



Dual Needle Core Biopsy

Development and Deployment of a Novel Medical Device

Rocky Ackroyd, PA, MHS

AAPA 2026 Annual Meeting | Phoenix, Arizona

Disclosures

Forward-Looking Statement: RockPoint Biopsy, LLC was formed to commercialize the recently patented Dual Needle Core Biopsy Device. The device is currently undergoing final development and regulatory preparation, with targeted FDA clearance and commercial launch in 2027.

From Concept to Device

1

Introduction to the Concept
with a validation study

2

The Value of Tissue
for patient care and research

3

Development of a Medical Device
the process: team, equipment



Spirit of Massachussettes - 1984

Introduction to the Concept

with a validation study



Clinical History

Patient with breast cancer and clinically positive lymph nodes



Clinical History

Patient with breast cancer and clinically positive lymph nodes

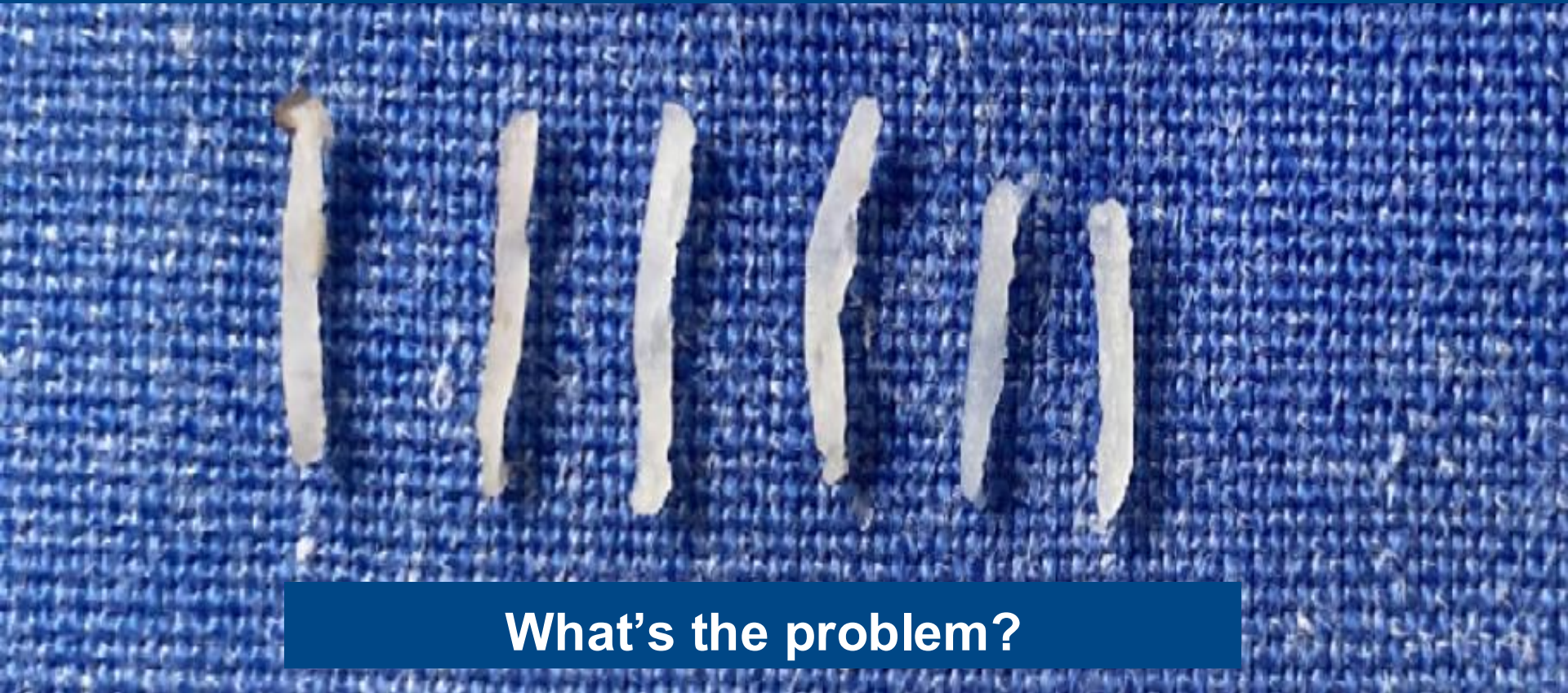


Surgeon Requests

"Send three cores for diagnosis and three for research"

Clinical History

Patient with breast cancer and clinically positive lymph nodes



What's the problem?

Surgeon Requests

"Send three cores for diagnosis and three for research"

Clinical History

Patient with breast cancer and clinically positive lymph nodes



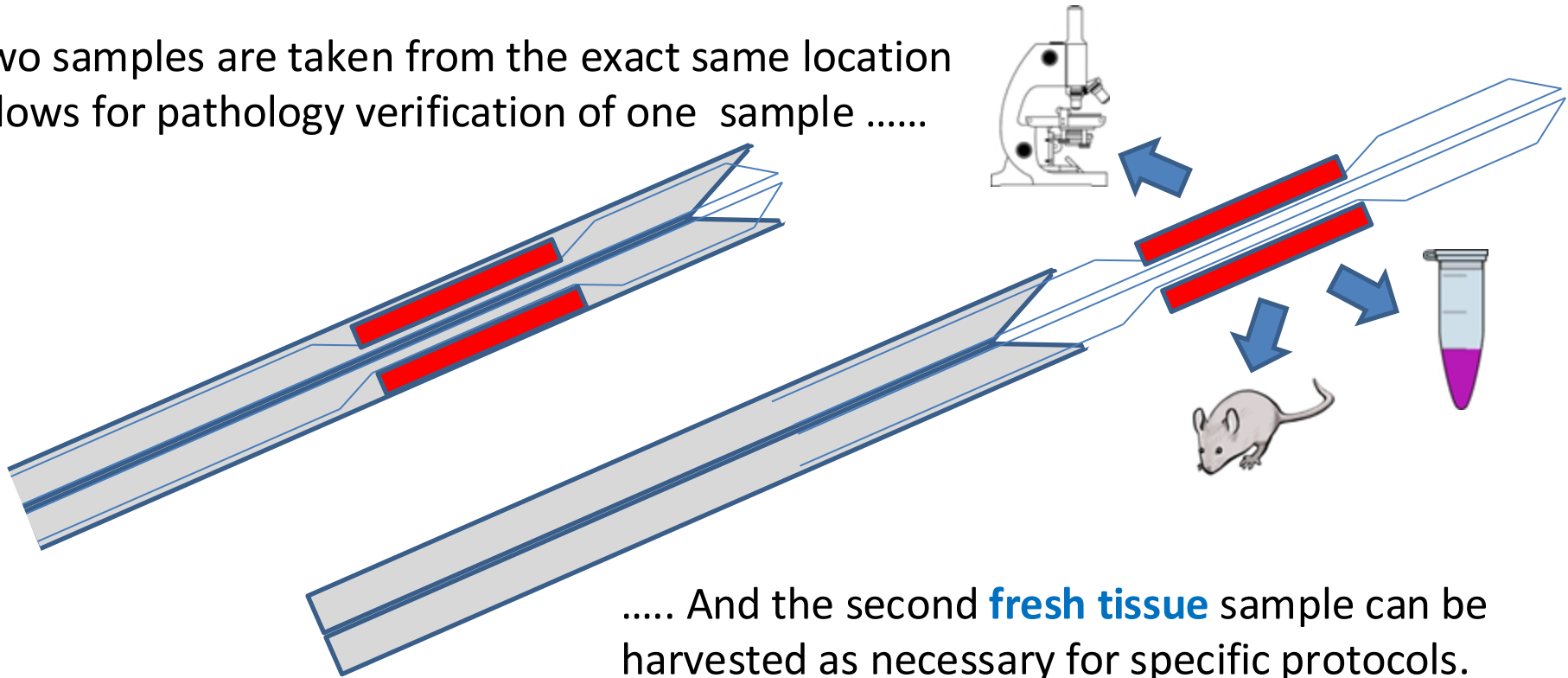
Which cores have cancer — and is there any tumor in any of them?

Surgeon Requests

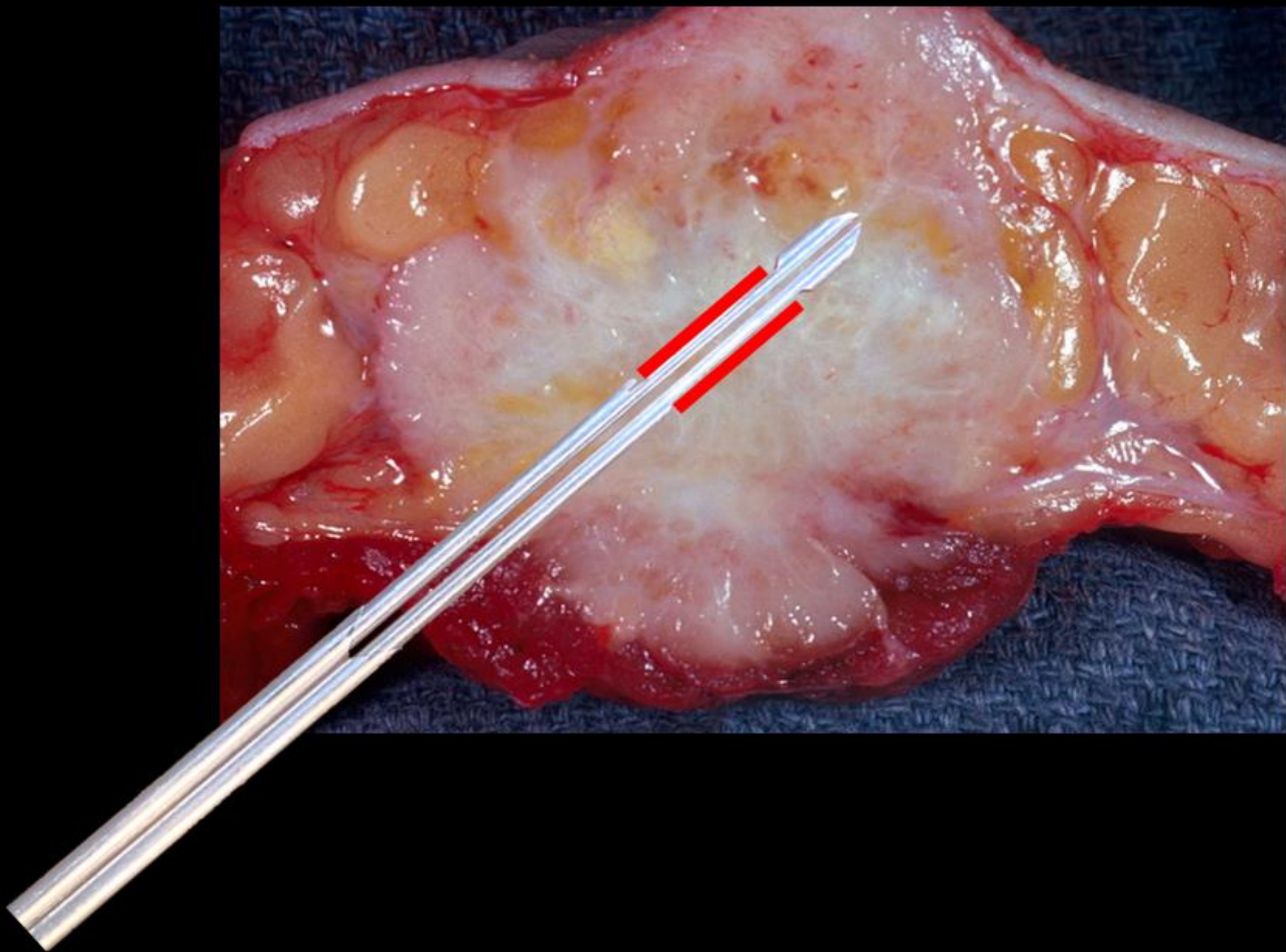
“Send three cores for diagnosis and three for research”

Dual Needle Core Biopsy Device

Two samples are taken from the exact same location allows for pathology verification of one sample









What is the value of two equivalent samples?

Benefits:

Additional Tissue for Special Testing Additional Tissue for the Research Community



Access to **biopsy equivalent** material



Pathology verification on the diagnostic core virtually eliminate potential false positive or false negative due to sampling error



BioBanking: Increasing ability to collect small otherwise “unbankable” cancers and fresh tissue



Fresh Tissue Availability – DNA and RNA integrity. Many investigators require fresh tissue.



Comparison testing done on diagnostic cores with novel testing of research core (in various media, fresh, frozen, or alternative fixative)

Proof of Concept

Validation Study



Building a Wooden Ship

Introduction

In April 1983, construction began at Boston's Charlestown Navy Yard on the S.S.S. *Spirit of Massachusetts*, a wooden sailing schooner modeled after a famous New England fishing vessel of the nineteenth century. Built of traditional materials, with tools and skills that have been used for centuries in the shipbuilding trades, she will serve—upon completion in the summer of 1984—as a school ship for the New England Historic Seaport, and as an ambassador to the rest of the world for Boston, for Massachusetts, indeed for all New England. She is *our* ship, one in which we can all take pride.

Since its founding in 1974, it has been the purpose of the New England Historic Seaport to promote a deeper understanding of, and appreciation for, New England's maritime heritage. Our heritage was first and remains foremost a coastal one, because New England was settled by people who came here on arduous voyages across the mighty Atlantic Ocean. For generations these settlers made their lives and livelihoods on or near the beautiful natural harbors of the area; ships and boats were the lifeblood of the community. More recently, some aspects of modern life have tended to obscure this precious heritage, and its ongoing meaning for New Englanders. The S.S.S. *Spirit of Massachusetts* is intended as a reminder of that legacy, and as a trainer of New England's youth in the ways of the sea.

Learning to sail a tall ship is much more than the acquisition of an ancient skill. It demands hard work.



Validation Study: Methods

An IRB approved study utilized 30 residual formalin fixed surgical pathology cancer cases slated for discard per hospital tissue retention policy. The cases were tested with a 17g dual core biopsy device.

Both cores were submitted in a single cassette for routine histology processing and subsequently evaluated by a pathologist for consistency of the pair of samples.

The two cores were scored for diagnostic equivalence.

Validation Study



Dartmouth
Health

Dartmouth Hitchcock Medical Center
Dartmouth Hitchcock Clinics



Collaborators

Kristen E. Muller, DO

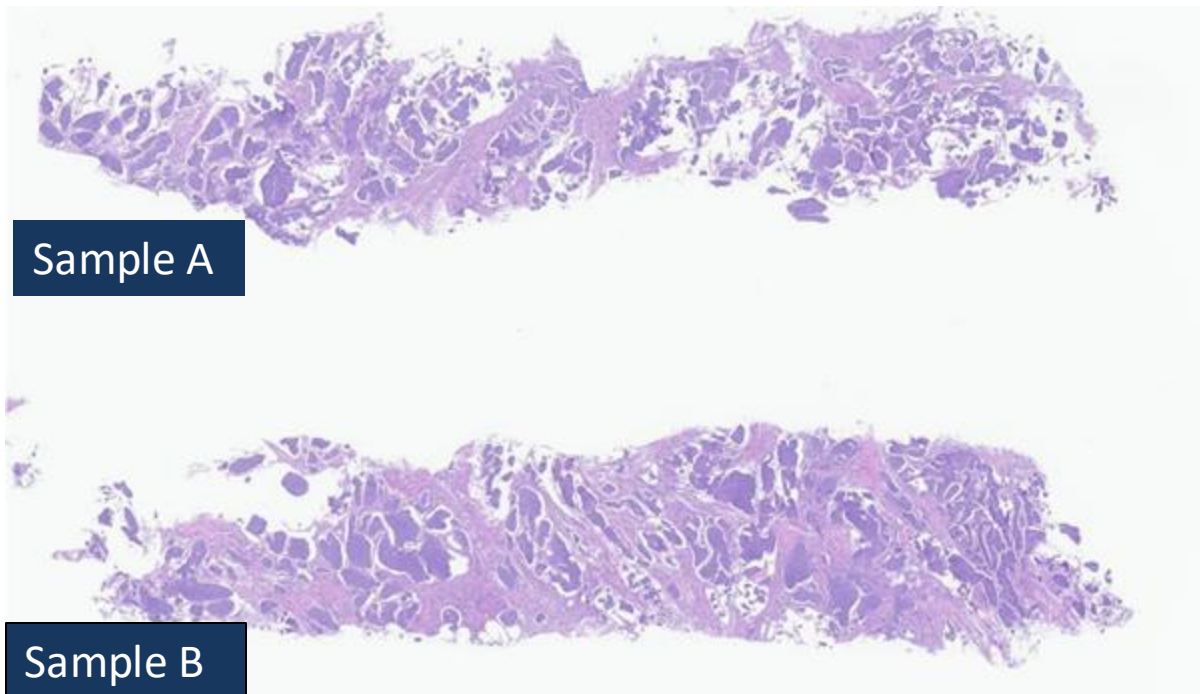
Ourania Parra, MD

Greg Tsongalis, PhD, HCLD

Steve Boyle, PA, ASCP

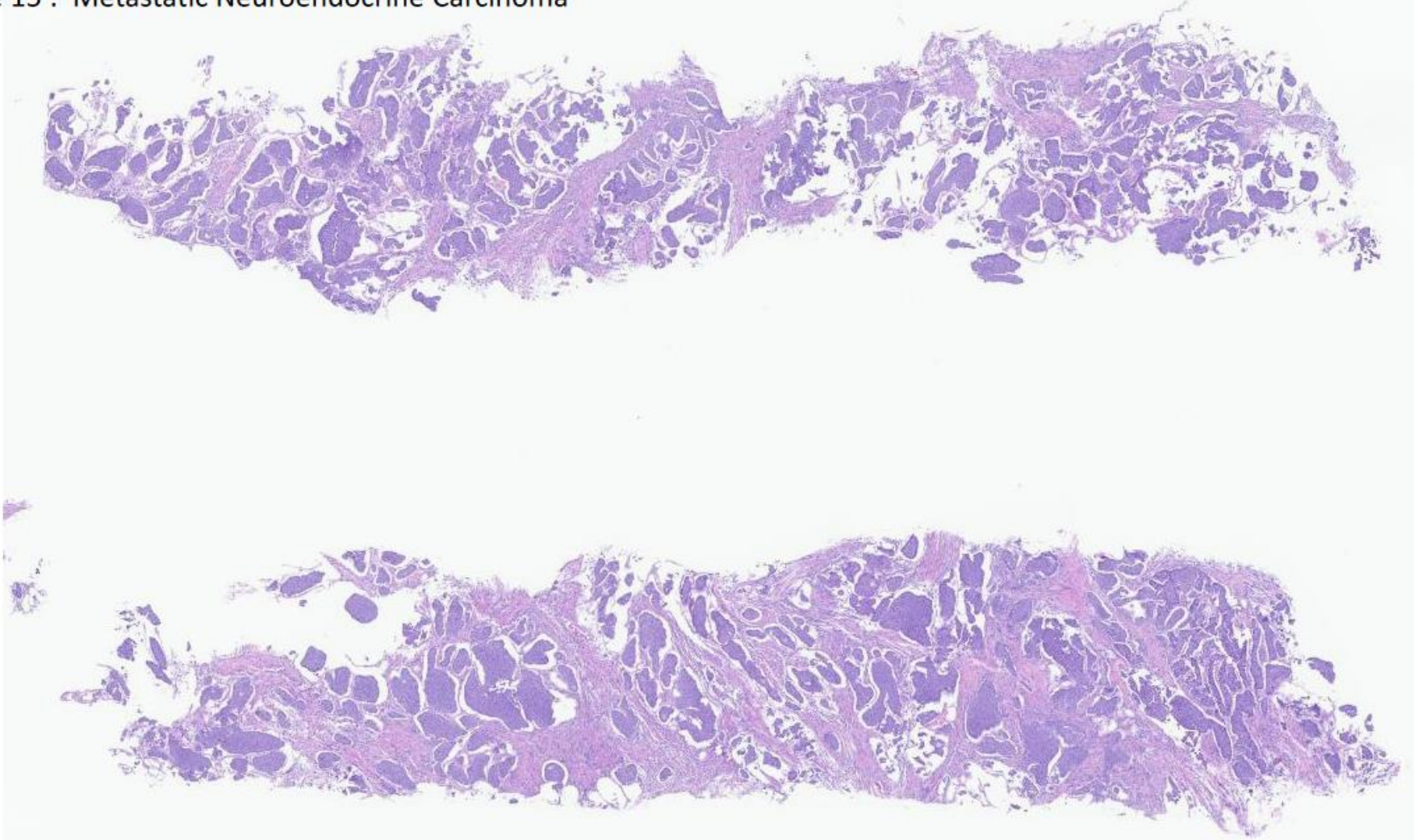
Validation Data

Initial IRB studies show excellent concordance of the samples with objectively quantified attributes

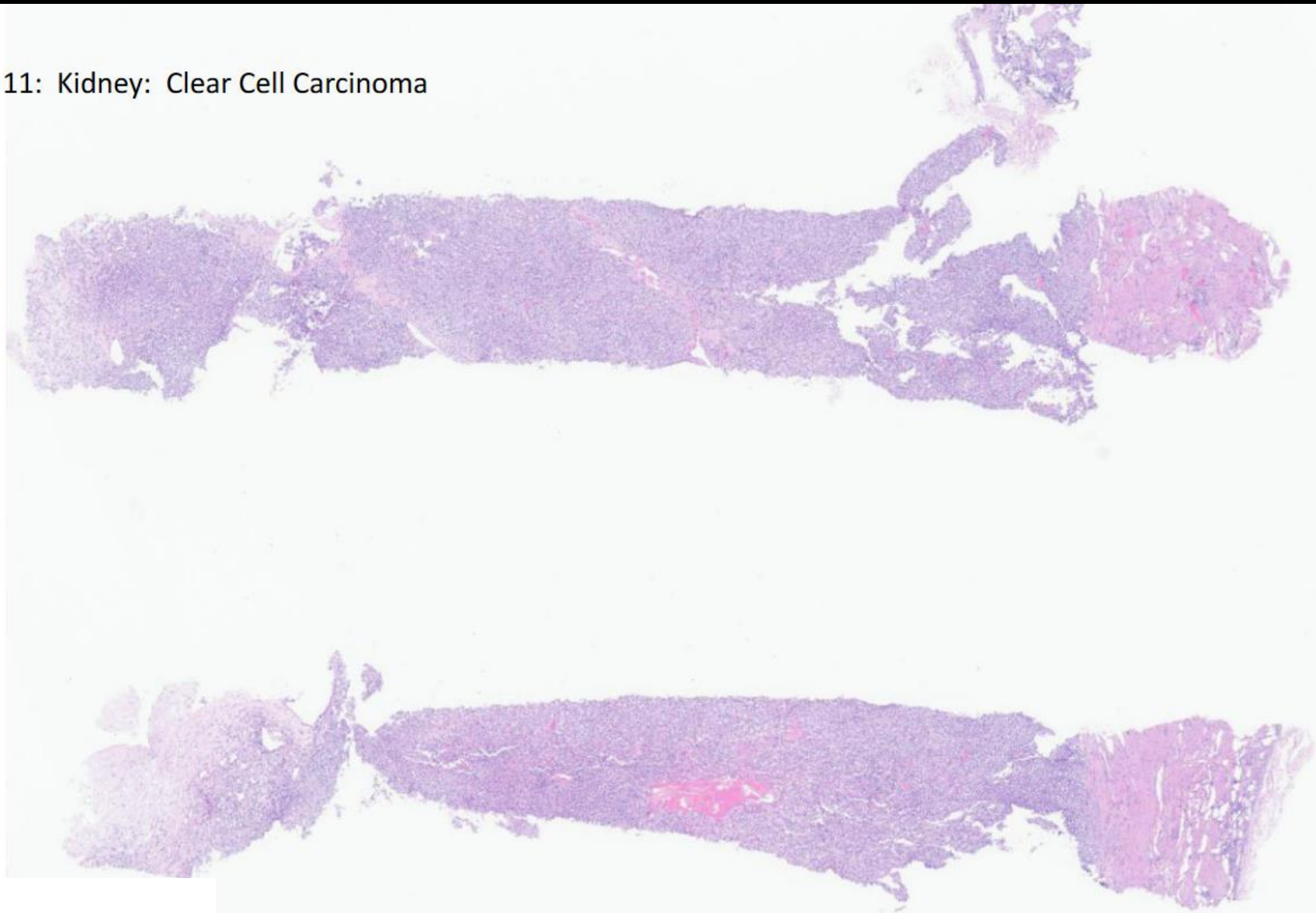


Ovary: Metastatic Neuroendocrine Carcinoma		
	Sample #A	Sample #B
Percentage "Identical"	100	100
Sample Quality (1-5)	5	5
Tumor %	80	80
Inflammation %	0	0
Fibrosis %	0	0
Necrosis %	0	0

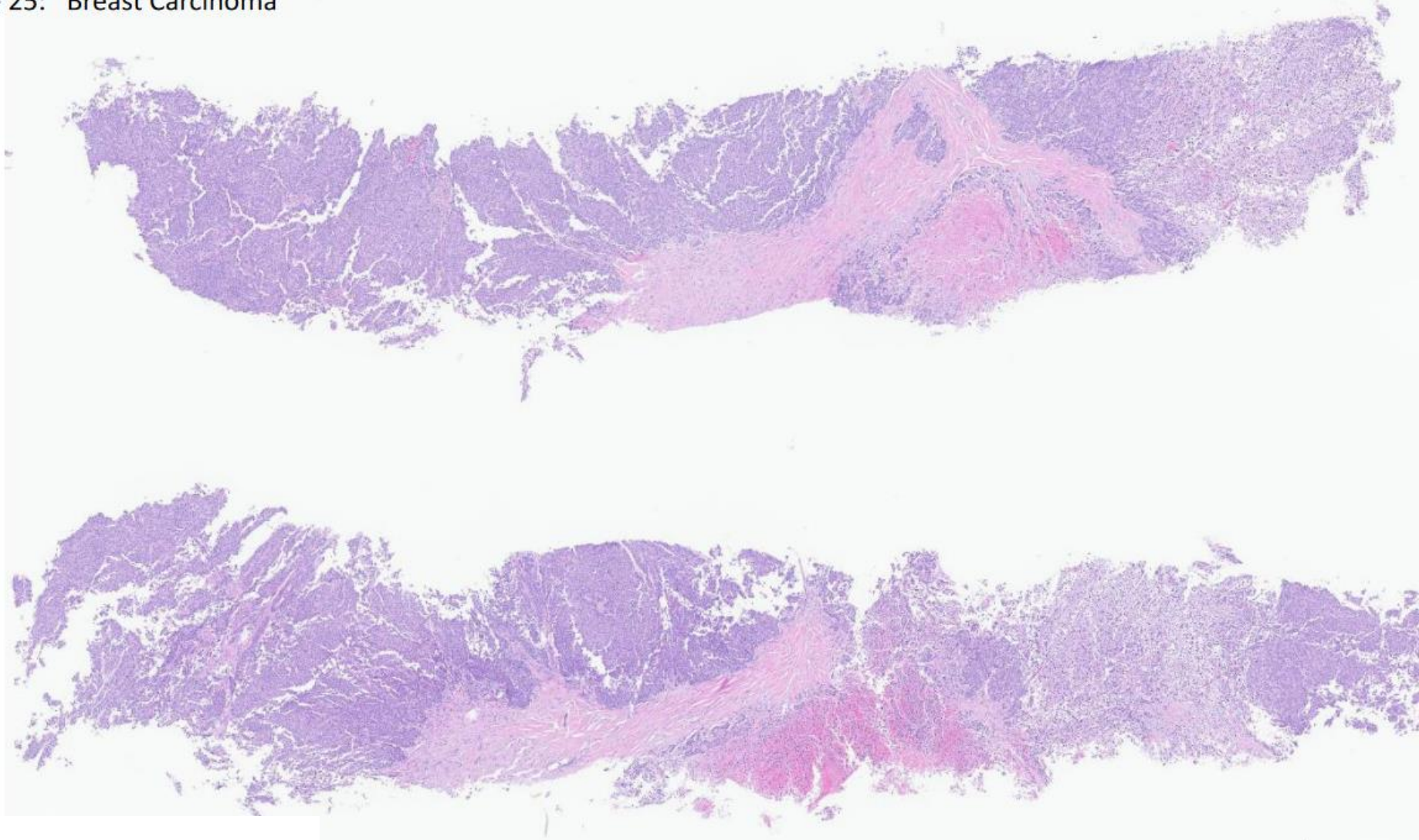
Case 15 : Metastatic Neuroendocrine Carcinoma



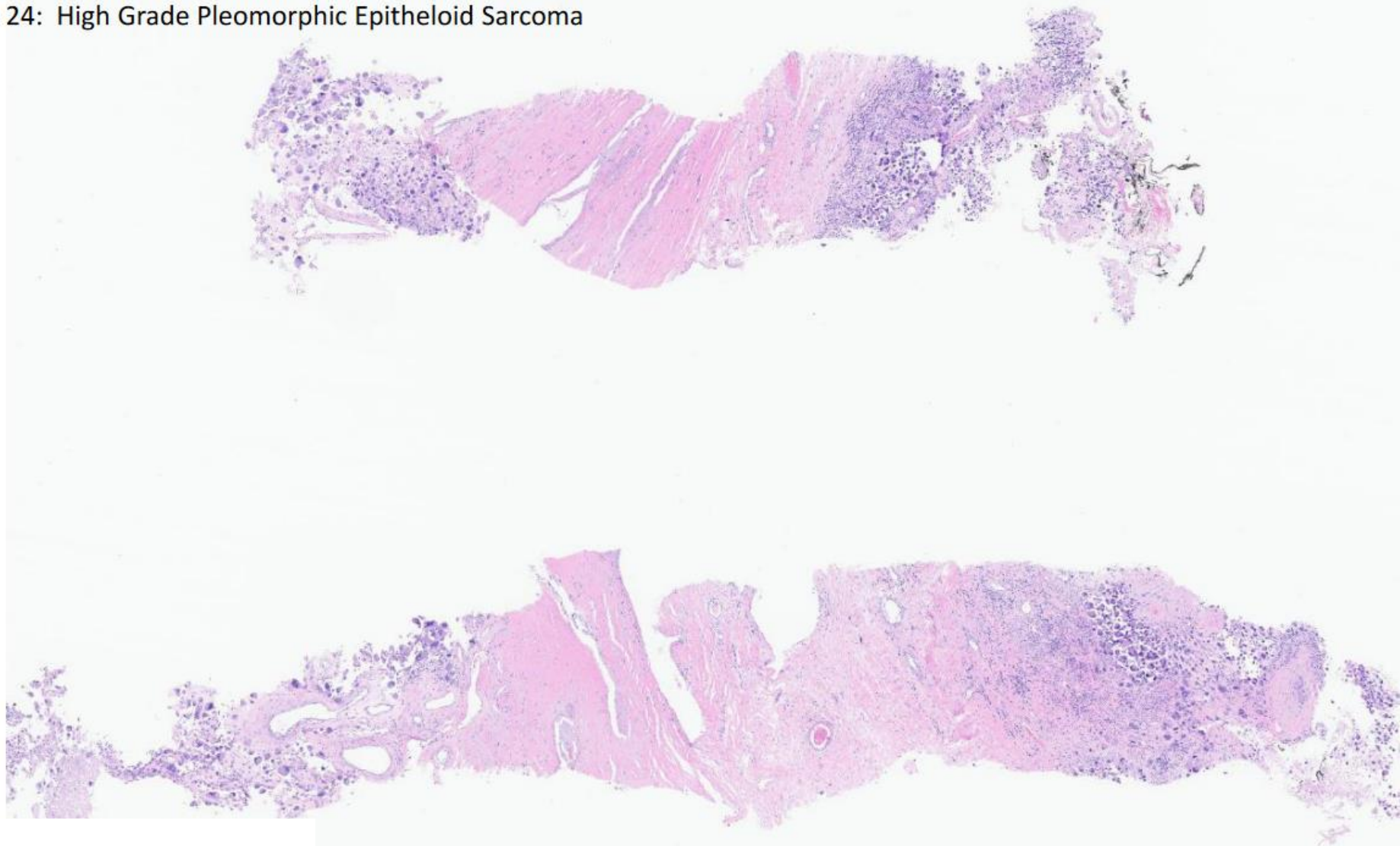
Case 11: Kidney: Clear Cell Carcinoma



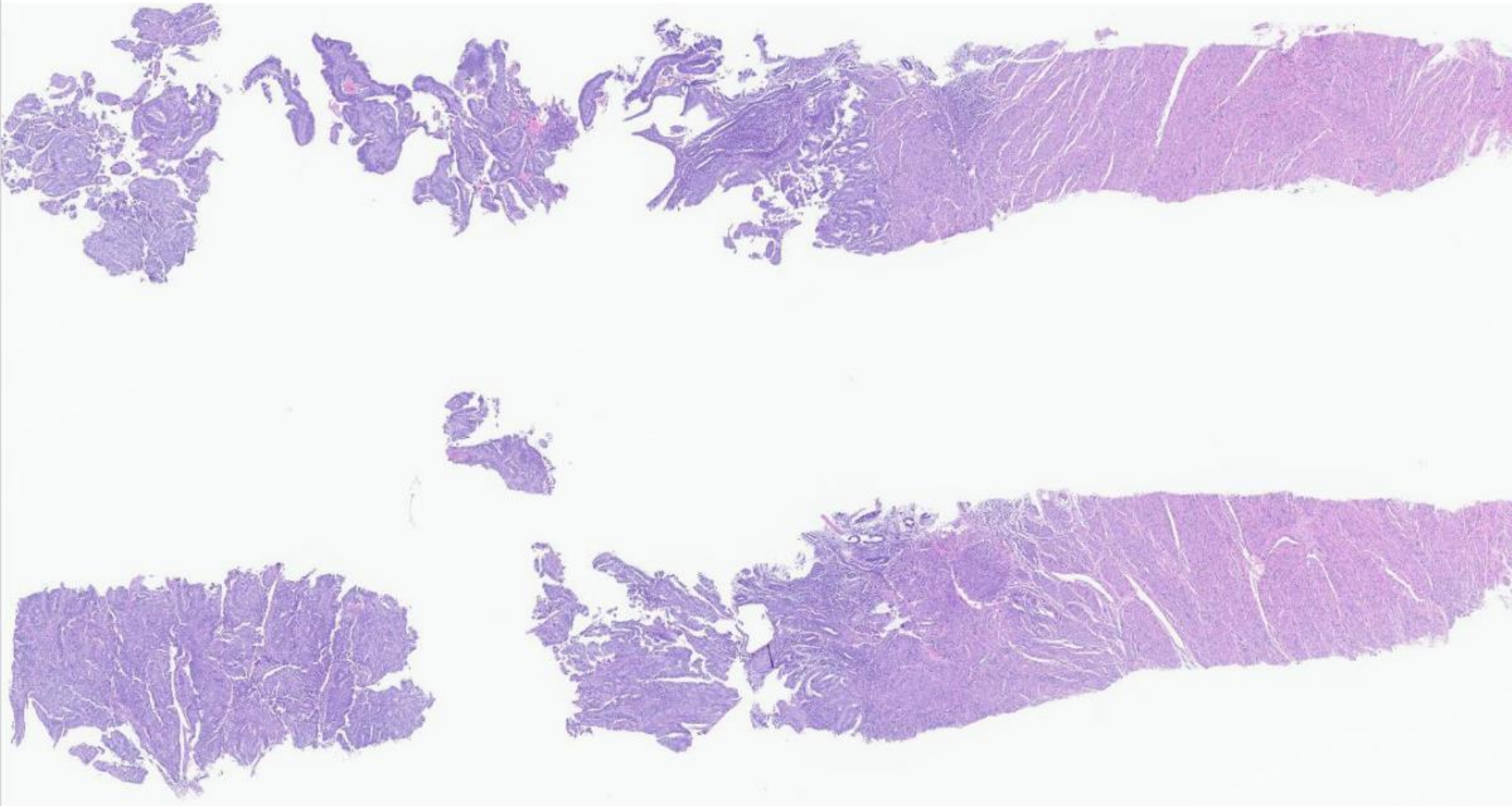
Case 25: Breast Carcinoma



Case 24: High Grade Pleomorphic Epithelioid Sarcoma



Case 27: Uterus – Endometrial Carcinoma



Thirty cases were tested

92% of passes had 80% or greater concordance

PERCENT CONCORDANCE		
Concordance	Passes (n=72)	Percent
100	43	60%
90-99	12	17%
80-89	11	15%
70-79	1	1%
60-69	1	1%
50-59	2	3%
40-49	0	0%
30-39	2	3%

Table 1: 92% of passes (72) had 80 % or greater concordance in morphology between cores.

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Pathology Verification: One of each pair of cores is reviewed microscopically
(Paraffin section or Frozen)

PASS #1



PASS #2



PASS #3



PASS #4



PASS #5



Matched pairs of tissue

Pathology Verification: One of each pair of cores is reviewed microscopically
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PASS #1

PASS #2

PASS #3

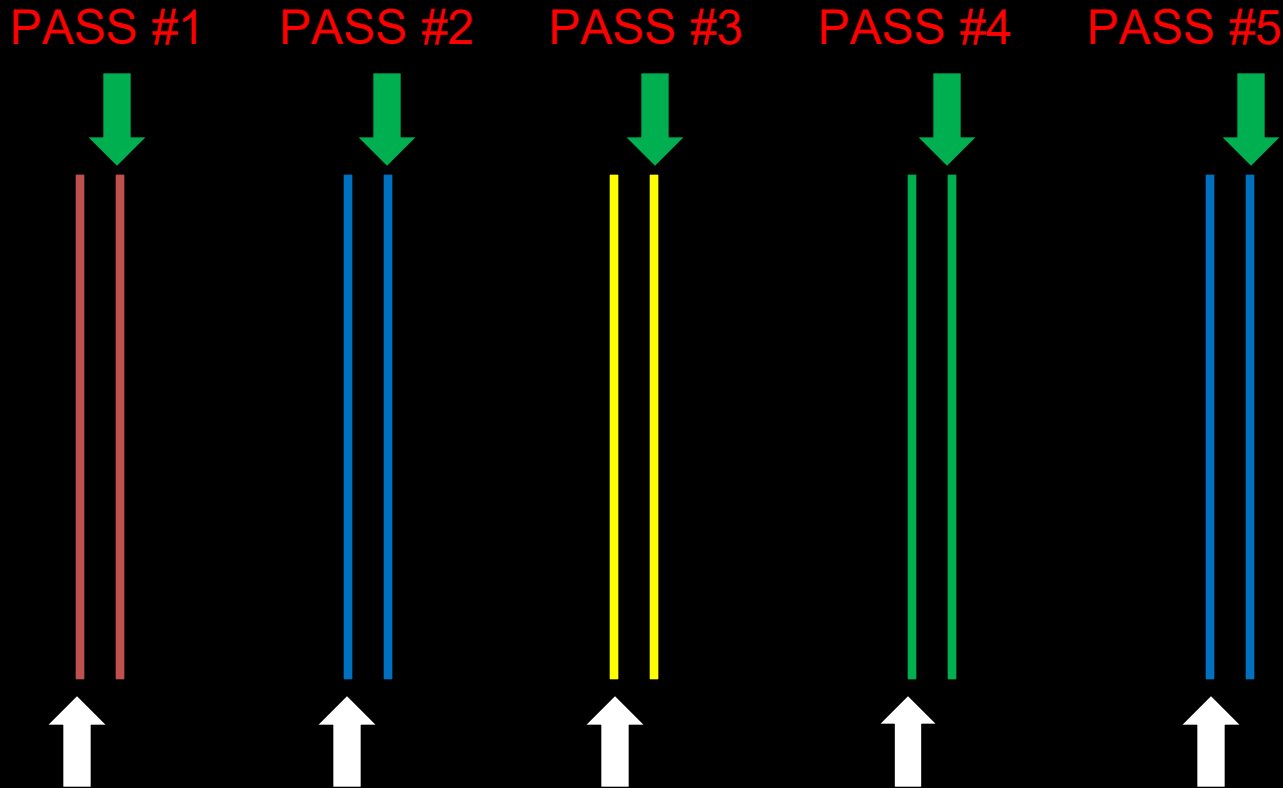
PASS #4

PASS #5



Diagnostic Sample

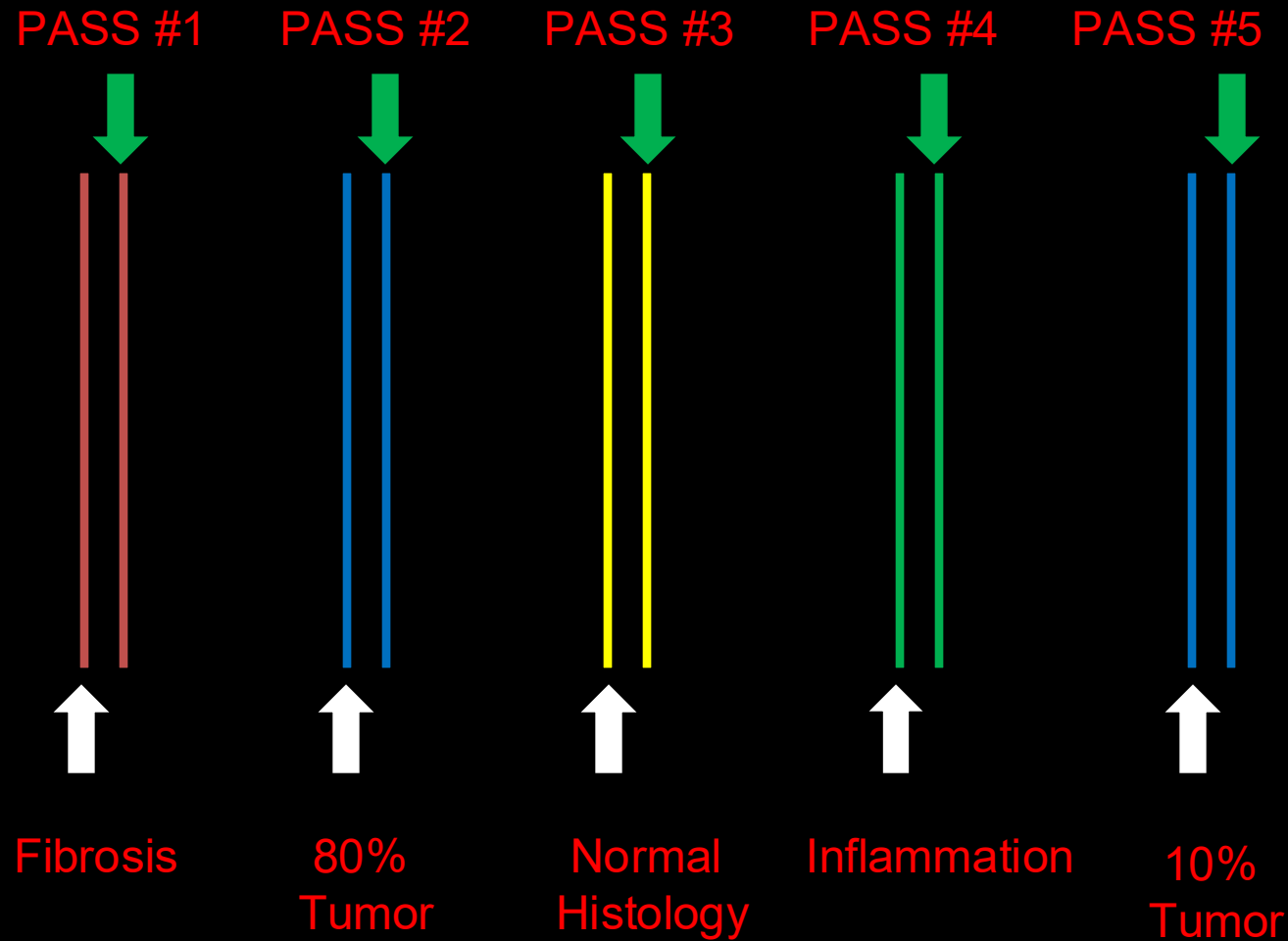
Pathology Verification: One of each pair of cores is reviewed microscopically
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Diagnostic Sample

Research Sample

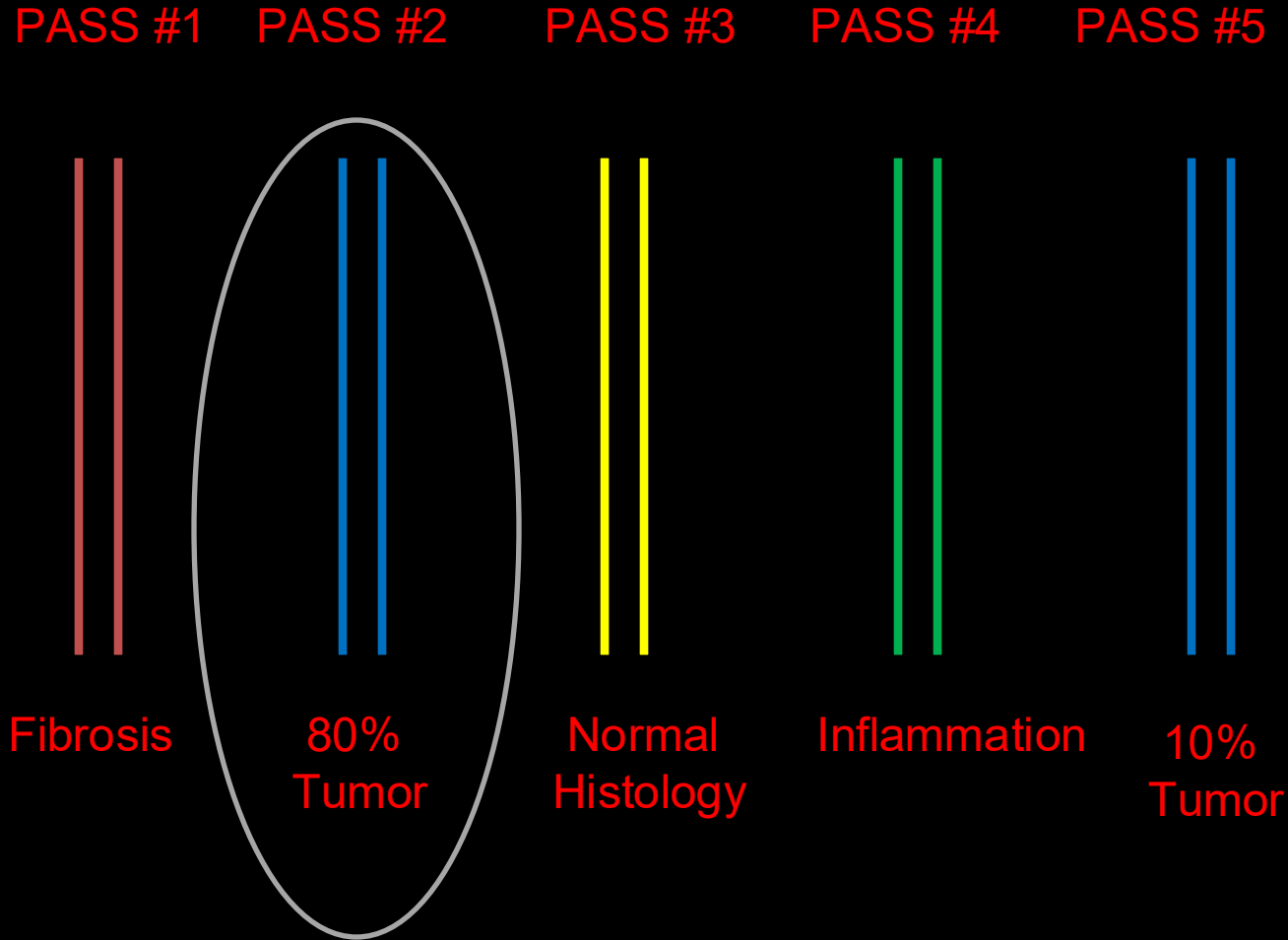
Pathology Verification: One of each pair of cores is reviewed microscopically
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Diagnostic Sample

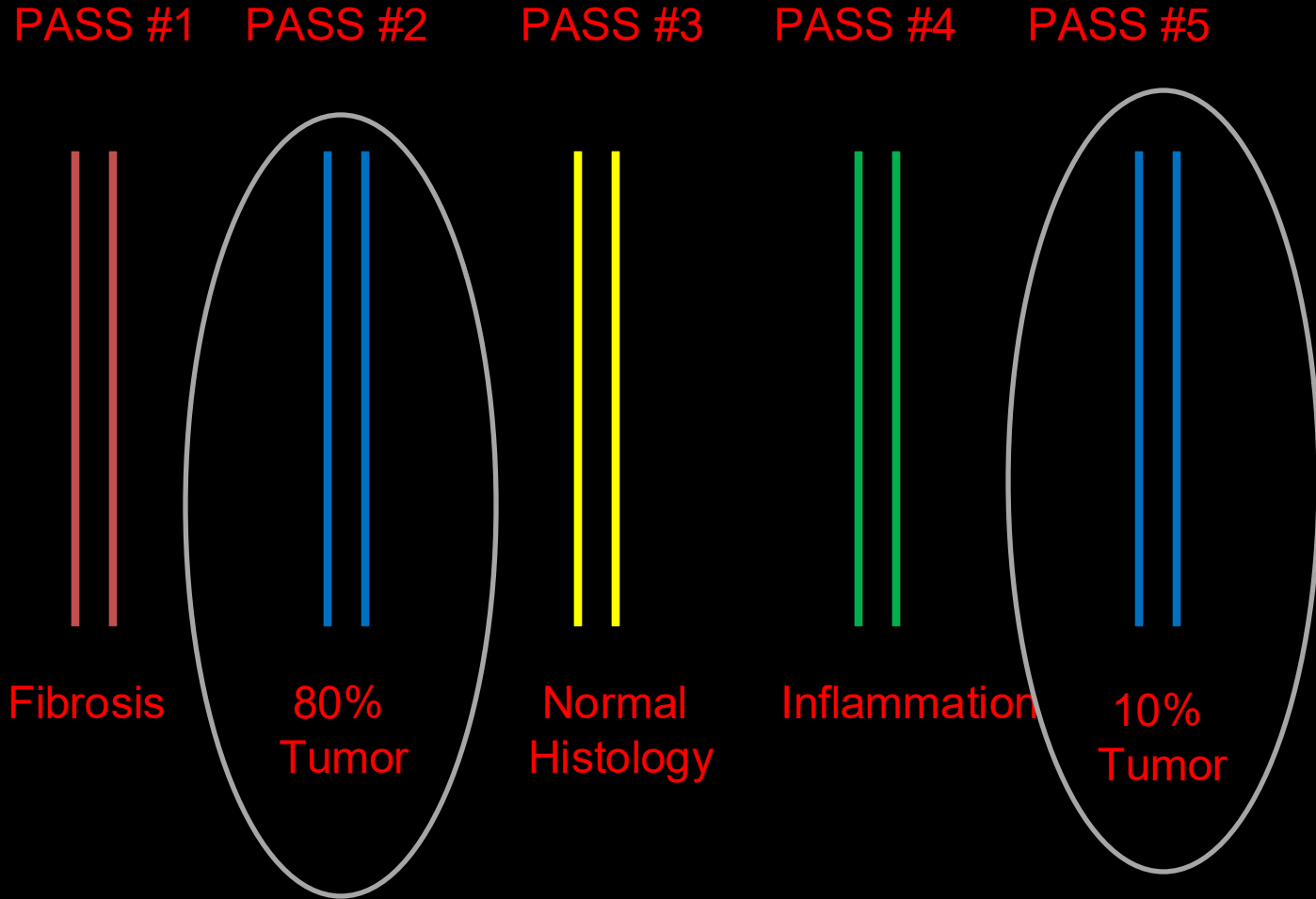
Research Sample

Pathology Verification: One of each pair of cores is reviewed microscopically
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Second Core submitted for \$1000 Clinical test, banked or for research.
Eliminates false positive or negative cases due to sampling error.

Pathology Verification: One of each pair of cores is reviewed microscopically
(Paraffin section or Frozen)



Sensitivity Studies – will a tumor with 80% tumor and 10% tumor produce the same result?

Validation of Dual Needle Core Biopsy

Accelerating Precision Medicine through Innovation

Rocky Ackroyd, Pathologist Assistant, MHS | RockPoint Biopsy, LLC
Ouriania Parra, MD, Dartmouth Hitchcock Medical Center

INTRODUCTION

Precision medicine is dependent on the ability to test tissue samples for unique markers that can lead to the development of new diagnostic tests, innovative treatments, and potential cures. New discoveries are limited by lack of tissue to test, especially at the time of initial biopsy. As diagnosis is the first priority, core biopsy samples are rarely if ever sacrificed for novel testing or research. With this challenge in mind, a prototype dual needle core biopsy device has been developed, which takes two directly adjacent samples from a tumor - one for diagnosis and one for precision medicine or other studies (Fig 1). Furthermore, the second core can be retained fresh for in vivo/vitro studies which is never possible with formalin fixed tissue.

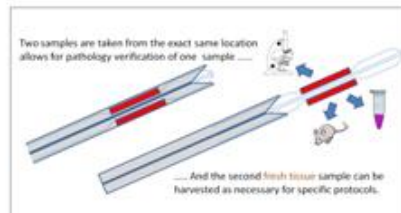


Fig 1: Diagnostic core vs Research core

METHODS

The study utilized 30 residual formalin-fixed surgical pathology cancer cases slated for discard per the participating hospital tissue retention policy. The cases were tested with a 17g dual core biopsy device (Fig 2a). Both cores were submitted in a single cassette for routine histology processing and subsequently reviewed for quality and concordance of diagnostic histology (Fig3). Core samples were evaluated by a pathologist and scored for the consistency in morphology (presence, absence and percentage of tumor) (Fig 2b).

RESULTS

This study demonstrated that a Dual Needle Core Biopsy device acquires "equivalent" core samples of cancer tissue in a single pass (Fig 3). Thirty surgical resections cases were biopsied (n=72) with the device. Sixty percent of the core biopsies had 100% concordance while 92% were greater than 80% concordant (Table 1). Lack of consistency in 8% of the biopsies was typically due to fragmented specimens with loss of tissue integrity and were difficult to biopsy.

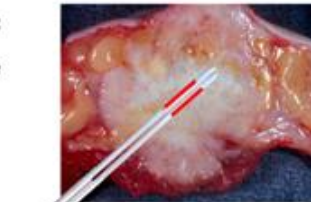


Fig 2a: Sampling with dual core

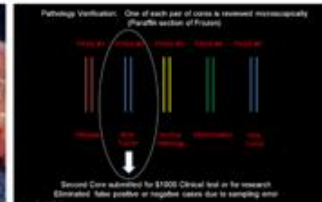


Fig 2b: Pathology Verification for sample selection

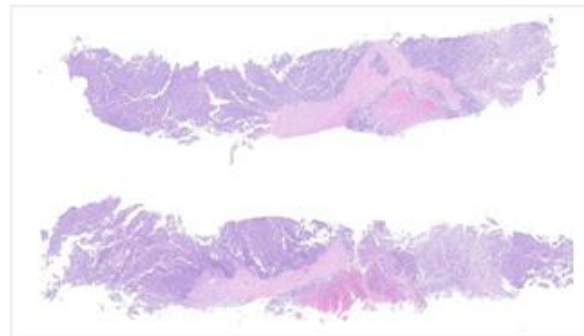


Fig 3: Case 25 - Breast Carcinoma: Equivalent Cores

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CONCLUSIONS

- This validation study has shown that equivalent core samples can be taken at the time of biopsy (Table 1). The second core is available for research or clinical testing without risking patient diagnosis.
- The additional fresh tissue core provided to research efforts has the potential to accelerate precision medicine discoveries and ultimately improve patient outcomes.
- Eliminating false positive or negative results by only utilizing cores that have been verified to contain cancer (with a documented tumor percent) (Fig 2b).
- Saving medical dollars and resources by only submitting tissue verified to have cancer (Fig 2b).

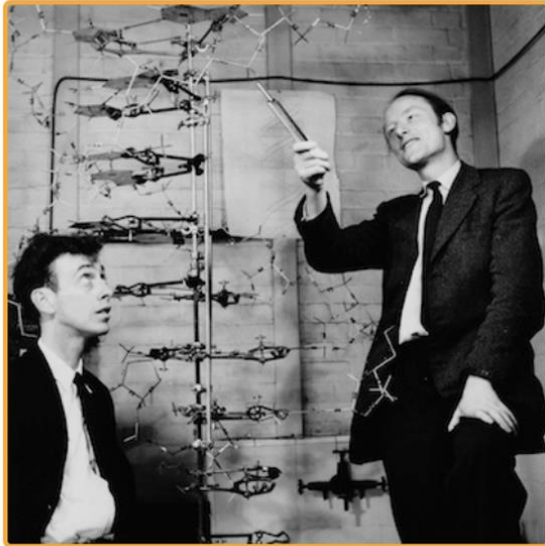
The Value of Tissue

Clinical Testing and Research



Medicine is in a rapid phase of a “genomic revolution”

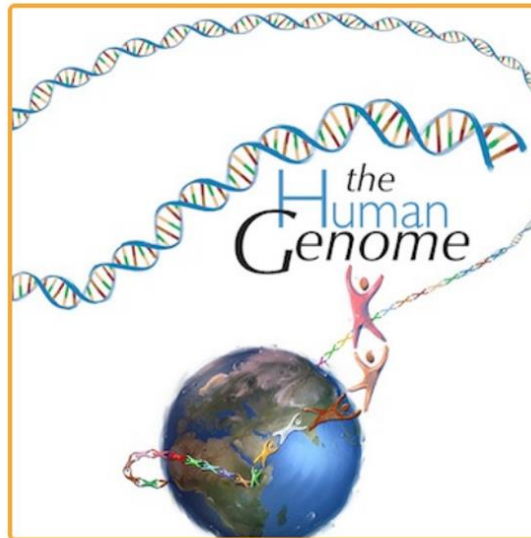
Precision Medicine and Personalized Medicine
are accelerating as we speak



James Watson and Francis Crick discover the double helix structure of DNA

When Francis Crick and James Watson modeled the structure of [DNA](#), they used paper cutouts of the bases (A, C, G, T) and metal scraps from a machine shop. Their model represented DNA as a [double helix](#), with sugars and phosphates forming the outer strands of the helix and the bases pointing into the center. Hydrogen bonds connect the bases, pairing A-T and C-G; and the two strands of the helix are parallel but oriented in opposite directions. Their 1953 paper notes that the model "immediately suggests a possible copying mechanism for the genetic material."

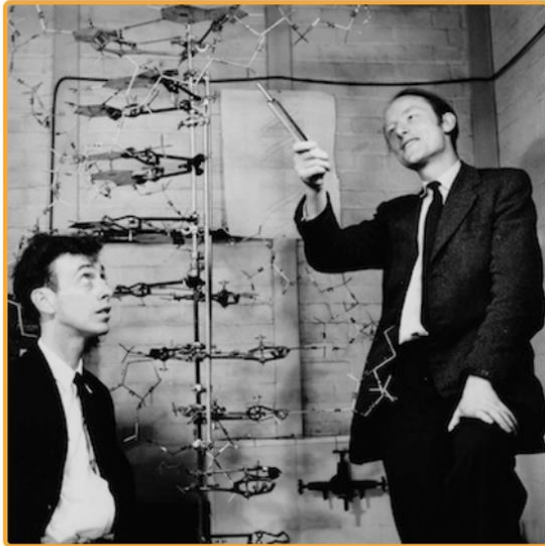
1953



Human Genome Project completion announced

In 2003, the [Human Genome Project](#)'s ambitious goals had all been met or surpassed. The sequences produced by the Human Genome Project covered about 99 percent of the human genome's [gene](#)-containing regions. Not only was the project finished two-and-a-half years ahead of time, but it was also significantly under budget. In addition, to help researchers better understand the meaning of the human genetic instruction book, the project successfully undertook a wide range of other goals: from sequencing the genomes of organisms used in disease research, to developing new technologies for studying whole genomes. The Human Genome Project has been compared to the moon-landing project as an outstanding scientific achievement of humankind.

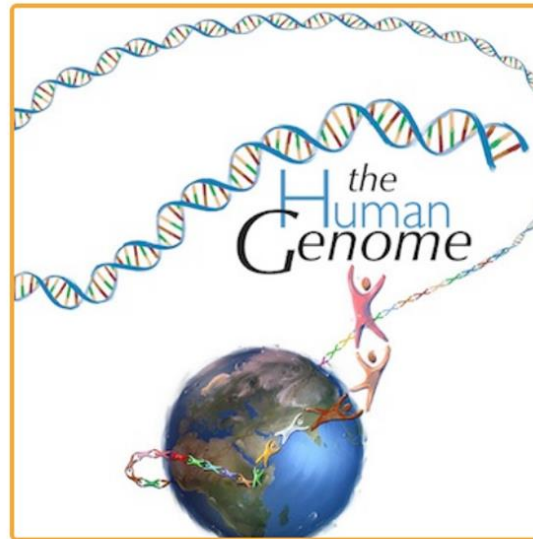
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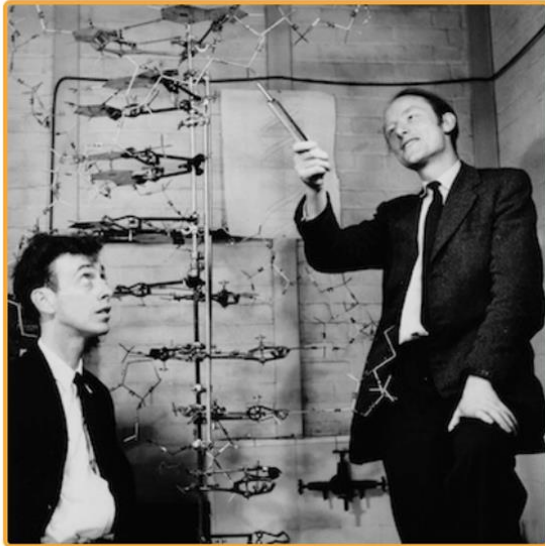
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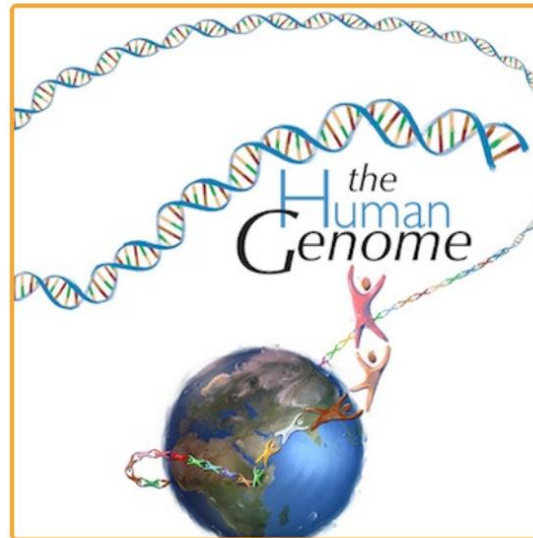
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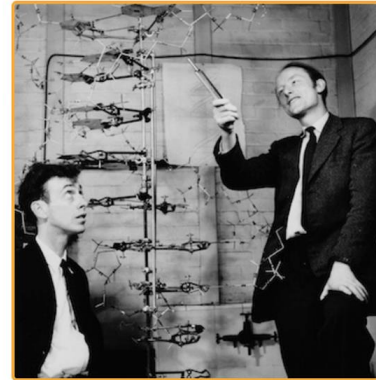


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2003

So what has happened since 2003?



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1953

In 2003, sequencing the first human genome:
\$2.7 Billion and **13 years** of international effort.

In 2026, the same process takes as little as **a few hours** and costs between **\$200 and \$600**.

Medicine is in a rapid phase of a “genomic revolution”

Precision Medicine and Personalized Medicine
is accelerating as we speak

***Tissue is required for research and new
medical discoveries***

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*Tissue is required for research and new
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***Fresh Tissue** is even more valuable for
precision and personalized medicine*

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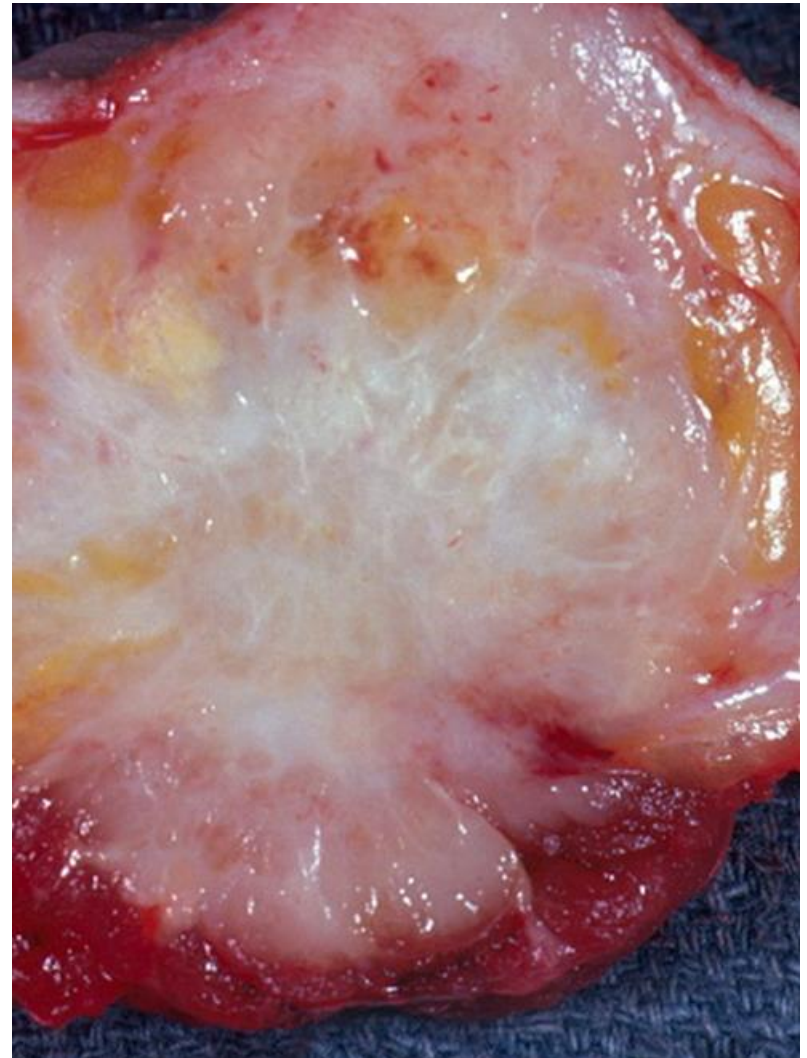
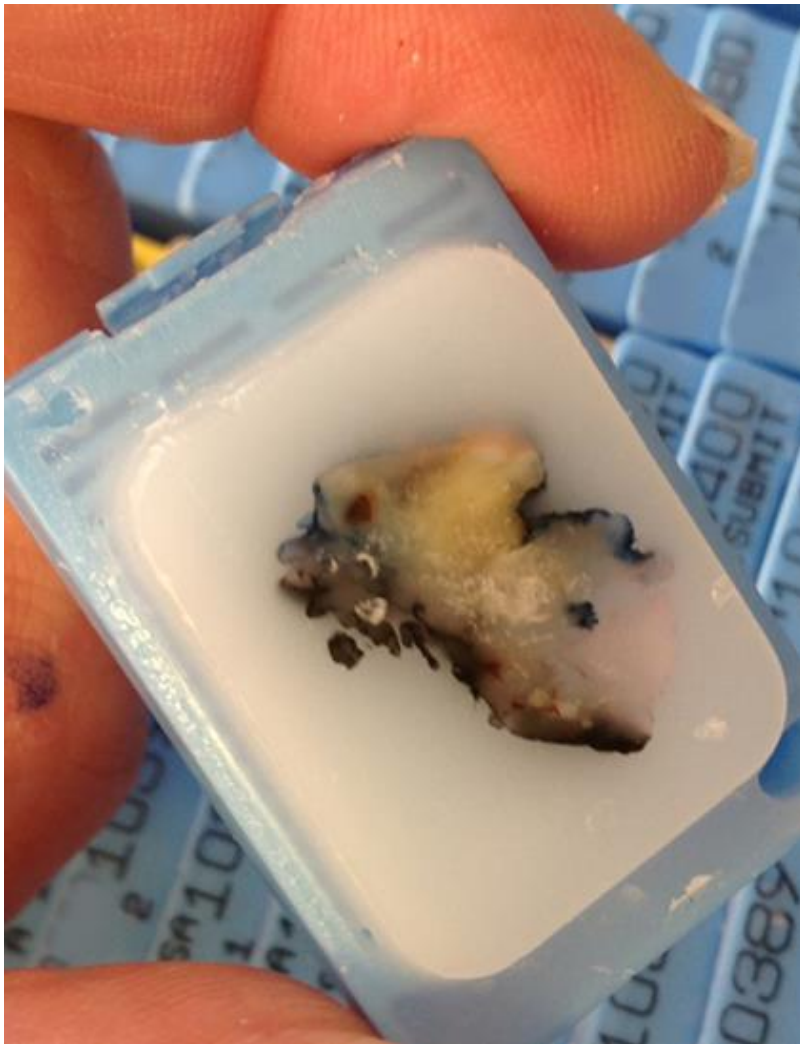
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PATHOLOGY WILL BE INVOLVED

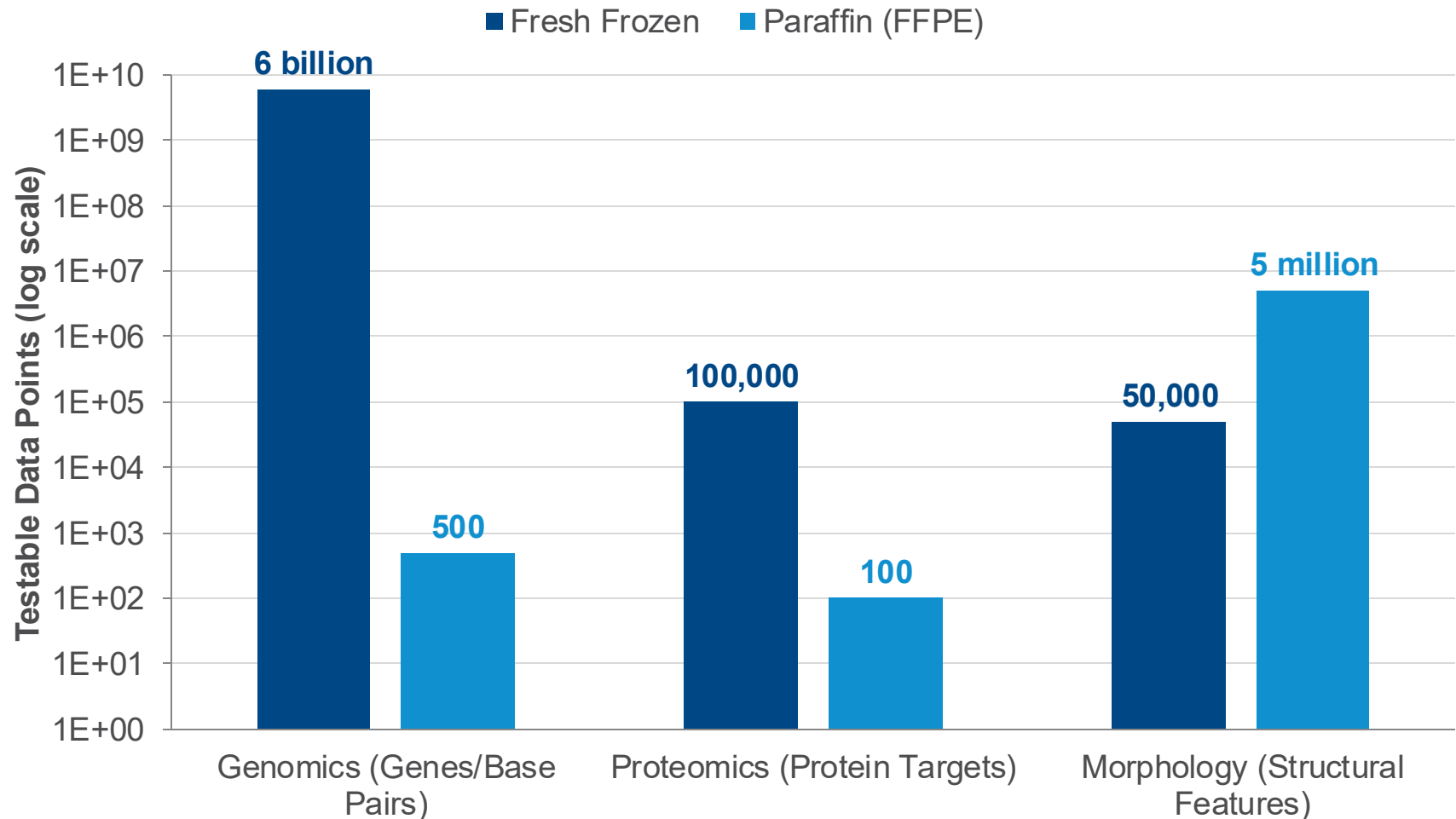
Paraffin (FFPE) vs Fresh Tissue



Testable Data Points: Head-to-Head Comparison

A single tissue section yields vastly different amounts of data depending on how it is preserved.

Fresh Frozen vs. Paraffin (FFPE)



Testable Data: Fresh Frozen vs. Paraffin (FFPE)

Research Assay	Fresh Frozen Tissue	Paraffin / FFPE Block
Genomic Sequencing	~20,000+ genes (full genome, unfragmented RNA)	~300–500 genes (fragmented targeted panels)
Proteomics (Mass Spec)	~10,000+ native proteins (full molecular mass)	~500–1,000 proteins (cross-linked debris)
Spatial Biology Multiplex	Poor — tissue degrades and tears during washing	~40–100 targets (excellent tissue stability)
Morphological Features	Low — ice crystals warp cellular details	Millions of cells (flawless architecture)

Problem

Access to fresh tissue is a barrier to advanced cancer care



Insufficient tissue

Samples of fresh live tumor tissue are rarely available for advanced genetic testing and research.



One sample, two demands

Confirming the diagnosis consumes the same tissue required to select the appropriate therapy.



Clinical Trials

More and more clinical trials are requiring fresh tissue sample for enrollment (this is forecasted to increase)



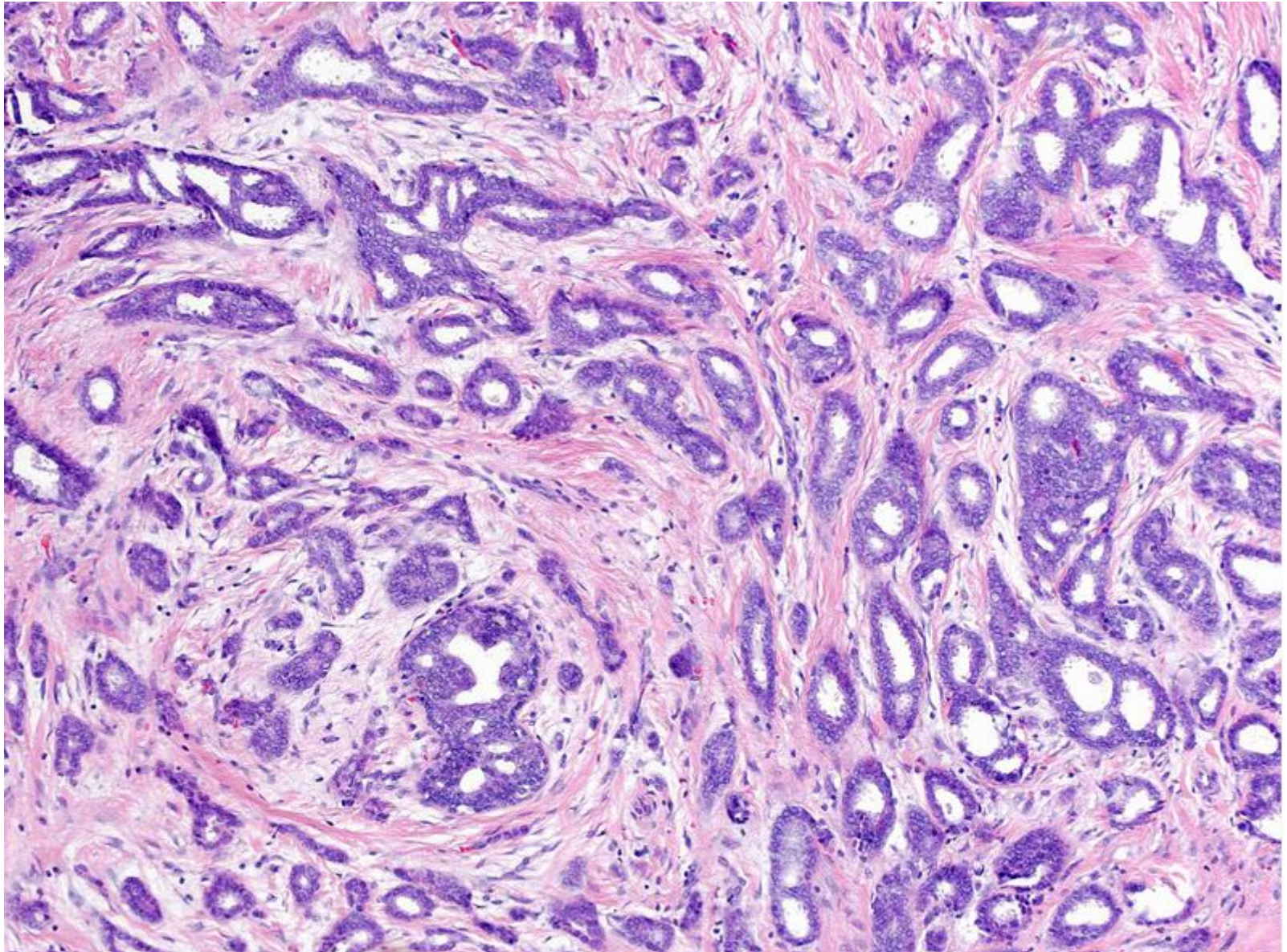
**Patient Diagnosis
Vs
Precision medicine**



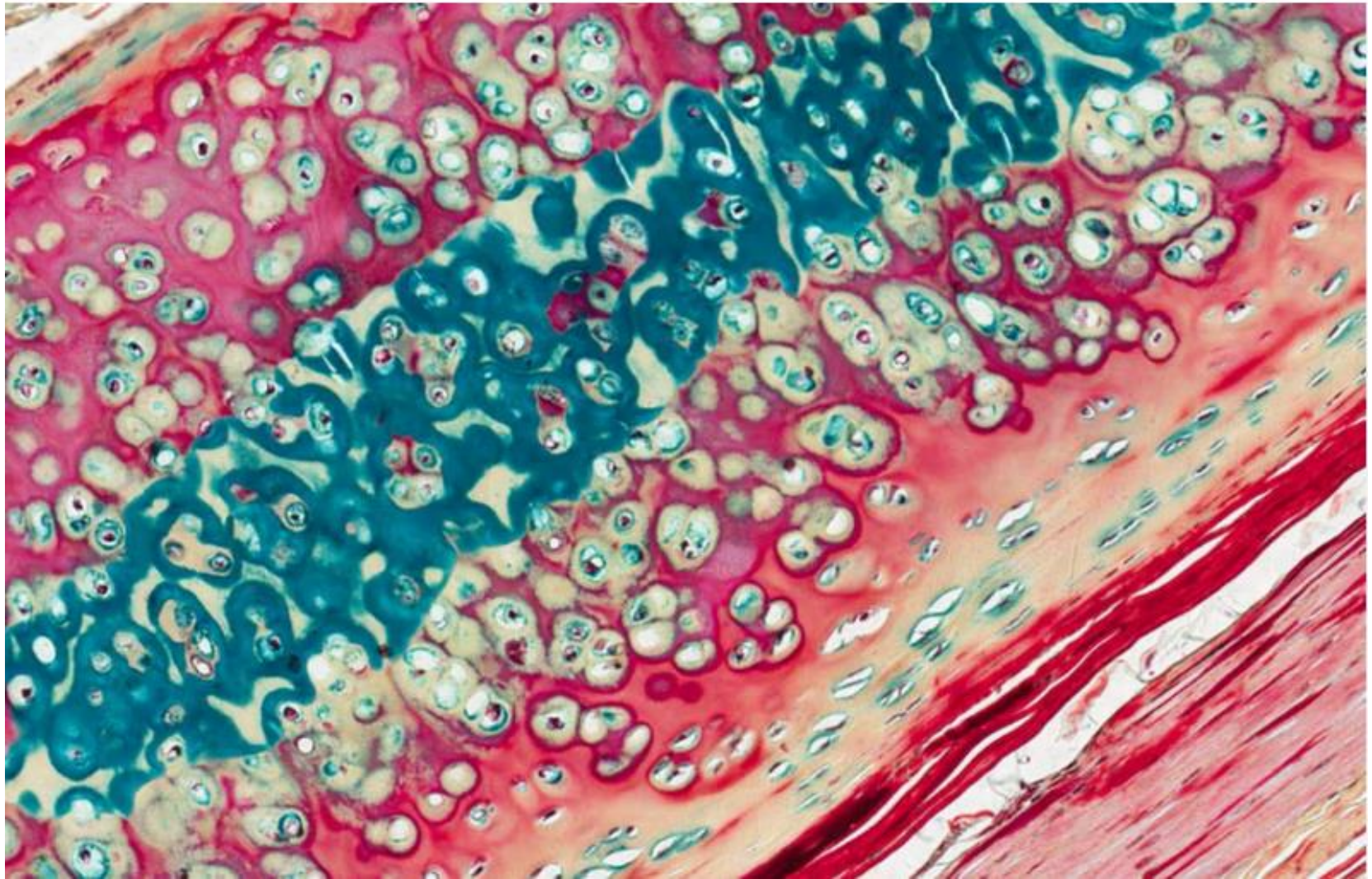
Paraffin Blocks are Data Repositories



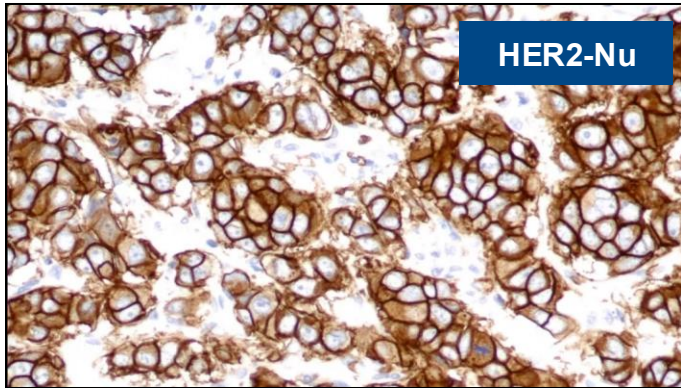
Paraffin (FFPE): Morphology



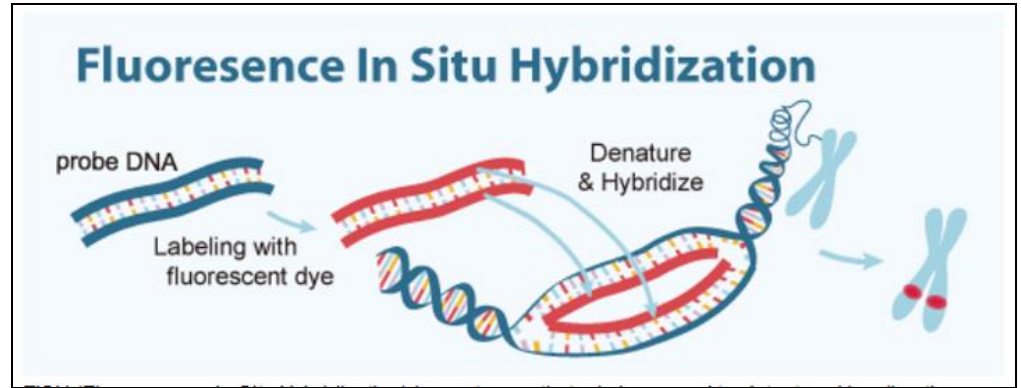
Paraffin (FFPE): Special Stains



Paraffin (FFPE): Traditional Pathology Techniques

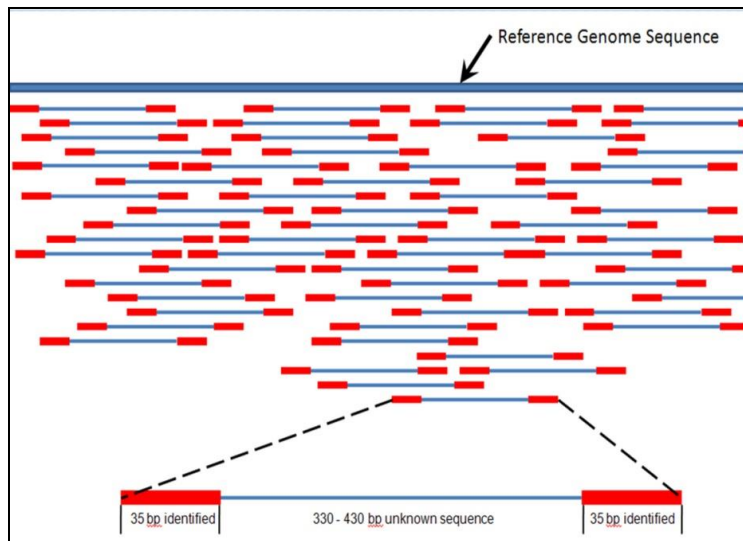


**Immunohistochemistry
(IHC)**

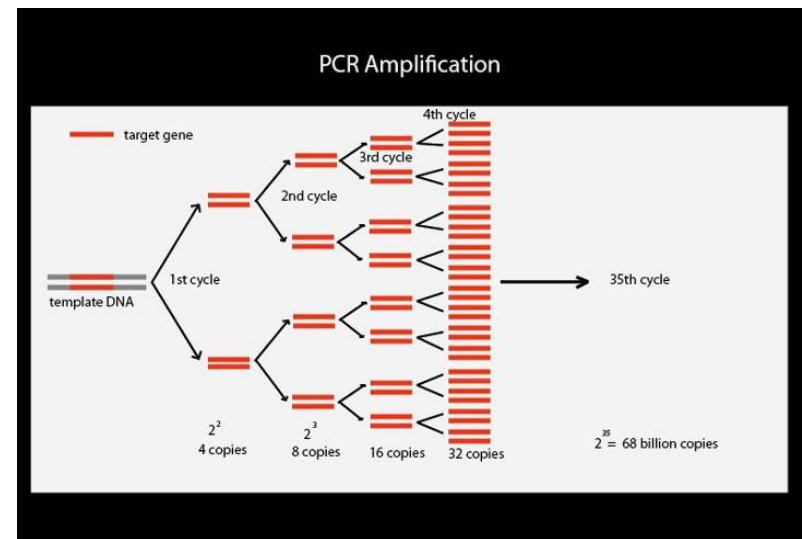


In-Situ Hybridization (FISH)

Paraffin (FFPE): Molecular Diagnostics

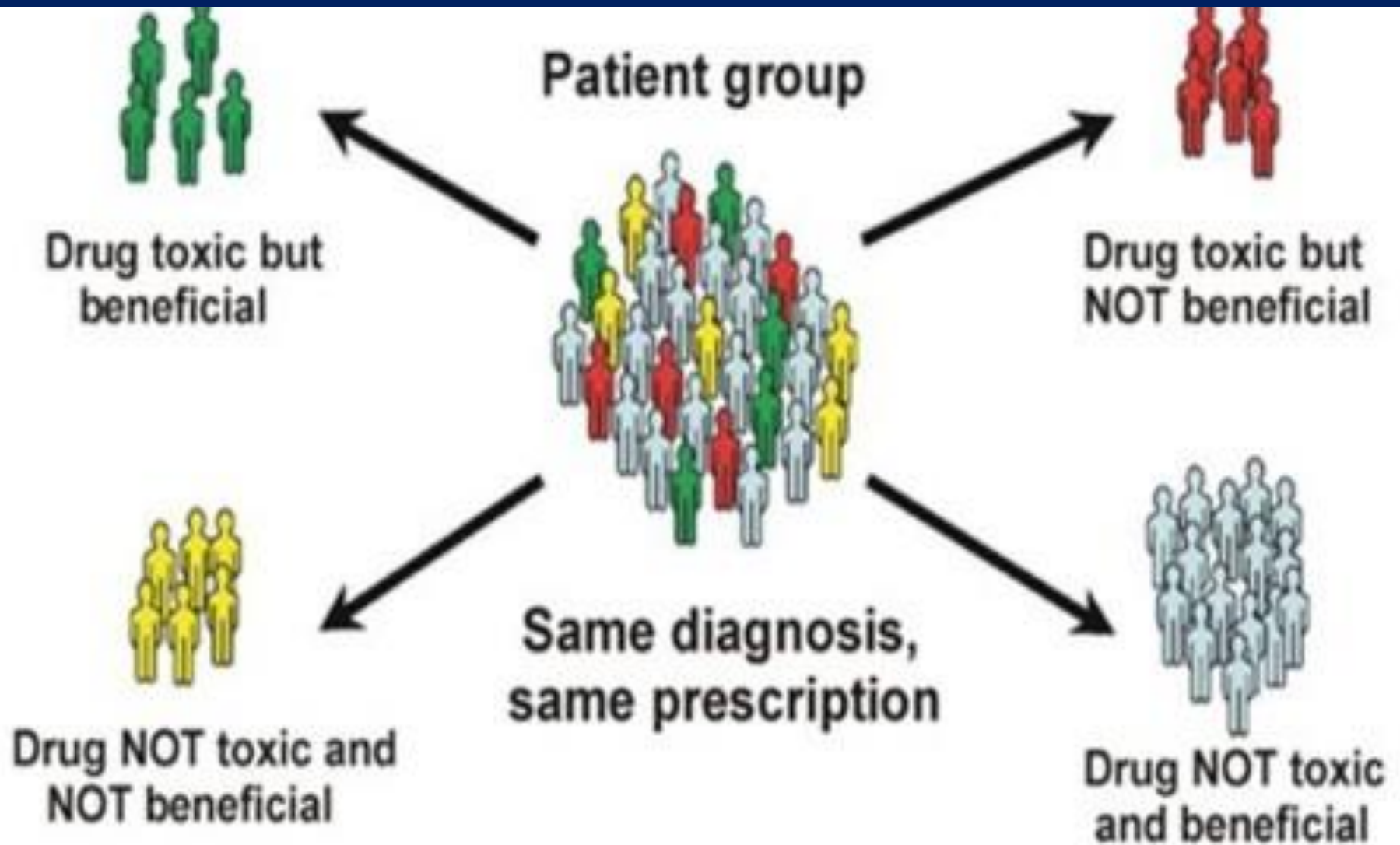


NextGen Sequencing

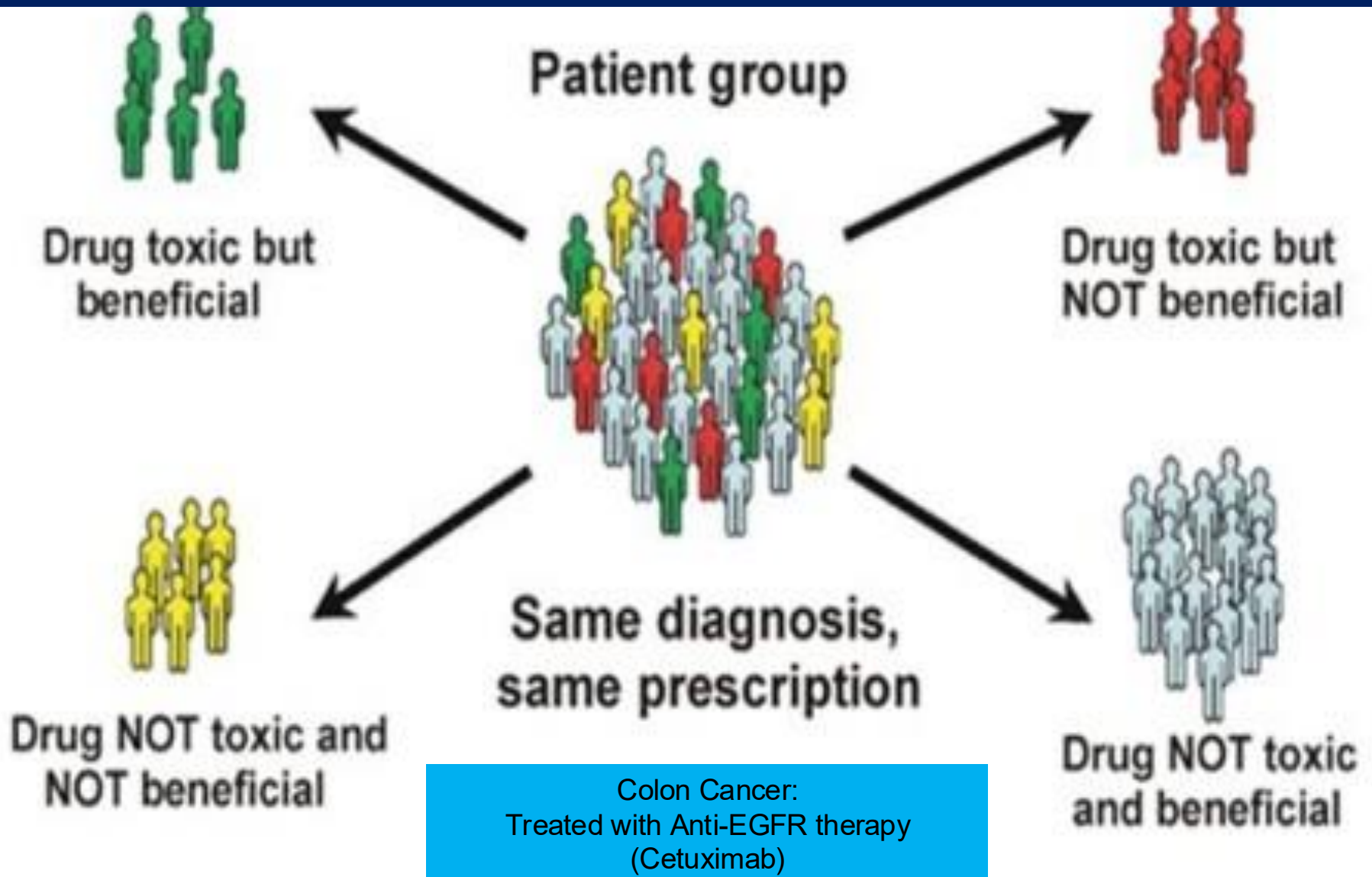


PCR: Polymerase Chain Reaction

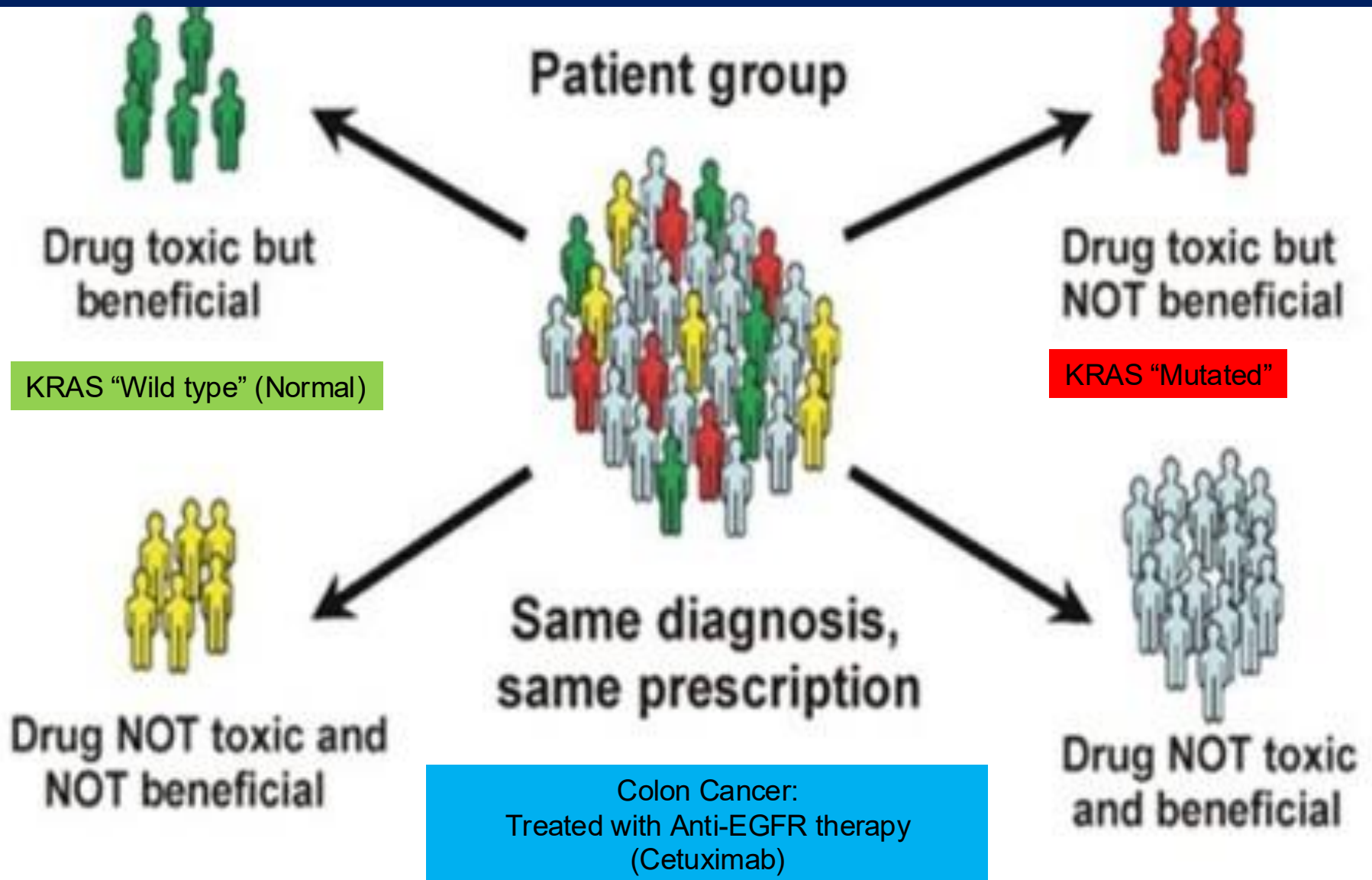
Precision Medicine



Precision Medicine

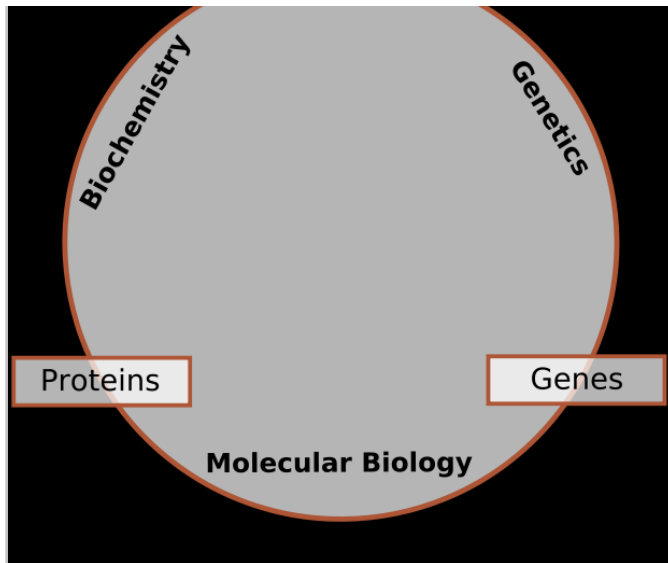


Precision Medicine

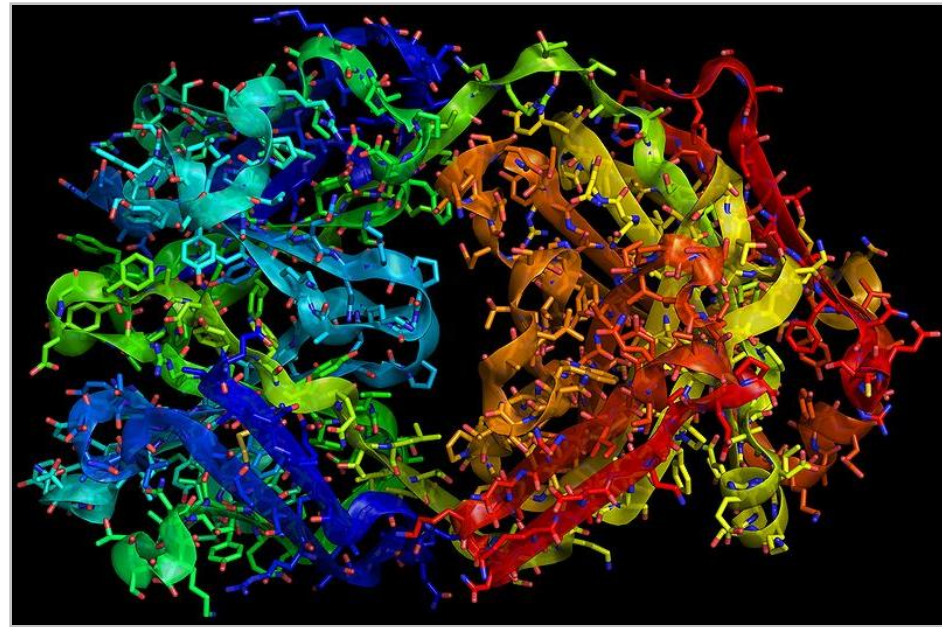


Precision Medicine

- Increasing need for high-quality tissue samples to advance medical research
- Translational research
 - Personalized Medicine



BREAST CANCER and Her2-neu



Herceptin (blocks Her2neu receptor)

Paraffin (FFPE) : Advantages

FFPE is the global standard for pathology because it solves the massive logistical hurdles of hospital workflows.

Morphology

Indefinite Room-Temperature Storage

Low Cost and Easy Transport

Massive Historical Archives

Highly Standardized Workflows

Preserves Spatial Architecture

Hospitals should never throw out old paraffin blocks.

Tests that *cannot be done* with Formalin-fixed tissue

These tests fail or become highly inaccurate due to the chemical cross-linking, molecular fragmentation, and denaturation caused by formalin.

- **Full-Length RNA Sequencing**
- **Organoid Research and traditional tissue culture**
- **In Vivo Xenografts (PDX)**
- **Solid Tumor Flow Cytometry**
- **Western Blotting for Native Proteins**
- **Fresh Frozen Section IHC**
- **Functional Bioassays**
- **Intact Chromatin Assays (ChIP-seq)**



**Medicine is a
rapid phase of
a “Genomic
revolution”**

Precision Medicine and
Personalized Medicine
are evolving as we speak

FRESH TISSUE

*is even more valuable for
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EXPONENTIALLY

*Increases the Data Points
available in tissue testing*

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Fresh Tissue: Advantages



FRESH TISSUE

What Formalin Fixation Permanently Destroys

- **Enzyme Activity:** Living enzymes are denatured; functional enzyme assays and histochemical tests for active enzymes are impossible.
- **Live Cells:** All cells are killed, ruling out cell culture, viable-cell flow cytometry, and functional cell assays.
- **High-Quality RNA:** RNA is fragmented and chemically modified, ruining full-length RNA sequencing (RNA-seq) and large-transcript analysis.
- **Cell Membrane Lipids:** Lipids are leached and modified, preventing accurate lipidomic profiling and altering membrane-bound antigens.
- **Unmodified Proteins:** Proteins are cross-linked, heavily compromising mass spectrometry for native structures and post-translational modifications.

Tests Performed Using Fresh, Frozen, or Live Tissue

Whole Genome Sequencing (WGS)

Live Cells: In Vivo or In Vitro studies

Patient-Derived Organoids (PDOs) & Tumor Spheres

Optical Genome Mapping (OGM)

Clinical Trials Requiring Fresh Tissue for Enrollment

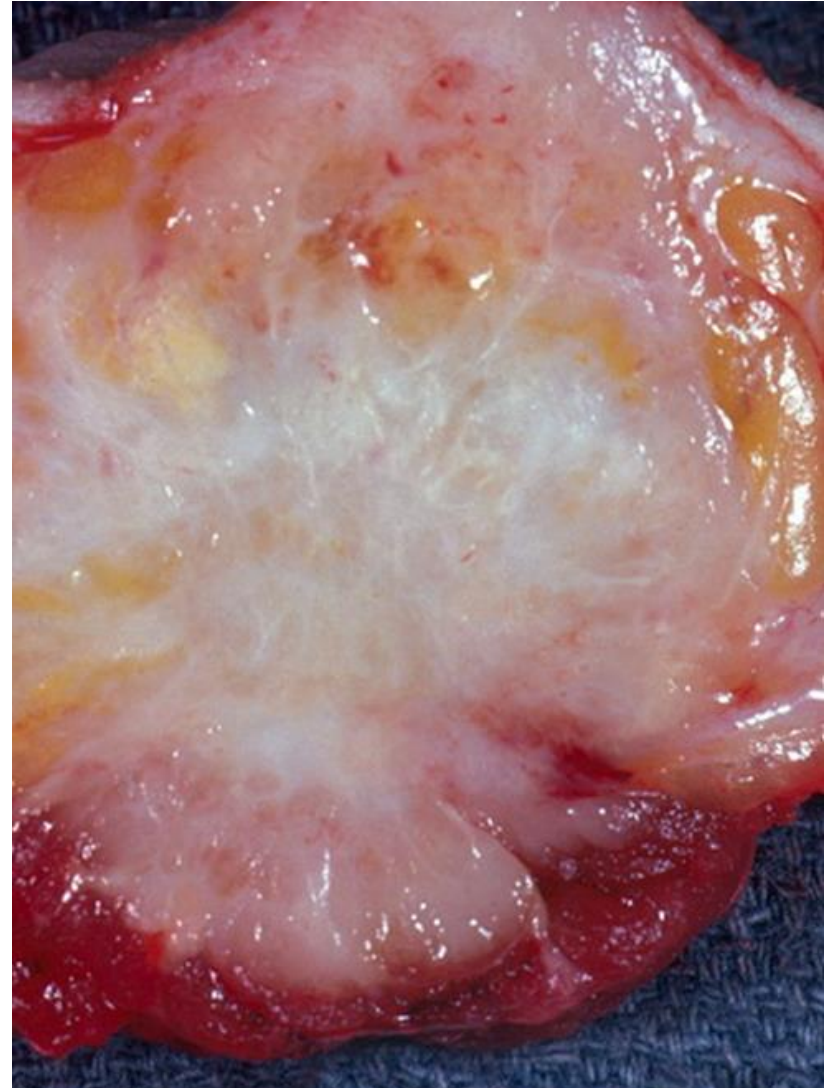
Patient-Specific Immunotherapy

Single-Cell RNA Sequencing (scRNA-Seq)

Flow Cytometry (Solid tissue)

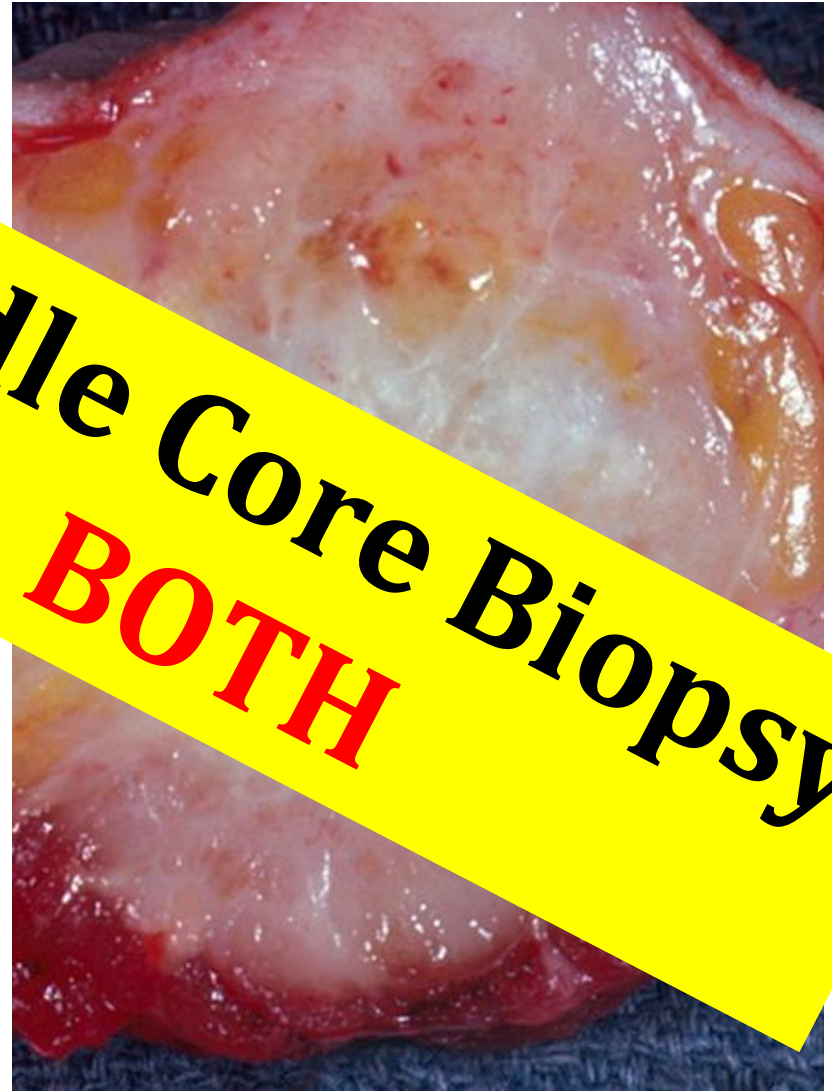
Live or snap-frozen specimens are mandatory when native protein structures, absolute molecular integrity, or active cell processes are being measured.

Paraffin (FFPE) vs Fresh Tissue



Paraffin (FFPE) vs Fresh Tissue

The Dual Needle Core Biopsy Device Creates BOTH

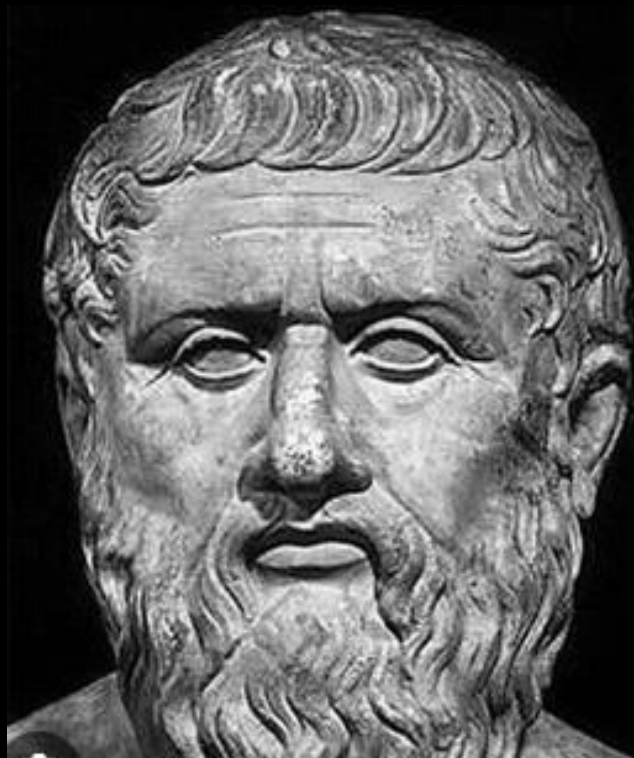


Click For Movie

The Development of a Medical Device

The Process: Team, Equipment, Deployment



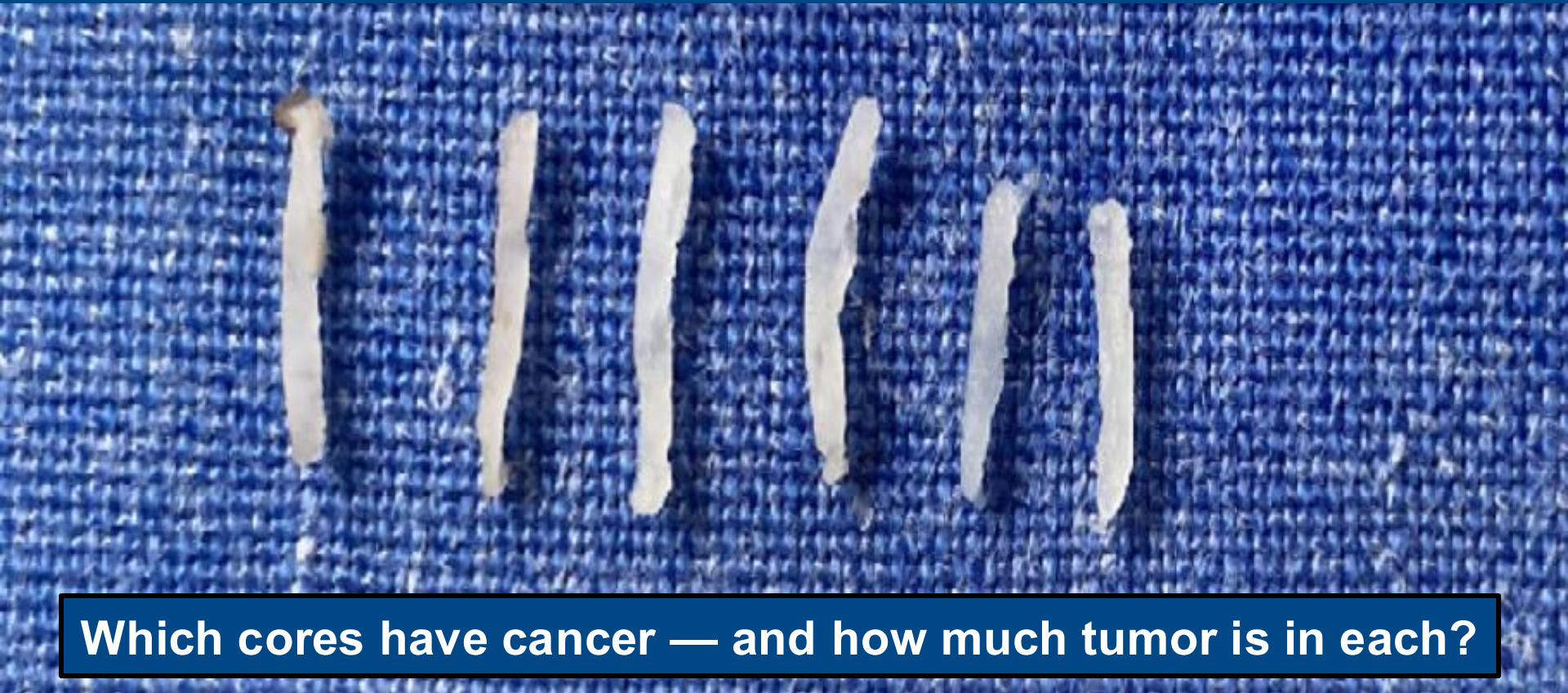


Necessity is literally the mother of
invention.

— *Plato* —

Clinical History

Patient with breast cancer and clinically positive lymph nodes



Which cores have cancer — and how much tumor is in each?

Surgeon Requests

“Send three cores for diagnosis and three for research”

The Innovative Process

DONE

- Concept
- Patent Process & Patent Allowance
- Development of Prototype
- Testing Prototype
- Validation Testing
- Present at Conferences

1

2

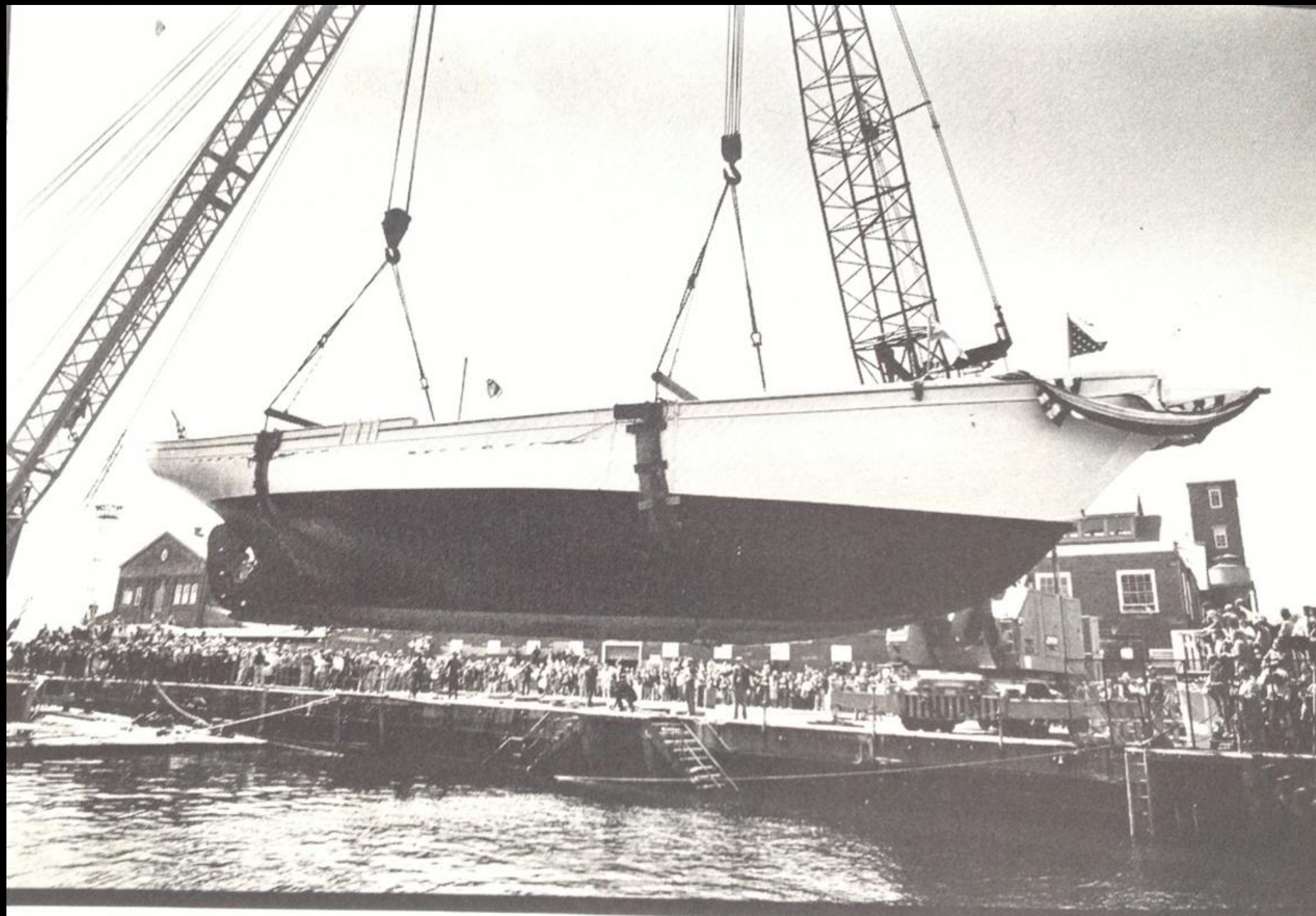
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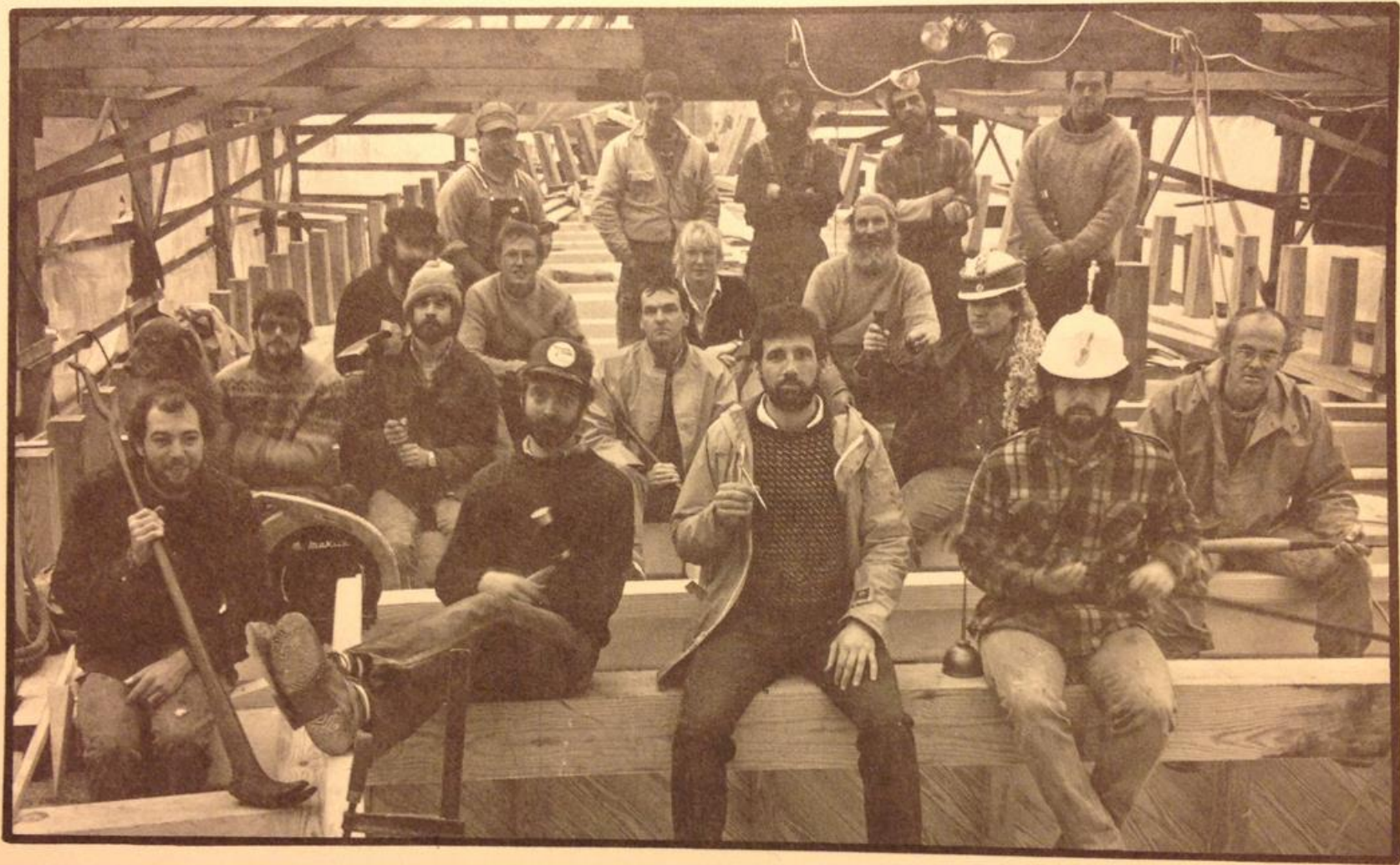
TO BE DONE

- Manufacturing Process
- Bringing to Market
- Venture Capital & Financing
- Pitch Deck
- Partnering vs Licensing
- Present at Conferences

IN PROCESS

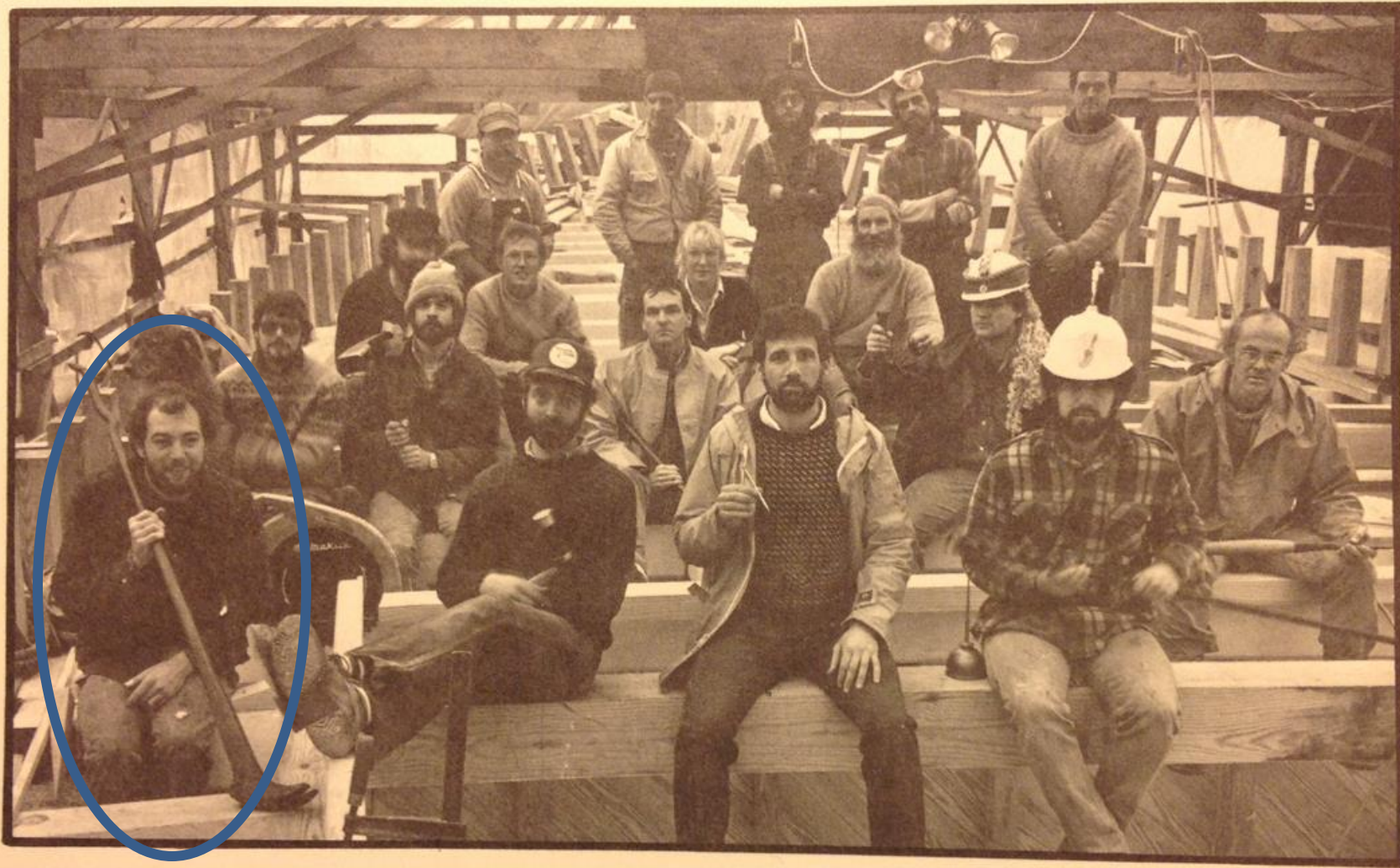
- Efficacy Testing
- Refining Design
- FDA Approval
- Low-Volume Prototype Development
- Present at Conferences





SHIPWRIGHTS

Front Row (Left to Right) — Rocky Ackroyd, Mark Welling (Shipwright Foreman), Andy Davis (Master Shipwright), David Berman;
 Second Row — Zuppa, Timothy Nagle, John Van Soest, Ronald Duprey (Rigger), David Mullin (Rigger); Third Row — Ronald Bowes,
 Randy Hanford, Sarah Talbot (Painter), Alan Richter; Back Row — Frank Rapoza (Caulker), Philip Rice, David Short, Eugene Scalco
 (Caulker), John Janowicz; Missing — Kevin Jackson, John Moore, Karen Holtz (Painter), William Stevenson, Muriel Curtis, (Rigger),
 David Swallow.



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 (Caulker), John Janowicz; Missing — Kevin Jackson, John Moore, Karen Holtz (Painter), William Stevenson, Muriel Curtis, (Rigger),
 David Swallow.

Development Team

Tho Ngo



Val Kratzman



David Nemiah



Sean Sweeney



TEKH Consulting, LLC



**MAINE CENTER
FOR ENTREPRENEURS**



BrandReady
USA

tredecim
X:
LLC

Tho Ngo



TEKH Consulting, LLC

Sean Sweeny



X:
tredecim
LLC

(12) United States Patent ~~Ackroyd~~

(10) Patent No.: US 11,589,846 B2
(45) Date of Patent: Feb. 28, 2023

(54) DUAL NEEDLE CORE BIOPSY INSTRUMENT

(71) Applicant: **Robert K Ackroyd**, Windham, ME (US)

(72) Inventor: **Robert K Ackroyd**, Windham, ME (US)

() Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 332 days.

(21) Appl. No.: **14/850,994**

(22) Filed: **Sep. 11, 2015**

(65) Prior Publication Data

US 2016/0074020 A1 Mar. 17, 2016

Related U.S. Application Data

(60) Provisional application No. 62/040,783, filed on Sep. 22, 2014.

(51) **Cl.** **A61B 10/02** (2006.01)

(52) **U.S. Cl.** **CPC** **A61B 10/0233** (2013.01); **A61B 10/025** (2013.01); **A61B 2010/0208** (2013.01); **A61B 2010/0225** (2013.01) **Field of Classification Search**

(58) None
See application file for complete search history.

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* cited by examiner

Primary Examiner — Rene T Towse

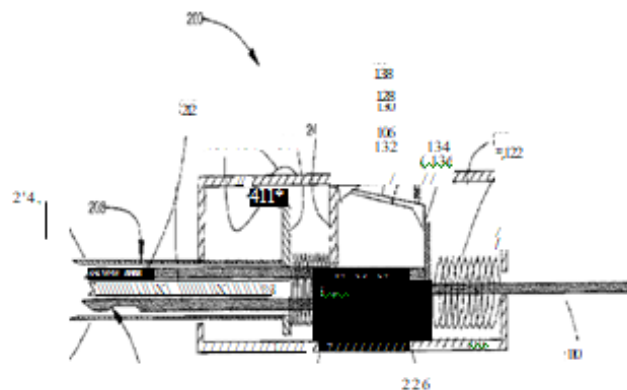
Assistant Examiner — Benjamin S McIlroy

(74) Attorney, Agent, or Firm — ~~Robert et al.~~ LLC; Sean L. Sweeny

(57) ABSTRACT

The embodiments presented herein present a single needle core biopsy instrument and modification required that convert the single needle core biopsy instrument to a dual needle core biopsy instrument. Depending on the design, the dual needle core biopsy instrument permits the simultaneous extraction of tissue or bone specimens taken at between 0.1 mm and 3 mm apart.

10 Claims, 9 Drawing Sheets





Val Kratzman

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Food Accelerators

MCE offers two unique Food Accelerator Programs that support Maine food and beverage companies: Cultivator and MarketShare.

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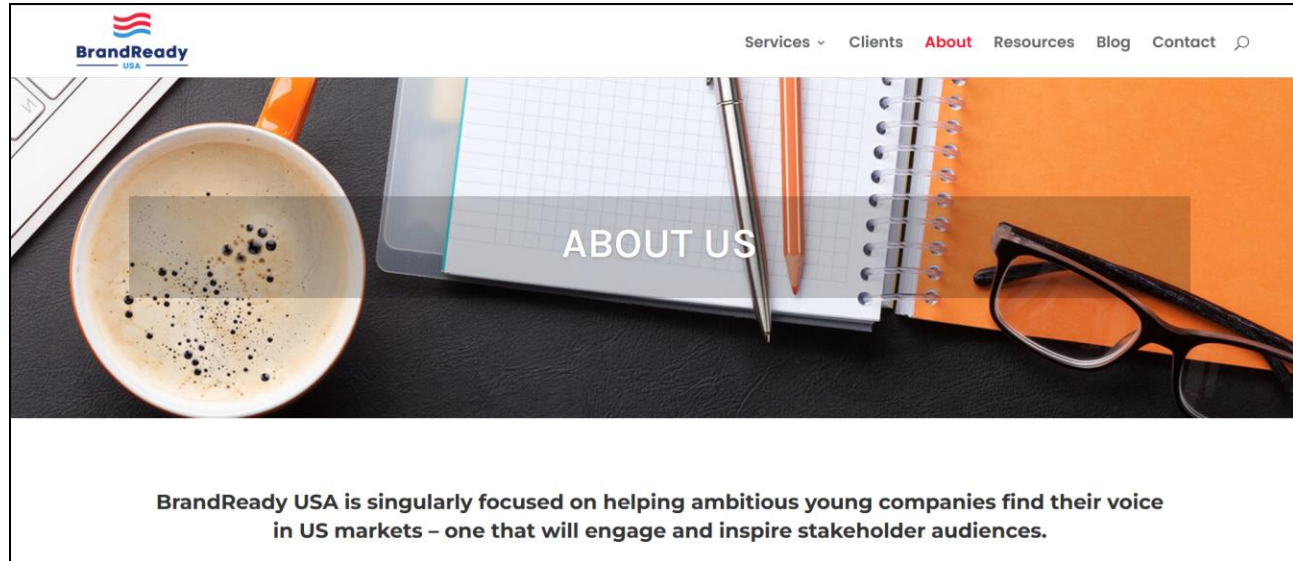
BioStartup

BioStartup provides Maine biotech, digital health, life sciences & medical device entrepreneurs with the resources they need to accelerate their business.

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David Nemiah



FDA Approval Process

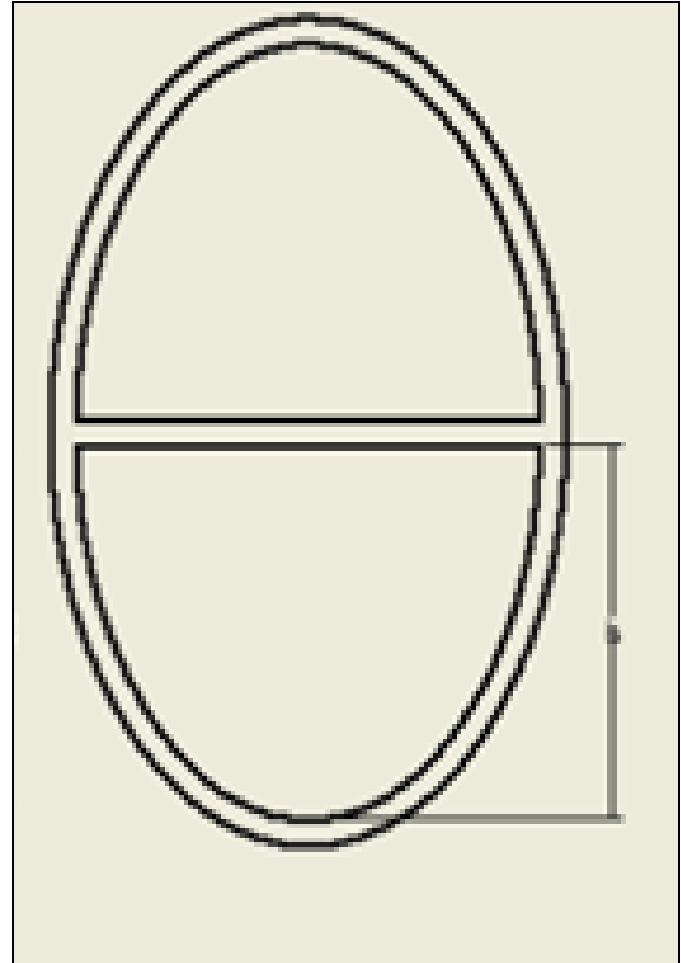
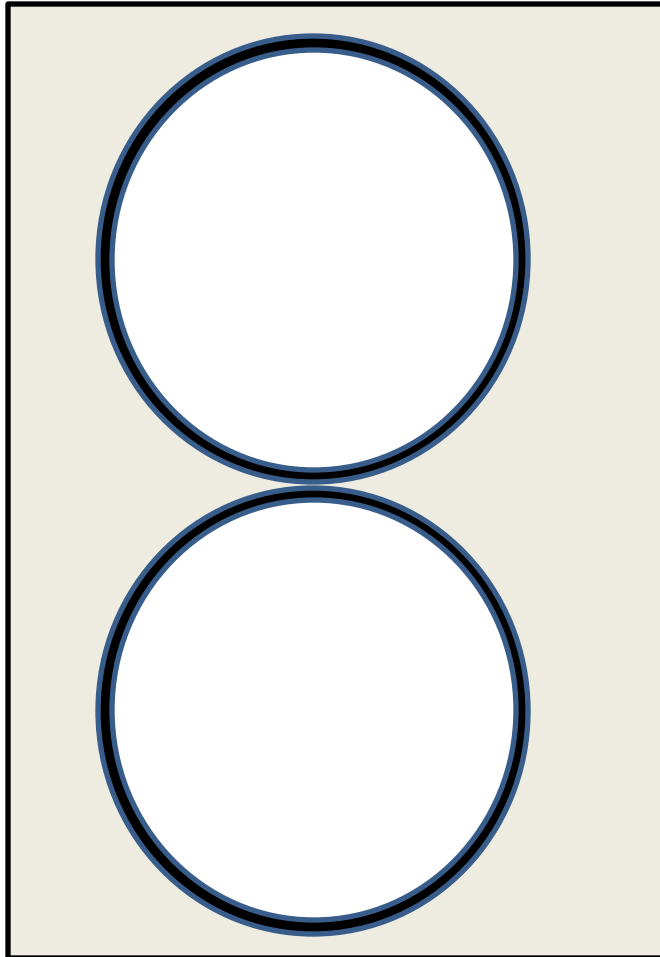


Quarles

What matters to you in the moment and
beyond, matters to us.
This is shared purpose.

FDA Approval Process

Dual Needle profile: Research vs Clinical Care
Refining the initial design profile



Prototype Tooling & Manufacturing

TOOLING & PRODUCT DEVELOPMENT
92 EGYPT ROAD, BUXTON, ME 04093
MARK GRAFFAM AND ROB SAMPSON
TOOLMAKING FOR OVER 30 YEARS 207-929-5900 PHONE AND FAX
STAMPING TOOLS - INJECTION MOLDS - TOOLING JIGS AND EDM FIXTURES
REPAIR - REPLACE - NEW PRODUCT DESIGN & BUILD - PROTO TYPES - ONE OFFS
HEAT TREATMENT OF AIR & OIL HARDENING TOOL STEEL



Advanced Manufacturing Center — UNH



University of
New Hampshire



John Olson Advanced Manufacturing Center



The John Olson Advanced Manufacturing Center is focused on advanced manufacturing technologies and a cross-curricular approach to engineering and manufacturing concepts that will provide hands-on, interdisciplinary

Pathology Collaborators



Dartmouth
Health

Dartmouth Hitchcock Medical Center
Dartmouth Hitchcock Clinics



Kristen E. Muller, DO

Ourania Parra, MD

Greg Tsongalis, PhD, HCLD

Steve Boyle, PA, ASCP

Pathology Collaborators



Dartmouth
Health

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Steve Boyle, PA, ASCP

Pathology Collaborators



Greg Tsongalis, PhD, HCLD

Laser system



VLO 60

MANUAL WELDING LASER

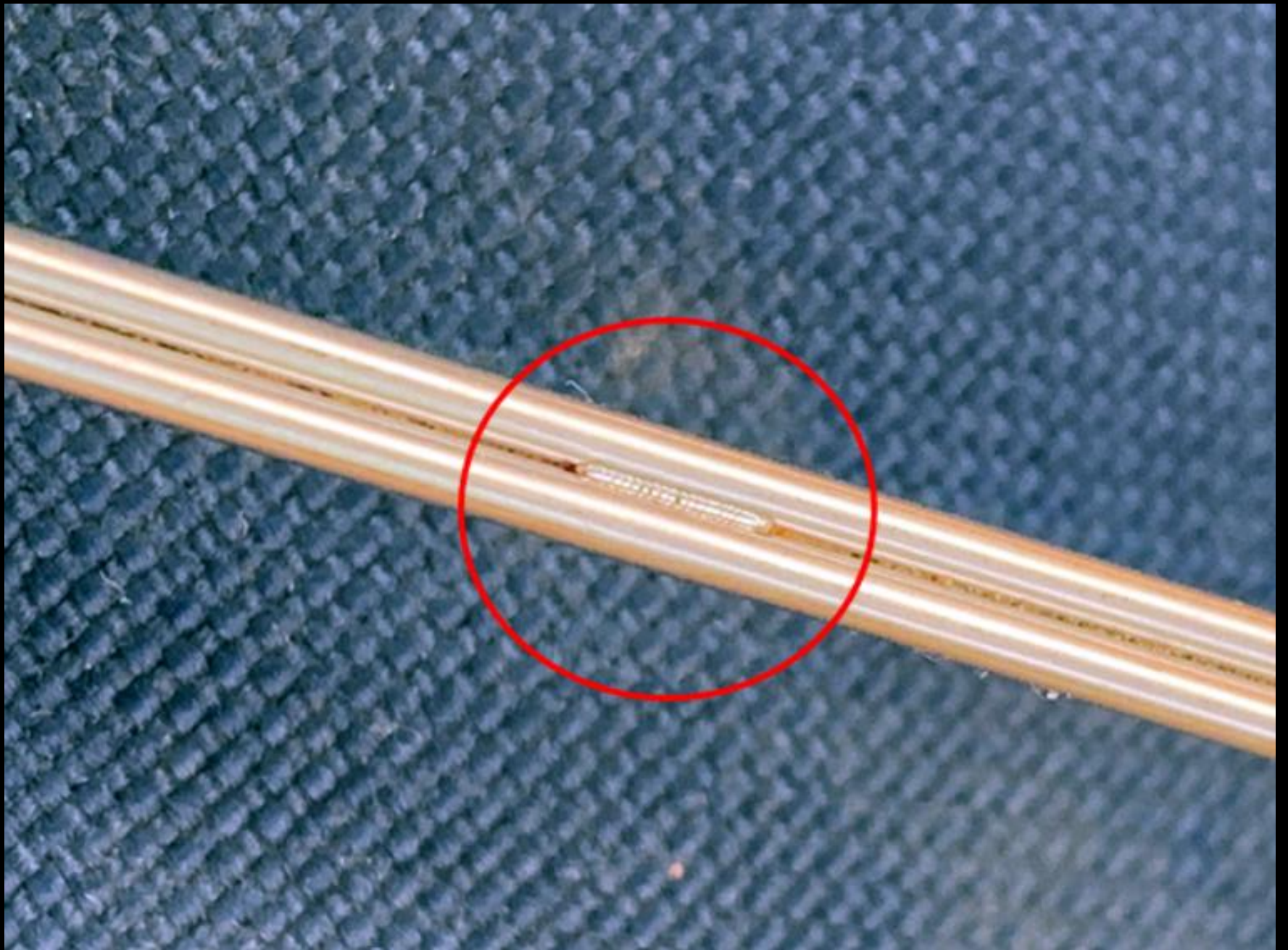
The VLO 60 is a compact laser welding device for demanding manual work with the best welding properties.

This desktop laser systems with 60 watts offers a reliable beam behavior and stand out for its consistent, powerful and yet soft welding behavior.

The VLO 60 has a sheet metal housing with a large opening at the front for easy and quick access to the spacious working chamber. The armrest is extremely comfortable - so relaxed work is guaranteed. The laser-safe leather curtain offers laser protection, so that the VLO 60 can also be placed in any work environment.



VLO 60



Surface Grinder



3D Printer



BARD Reusable Triggering Device

Single core only



Click for Movie

BARD Disposable Triggering Device

Single core only

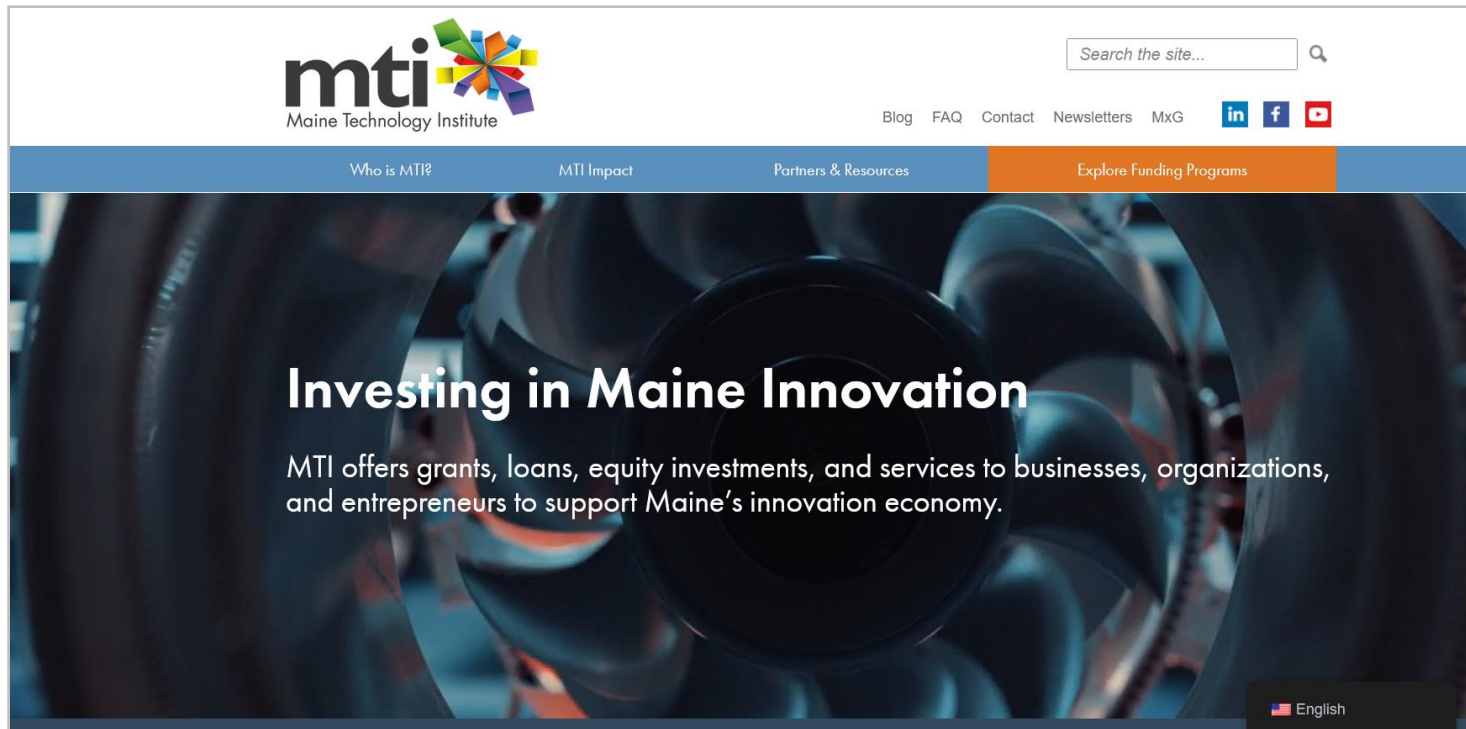


Quarles and Brady	\$ 2,713.50	Consultants for FDA Application
Tredecim	\$ 22,883.50	Patent Attorney
TPD	\$ 4,470.00	Tooling and Product Development (Machinist)
Web Consultant	\$ 500.00	Web and Graphics Consultant
Summer Intern	\$ 2,500.00	FDA Preparation Work
Alpha Laser	\$ 33,000.00	Micro Laser Welder
Surface Grinder	\$ 750.00	Sourced Used on eBay
Small Tools and Equipment	\$ 1,819.70	Shop Supplies
Microgroup - TE Connectivity	\$ 8,246.76	Needles and Cannula Supplies
General Administrative Items	\$ 1,450.79	State Reporting, Bank fees professional memberships
Marketing Materials	\$ 813.59	Posters / Handouts / Conference Booth Props / etc
Web Expenses	\$ 1,507.72	Web Development and e Mail Services
Travel: Tucson, Arizona	\$ 994.11	Poster Presentation: Tucson Symposium Innovations in Cancer Medicine
Travel: ISBER, Montreal, Canada	\$ 10,822.92	Abstract Presentation / Conference exhibition booth (\$8278.70)
Travel: Cedar Sinai Los Angeles, Ca	\$ 798.69	Collaboration on Research
	\$ 93,271.28	

Funding Partner: Maine Technology Institute



Maine Technology Institute Grant



Awarded a \$30,000 MTI grant (August 19, 2026) to support development of this technology.

NIH Grant **RFA-CA-27-002**

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI) Note: Not all NIH Institutes, Centers, and Offices (ICOs) participate in Announcements. Applicants should carefully note which ICOs participate in this announcement and view their respective areas of research interest at the ICO-Specific Scientific Interests website. ICOs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title	Advanced Development and Validation of Emerging Technologies for Basic and Clinical Cancer Research (R33 Clinical Trial Not Allowed)
Activity Code	R33 Exploratory/Developmental Grants Phase II.
Announcement Type	Reissue of RFA-CA-25-002
Related Notices	• Check for any recent Notices of NIH Policy Changes that may impact application requirements.
Funding Opportunity Number (FON)	RFA-CA-27-002

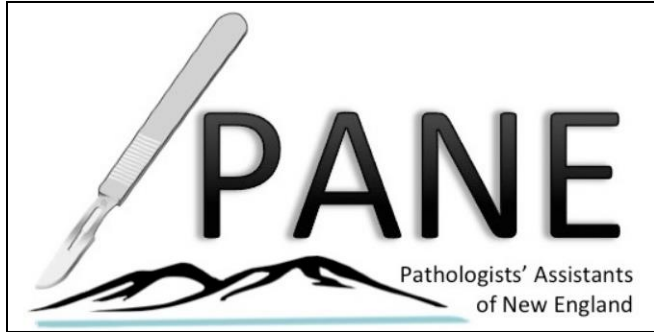
\$50,000 to \$300,000 Award

Through this Notice of Funding Opportunity (NOFO), the National Cancer Institute (NCI) invites grant applications proposing exploratory research projects focused on further development and technical validation of emerging technologies offering novel capabilities for the molecular or cellular characterization of cancer or for improved handling and quality control of biospecimens used for basic, clinical, or epidemiological cancer research. This NOFO solicits R33 applications where major feasibility gaps for the technology or methodology have been overcome, as demonstrated with supportive preliminary data, but still require further development and rigorous technical validation to encourage adoption by the research community. Well-suited applications must propose the development of technologies that offer the potential to accelerate and/or enhance research in the areas of cancer biology, early detection and screening, clinical diagnosis, treatment, cancer control, epidemiology. Technologies proposed for development may have potential for widespread applicability but must be focused in this proposal on cancer-relevant use cases. Projects proposing to apply or use existing technologies for hypothesis-driven research where the novelty resides in the biological or clinical target/question being pursued are not responsive to this solicitation and will not be reviewed.

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Conferences and Presentations (Past)



Yale Medical School: October 2024



1

2

3

4



Denver September 2025 Annual Meeting

Conferences and Presentations: Future



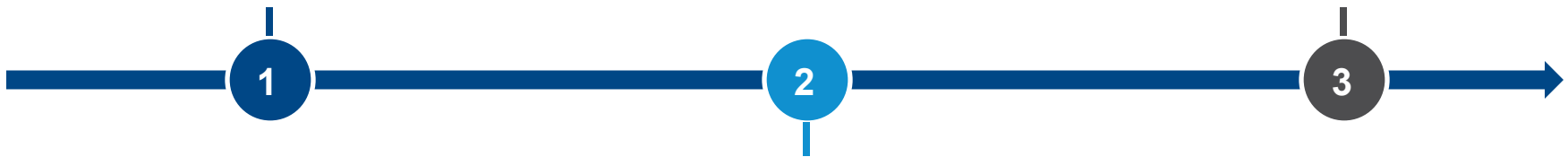
PROGRESS

Development of Device

- Patent granted (2022)
- Prototype built & initial testing validated function

2027

- Refine prototype for large-scale manufacturing (~10,000+/week)
- Complete FDA approval process
- Market at conferences:



Next Several Months

- Produce 1,000 needle sets for efficacy studies
- Refine the mechanics of the needles and function
- Establish collaborations at up to 5 sites
- Generate & publish data on accelerating cancer research







Left Overs

Possible studies

- Compare DNA and RNA (Paraffin vs Fresh)
- HER2 Nu on Fresh Tissue
- Neo-Adjuvent Therapy
- Organoid Studies
- Tumor Heterogeneity Studies
- Metastatic Lesions – Genetic basis of Biologic behavior

Tissue Banking:

- How many of you have tissue banks in you Instructions
- How many of you manage you tissue banks?
- How many of you allocate tissue for your tissue bank.

Final Thoughts

- If you had this tool in you practice – what would you do with it?
- Network Network Network!

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Spirit of Massachusetts

