BioIVT Triple Format (FFPE/FF, CNB/FNA) Specimen Collection for Diagnostic Assay Development

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Introduction

Core Needle Biopsies (CNB) and Fine Needle Aspirates (FNA) are the main biopsy methods used for pre-operative diagnosis, often determining the therapeutic approach for patient care. A CNB is created in a clinical setting using a hollow needle to remove a small piece of tissue from the area of concern. It can be a preferred type of biopsy because it removes more tissue than a fine needle aspiration. An FNA is created in a clinical setting whereby a needle is injected into the area of concern and a small amount of fluid and cells are aspirated into the needle for cytological and pathological assessment.

Both methods are a less invasive approach compared to surgical biopsies and provide an accurate diagnosis. These benefits make them highly valuable and necessary inclusions for the development of diagnostic assays. However, CNBs and FNAs are difficult to procure for research and development use because they are considered diagnostic material. In addition, the samples are often exhausted during diagnosis workup. BioIVT has successfully created a protocol to replicate CNB and FNA from fresh surgical collections, with the ability to create matched CNB, FNA and preserved tissue blocks (FFPE, OCT embedded or Fresh Frozen), advancing the development of companion diagnostic assays for clinical use.

Conclusion

In order to replicate the clinical scenario for diagnostic development, BioIVT has successfully created a protocol to replicate CNB and FNA from fresh surgical collections. These Tri-Format solutions can then be used in multiple down-stream applications to further advance diagnostic assay develop without compromising valuable clinical material.

Methods

Tissue Procurement - Fresh tissue was procured through the ASTERAND® Human Tissue network of surgical sites according to our specific collection protocol and project proposal requirements in accordance with regulations supporting subject/donor protection. Fresh tissue specimens along with clinical data were collected and delivered to our CAP certified lab for processing. Laboratory created CNBs, FNAs, and resection FFPE blocks were processed and reviewed in a two-level assessment: standard Histology review and Pathology review – completed by one of our board-certified pathologists for tissue type confirmation, diagnosis, cellular component estimation/determination, and to ensure tissue origin and diagnosis were consistent with clinical data.

Tri-Format Tumor Processing - Processing of tissue occurred according to aseptic technique immediately upon arrival of tissue in facility. The tumor was dissected into two mirrored sections, one of which was processed into a FFPE block.

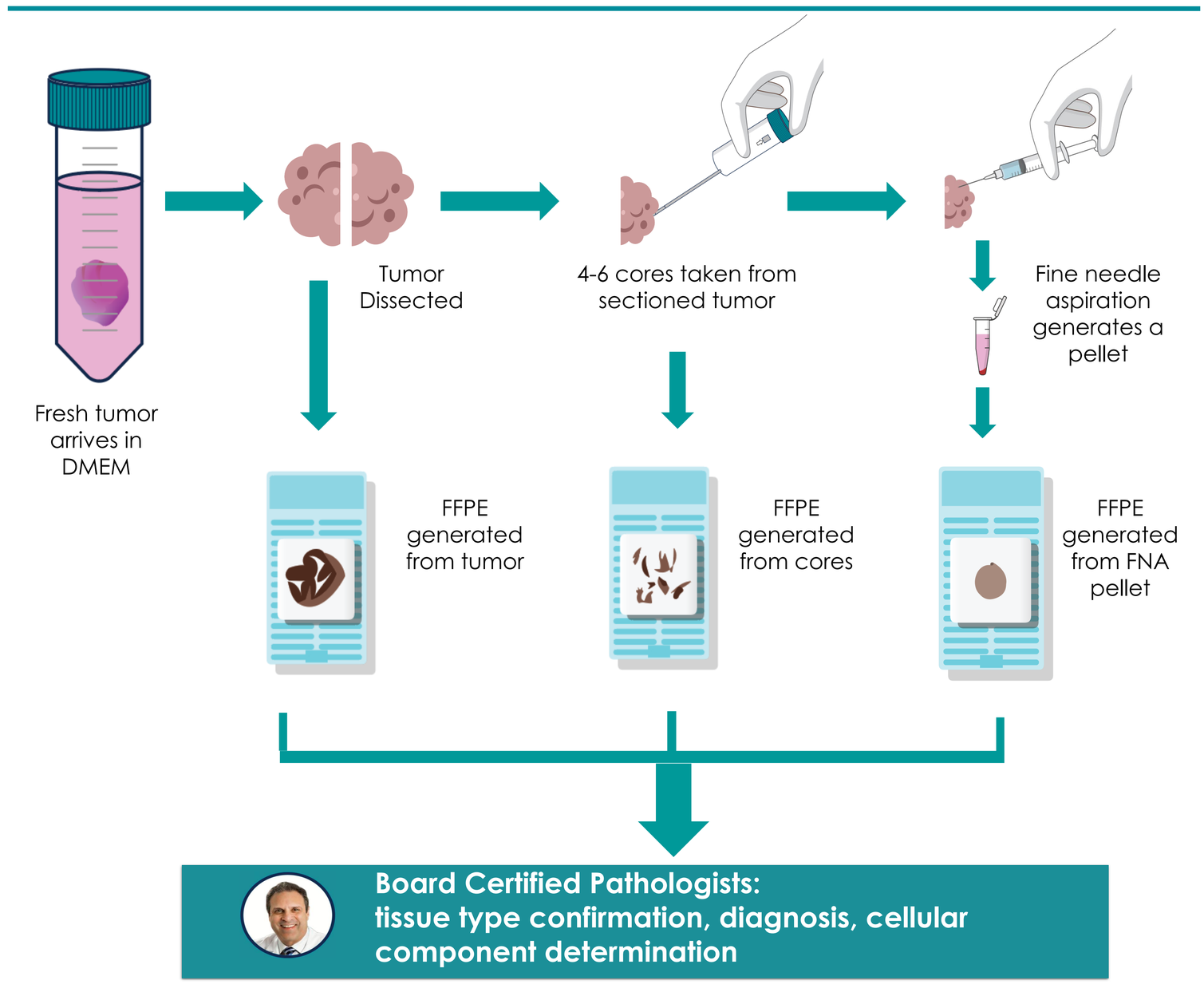
The second tumor section was used for both CNB and FNA generation. Using a standard core needle biopsy gun, lab technicians extracted up to 4-6 cores from the tumor. These cores were processed into a FFPE block.

The remaining tumor following CNB generation was used to create the Fine Needle Aspirate. Using a 14-gauge needle, the tumor was hydrated and disrupted by injecting ethanol. The aspirate was collected, pelleted, and washed. Then, the aspirate was processed into a FFPE block.

The resection, CNB, and FNA FFPEs were reviewed in a two level-assessment: 1) standard histology review and pathology review and 2) comparison of pathology data for all three formats for consistency among results.

Regulatory - BioIVT works with local and centralized US-based IRBs, EU-based IECs, and Health Ministries in other countries as required and is in compliance with our UK HTA license for the storage, use and disposal of human biomaterials.

Tri-Format Process



Use Case Scenarios

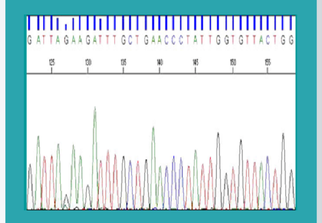
Histology and Pathology Services

- Staining, sectioning and pathology review
- Immunohistochemistry
- Specimen marking/ key feature annotation
- Serial sectioning and special staining projects
- TMA creation
- Whole slide imaging

Molecular Derivatives

- PBMCs
- Dissociated Tumor Cells (DTC)
- Nucleic acid isolation; RNA, DNA and Protein
- Quality assessment; Agilent Bioanalyzer, Qubit & Absolute quantification

Molecular Annotation



- Testing, including chemistry testing and Human impact/viral screen
- Mutation Screening including PCR and Next-Gen Sequencing
- HLA
- Microsatellite Instability (MSI) screening

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