (project specific)

- Micro Satellite Instability (MSI)
- Human Papillomavirus (HPV)

General sample and shipping Information

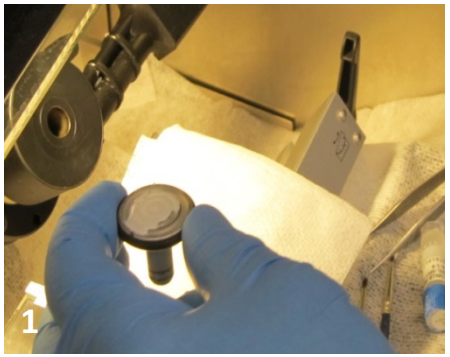
- All samples must be prescreened prior to shipping to the BCR. The Tissue Source Site (TSS) pathologist should review a physical top slide or image to confirm diagnosis and review for the presence/absence of tumor nuclei in both tumor or normal samples.
- Each sample must arrive with shipping information (manifest or electronic file).
  - If applicable the TSS should ship top slide and pathology report with sample(s).
- Please contact the BCR to discuss shipping procedures:
  - Frozen samples – cryoport (please use LN_2 resistant containers- no glass)
  - Ambient blood – ambient (or with cold pack in hot weather months)
  - Tissue scrolls – ambient (or with cold pack in hot weather months)
  - Glass slides or whole slide images (hard drive) – ambient

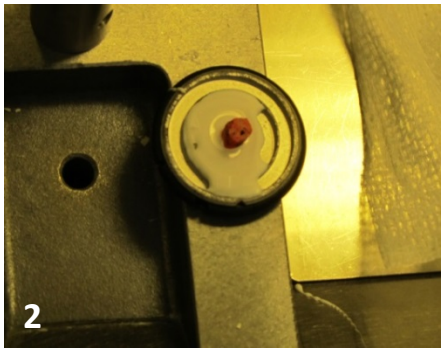
FedEx Express

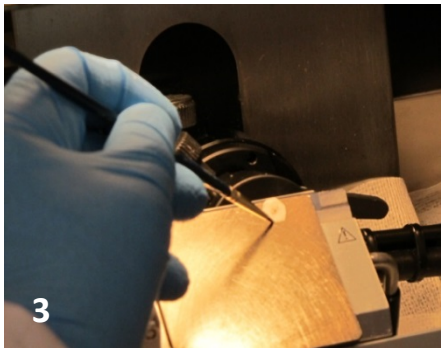


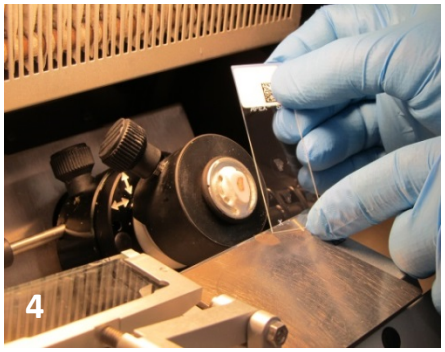
Frozen sample information

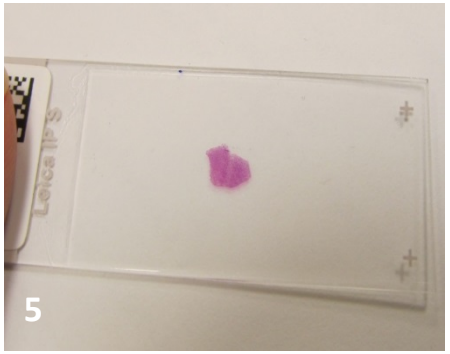
- Preparation of top slide for pathology review:
  1. Place a small quantity of OCT on cold adapter or “chuck” (~3mm deep)
  2. Place tissue on small amount of OCT (wait ~ 1 minute to harden)
  3. Cut a frozen section (~ 4 micron section)
  4. Collect section on slide
  5. Conduct H & E stain
  6. Conduct pathology review (confirm diagnosis and review for the presence/absence of tumor nuclei in both tumor or normal samples)
- Ship frozen samples in cryoport (see cryoport training video: http://www.nationwidechildrens.org/bcr-training-resources)

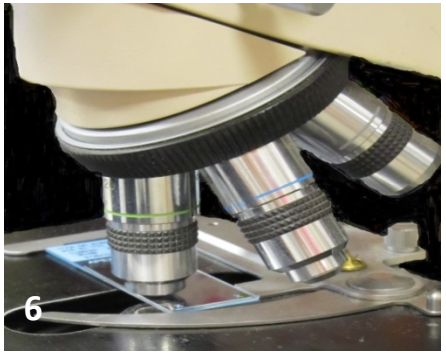










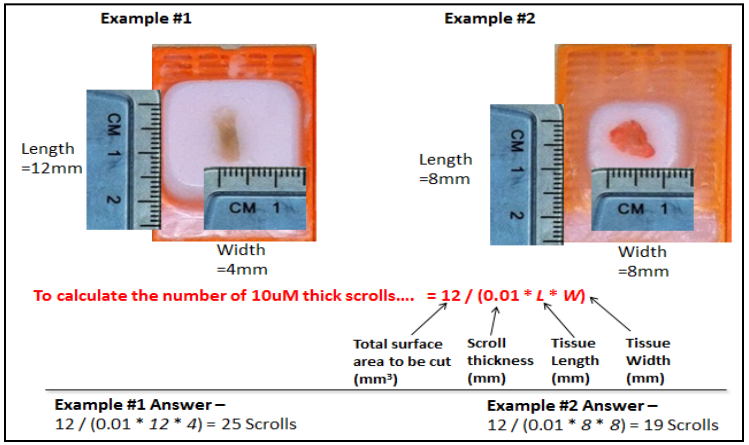


FFPE sample information

- Ship FFPE blocks or scrolls ambient or with cold pack April-September (contact BCR for shipping label)
- If collecting scrolls, please use the following steps for scrolls collection:
  1. Cut and H&E stain a top slide for pathology review
  2. Measure length and width (in mm) of tissue specimen surface within paraffin block
  3. Double click on excel table to the right to open editing function.
  4. Enter tumor length and width values measured in step 1
  5. Number of 10 micron scrolls required to create 12mm3 is shown in yellow
  6. Put scrolls in tube for shipping (Eppendorf or cryovial)
  7. Ship immediately to the BCR at ambient temperature (with cold pack April-September)

"Double Click" below to activate table

Scroll Calculator					
Enter tissue area width:	12	mm			
Enter tissue area length:	12	mm			
Enter scroll thickness:	10	microns	(please submit 10 micron scrolls)		
How much volume of tissue do you need?			12	mm3	
Cut this many scrolls >>>	8				



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Clinical data information

- Shipping manifest or electronic import file required for all sample submission (minimum data amount required to import samples)
- Data Submission method options (based on project requirements):
  - OpenClinica
  - XML (the TSS is required to map based on the BCR common data elements (CDEs) provided)
  - MediData Rave (approved NCI projects)
  - Other project-designated mechanism
- Data, whole slide images, and pathology reports (if applicable) will be uploaded to the DCC/GDC via XML. All samples are de-identified prior to upload (no limited data set).
- Form types (if applicable for project):
  - Sample submission form – information on submitted samples
  - Enrollment form – detailed patient information
  - Follow-up – information on survival and additional new tumor events past enrollment
  - Supplemental forms (radiation and pharmaceutical) – information collected on drug type or radiation received for the submitted specimen
  - Other malignancy form – details on any prior or synchronous malignancies