109 Digital Pathology: Current State, Future, and Opportunities

Keith J. Kaplan, MD
Carolinas Pathology Group

Disclosures/Disclaimers

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- American Pathology Foundation
- Aperio Technologies, Inc.
- Aurora MSC
- Caliper Life Sciences
- CBLPath, Inc
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- Digital Pathology Consultants
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- Meyer Instruments
- MikroScanTechnologies, Inc.
- Omnyx
- PathBoard LLC
- PathXL
- Philips Research
- SPOT Imaging Solutions
- The Dark Report
- Ventana Medical Systems, Inc.
- Visiopharm

Goals

- Telepathology applications
- Problems and barriers to use
- Practical use of telepathology – case based
- Experience
- Virtual IHC
- Cost-effectiveness
- Lessons learned

Definition

Telepathology is the practice of digitizing histological or macroscopic images for transmission along telecommunication pathways for diagnosis, consultation or education.

The Next Best Thing To Being There

And Now, Diagnosis by Satellite

The patient, a 66-year-old woman with cancer in her left breast, lay in a hospital in El Paso, Tex. The doctor about to make her diagnosis was nearly 2,000 miles away in Southwest Washington.

Sitting at a computer terminal in the Comsat building in L'Enfant Plaza last Wednesday, Dr. Alexander Miller, an expert in gynecological pathology, studied a televised image of a biopsy, a microscopic sample of tissue taken from the patient's breast. He quickly determined that the tumor had spread throughout the breast and that more surgery was necessary.

"You can have a piece of tissue under a microscope in Texas and an image in Washington so clear that you see the microscopic detail . . . well enough to make an immediate diagnosis."

Colburn, D 1986, 'The next best thing to being there', *The Washington Post,* 27 Aug, p. H7.

History (as told through e-mails)

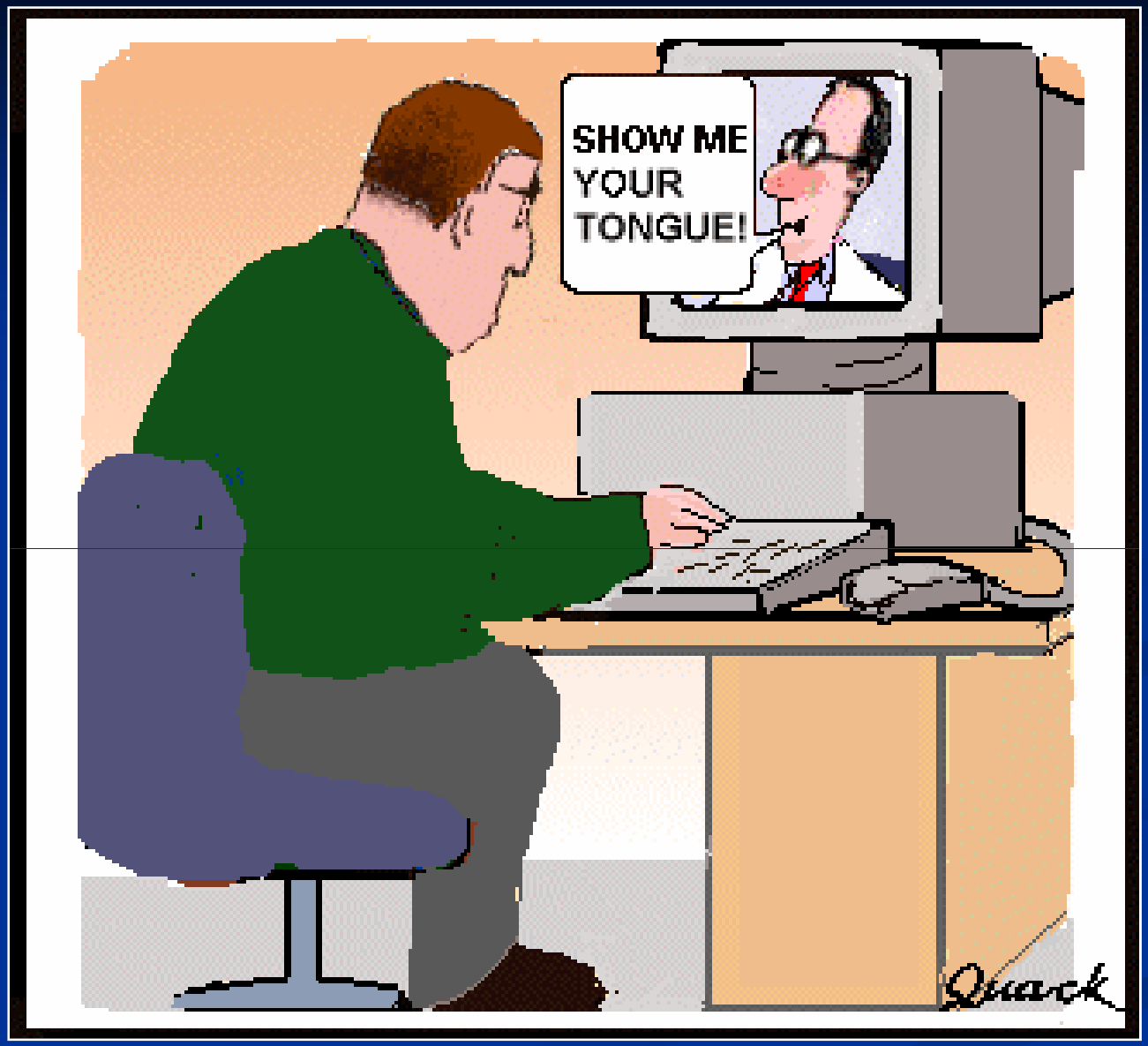
- 2003
  - If it is not glass, you can kiss my ***.
  - It would be cheaper to send the slides on the Concorde to AFIP than do telepathology
  - It would be cheaper and more efficient to fly the patient first-class to Mayo Clinic
- 2004
  - I read somewhere that computers can be used for assisting in rare event detection.
  - Are multiple slide carriages available?

History (as told through e-mails)

- 2004
  - You can be in the field and have access to a sub-specialty expert with decreased TAT. I put the slides on in the evening and have an answer in the morning.
  - I have installed a wireless network at home and can review the cases from home.
- 2005
  - I have assumed responsibility of training residents on the system.
  - We sent several cases to AFIP with rapid diagnosis and great service.

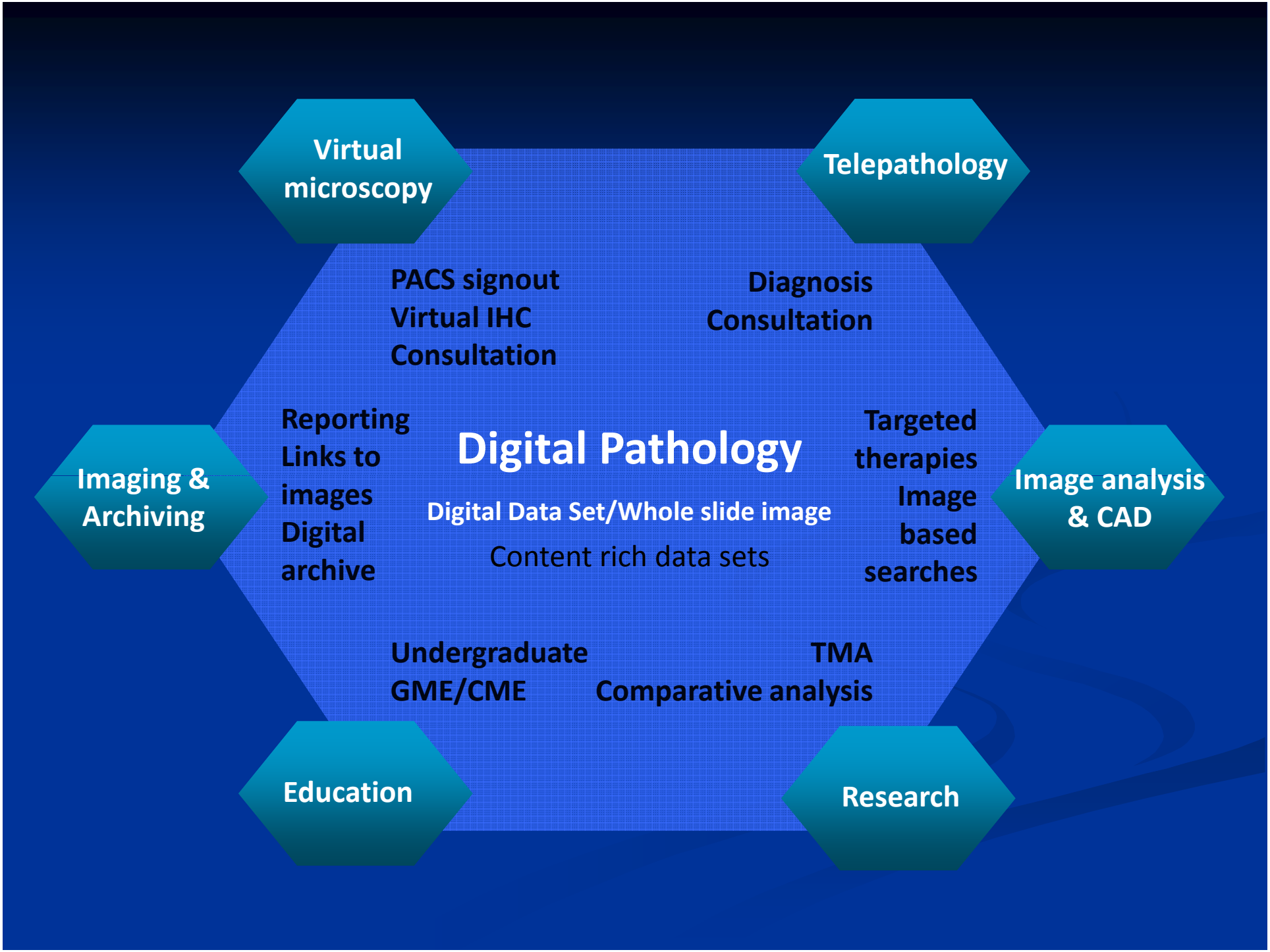
History (as told through e-mails)

- 2006
  - Thanks for all the support with our telepathology program. We have become very comfortable with the concept and are now moving on to high resolution scans. I am so excited by this – I envision the day when the slides will come off the autostainer and auto-coverslipper, thru the scanner and into our CoPath Pics Plus module so we can sign out on the computer without a microscope! Long gone are the days of "Kohler illumination"! – Welcome to the digital world!


SHOW ME
YOUR
TONGUE!
Quack

Telemedicine Services

- Telepathology
- Teleradiology
- Teledermatology
- Teleendoscopy
- Telecardiology
- Telepsychiatry
- Telesurgery
- TeleICU
- Telecare, education, research & administration


Virtual microscopy
Telepathology
PACS signout
Virtual IHC
Consultation
Diagnosis
Consultation
Imaging & Archiving
Reporting
Links to images
Digital archive
Digital Pathology
Digital Data Set/Whole slide image
Content rich data sets
Targeted therapies
Image based searches
Image analysis & CAD
Undergraduate
GME/CME
TMA
Comparative analysis
Education
Research

AT&T
1:25 PM
SMS
Text
Wednesday
29
Calendar
Photos
Camera
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Stocks
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Maps
73°
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Notes
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Flash
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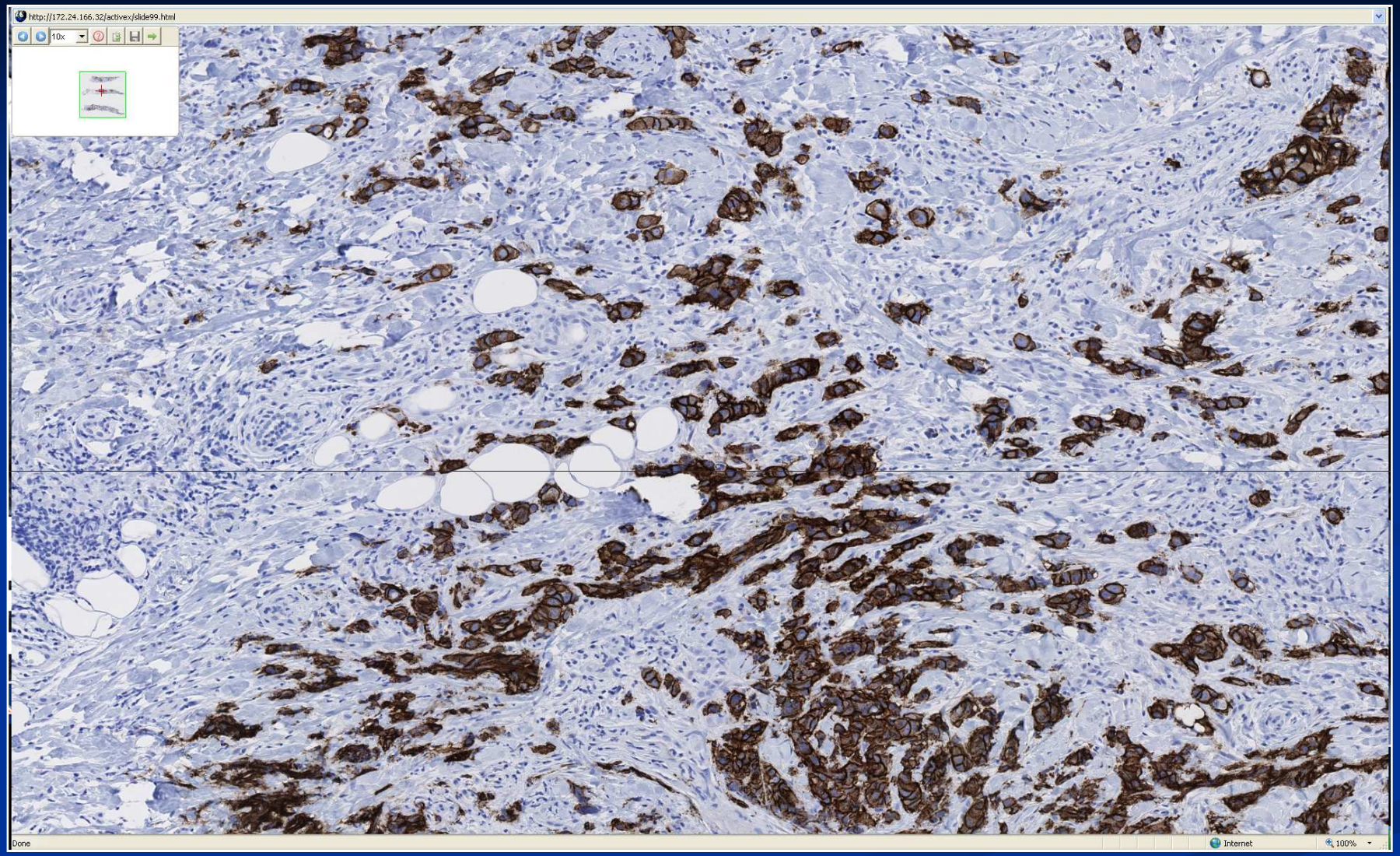
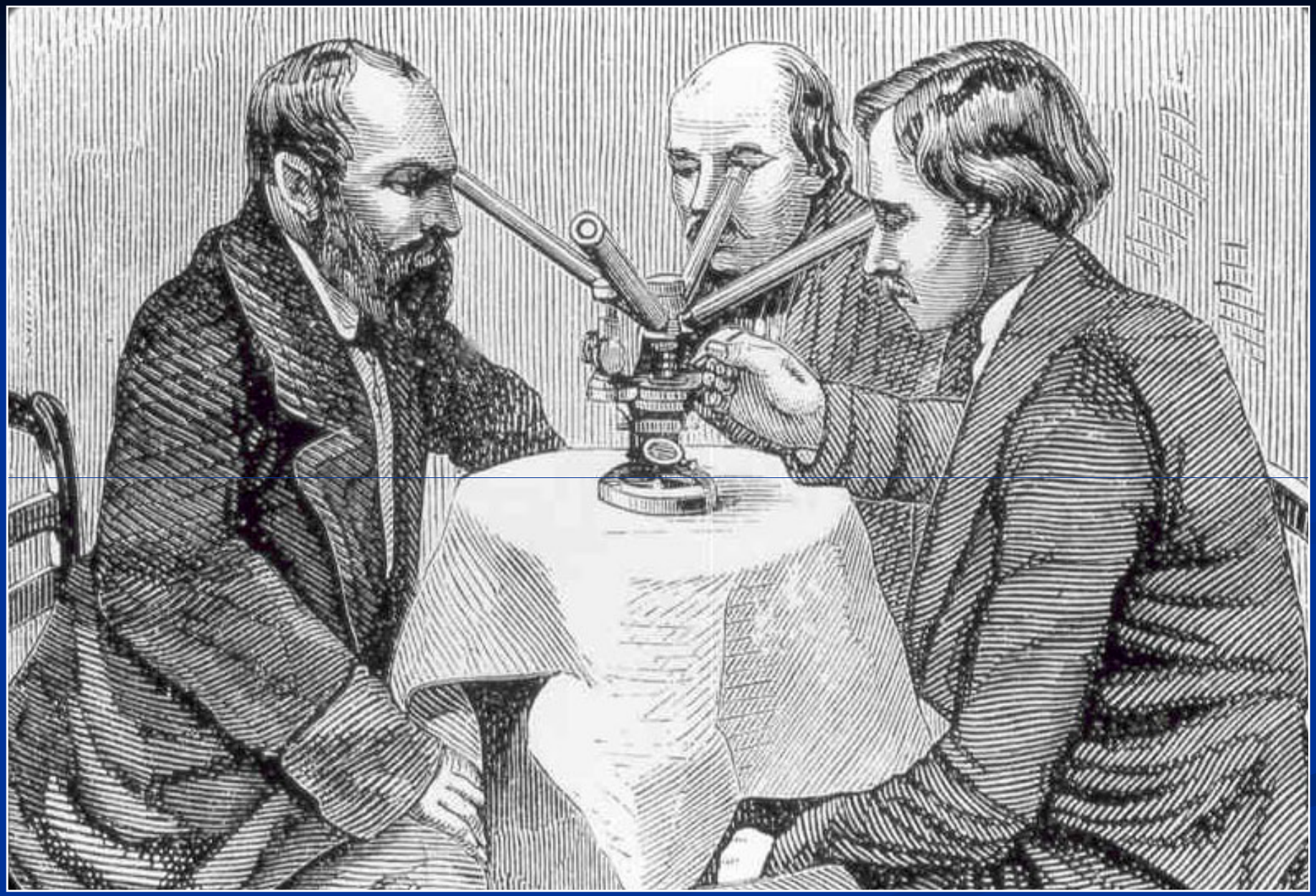
Mail
Safari
iPod



Consistent Persistent Efficient



Random review/QC

Previous pathology review/correlation

Research review Dx/grading/scoring (NCCTG)

Intra- and inter-departmental conferences

Consultation Distributed expert network

Archival material Interesting clinical and research cases

Applications

Type	Mode	Equipment required	
Static $	Static images stored locally and forwarded via e-mail	Digital camera attached to microscope	Hybrid systems that combine dynamic and whole slide imaging
Dynamic $$ (Robotic/live)	Live images from remote controlled microscope	Video/digital camera attached to a microscope with appropriate stage; software	
Virtual $$$ microscopy (whole slide imaging)	Digital slide accessed from remote server	Slide scanner; software	

Method	Application				
	Primary diagnosis	Secondary diagnosis	QA review	Conferences	Education
Static (lowest cost)	++	+	+	+++	+++
Live dynamic	+	++	++	++	+++
Robotic	+++	+++	++	+	++
Whole slide (highest cost)	++++	++++	++++	++++	++++

+ least effective **++++ most effective**

Reproduced with permission from Dr. J. Mark Tuthill

Virtual slides

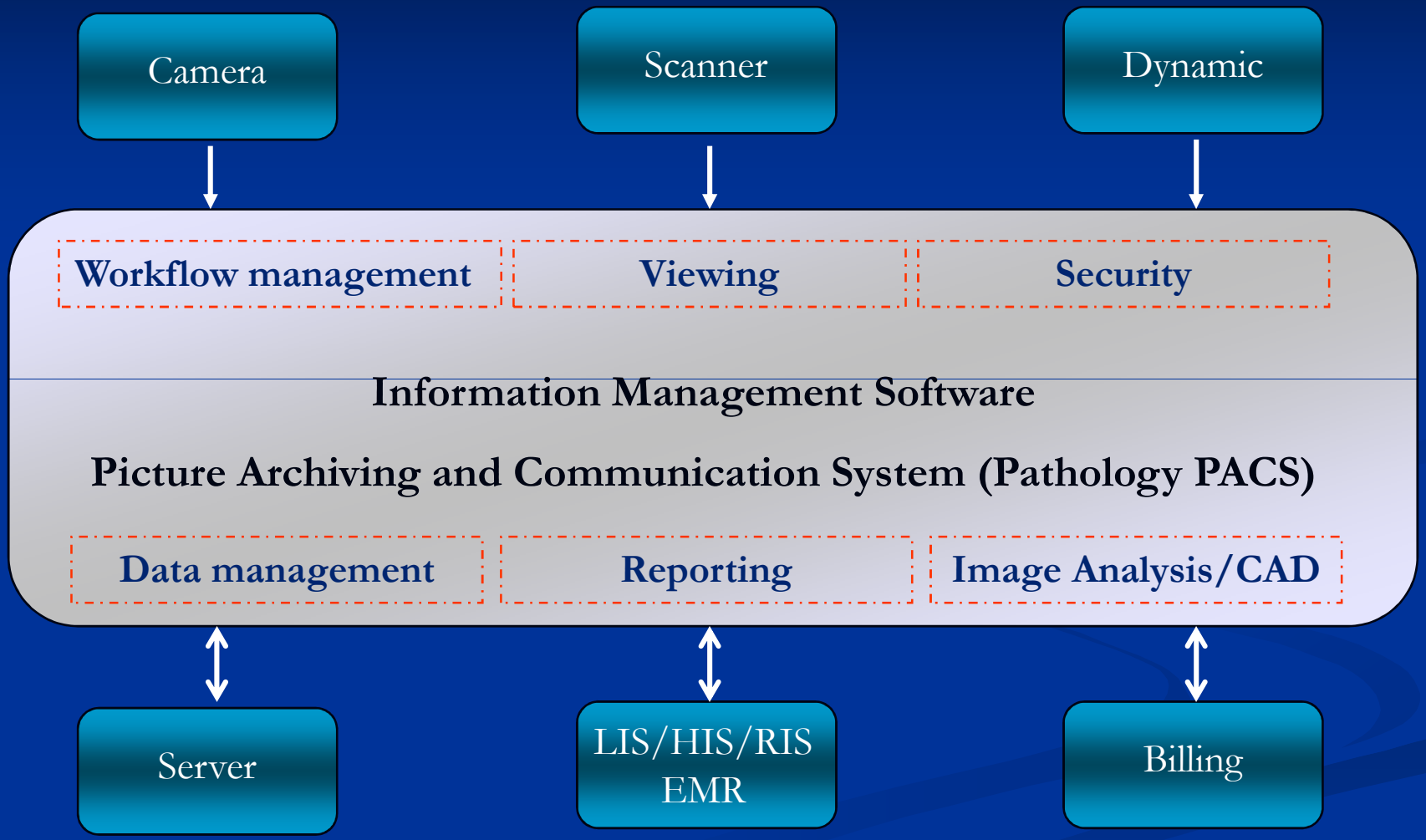
- Digital dataset of whole slide(s)
- Primary dx, consultation, collaboration
- Undergraduate medical education/CME/GME
- Quantitative analysis
  - US Labs (LabCorp), Clarient, Quest – Virtual IHC
- Qualitative analysis
  - CBIR/Artificial intelligence/neural networks

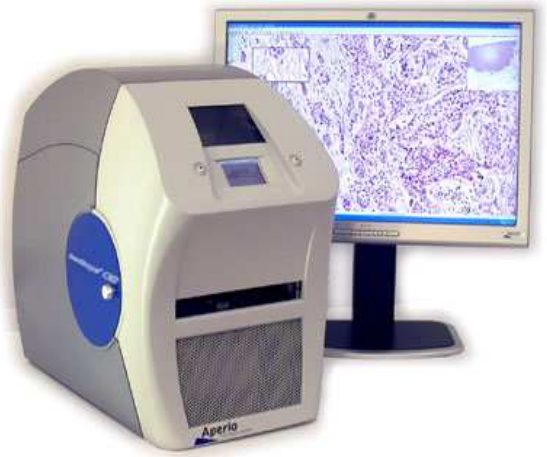
Projected Whole-Slide Scan Time with evolving Platforms

- 2011:
  - Best Possible: 1:30 (minutes)
  - Typical: 5:00-8:00
- 2014:
  - Best Possible: 0:12
  - Typical: 2:00
- 2018:
  - Best Possible: 0:03
  - Typical: 0:20
  - Worst Case: 4:00

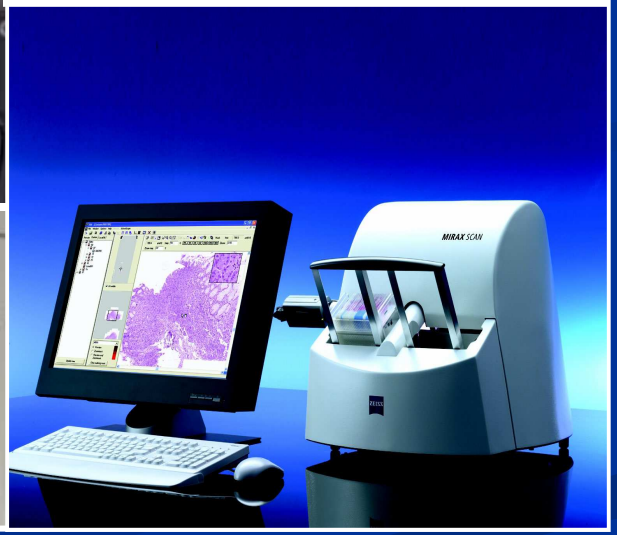
With high compression algorithms for clinical use

Applications




Aperio

NDP

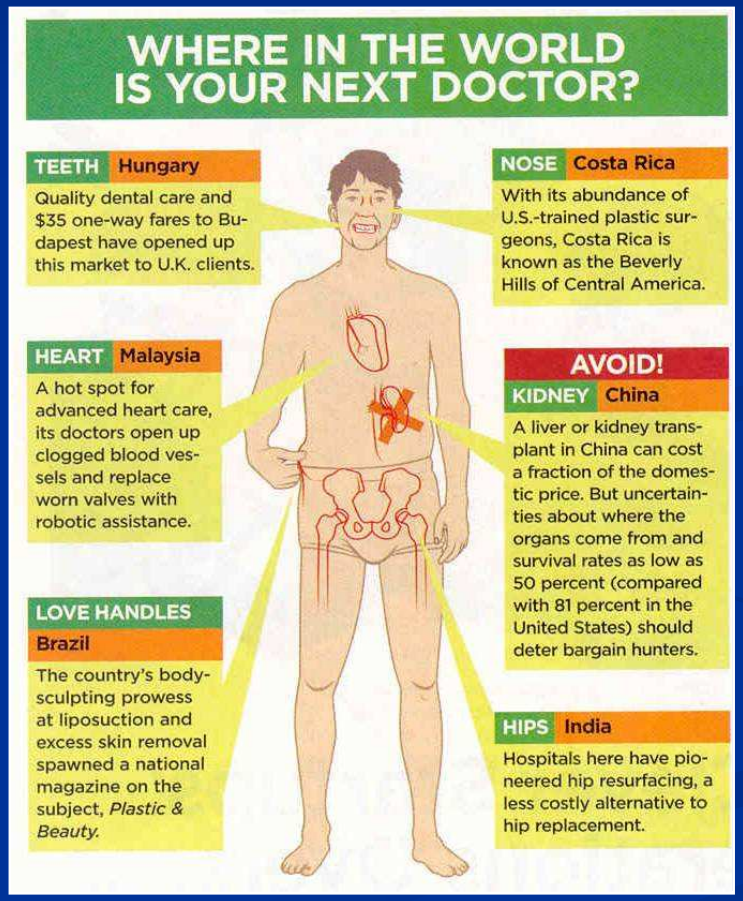
iScan

MIRAX SCAN

Problems

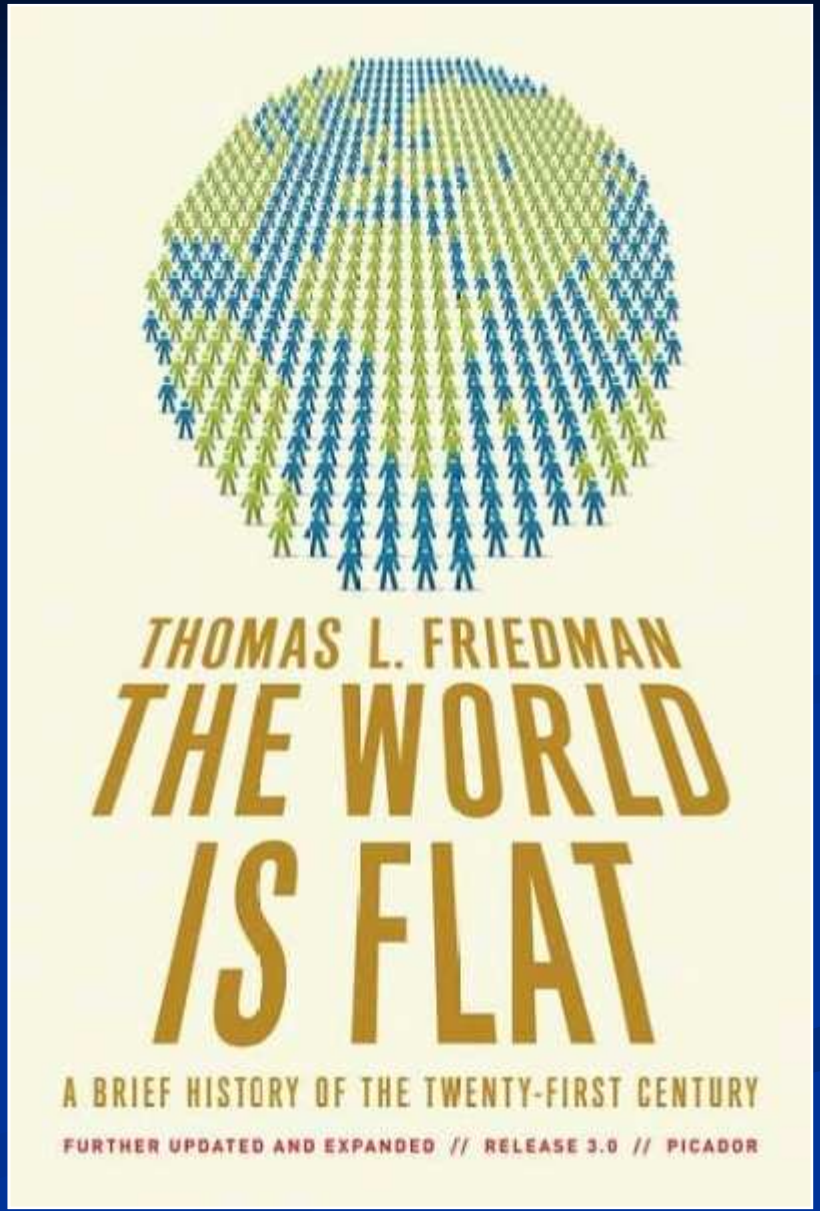
- Costs of implementation, lack of reimbursement, sustainment
- Lack of infrastructure and support personnel
- Older pathologists reluctant to adopt new technologies (generation gap)
- Cost effectiveness not proven (to some)
- Others show strong economic benefit
- The "FedEx" argument

Outsourcing

- Pathologist in India with Indiana medical license signing out cases from Indianapolis



- "Uploading" is the most disruptive force
- Web 2.0 – users comment, edit and create content
- Allows content by users, for users
- Best content immediately available
- Harness "collective intelligence"
- Digital pathology well-suited



Why telepathology?

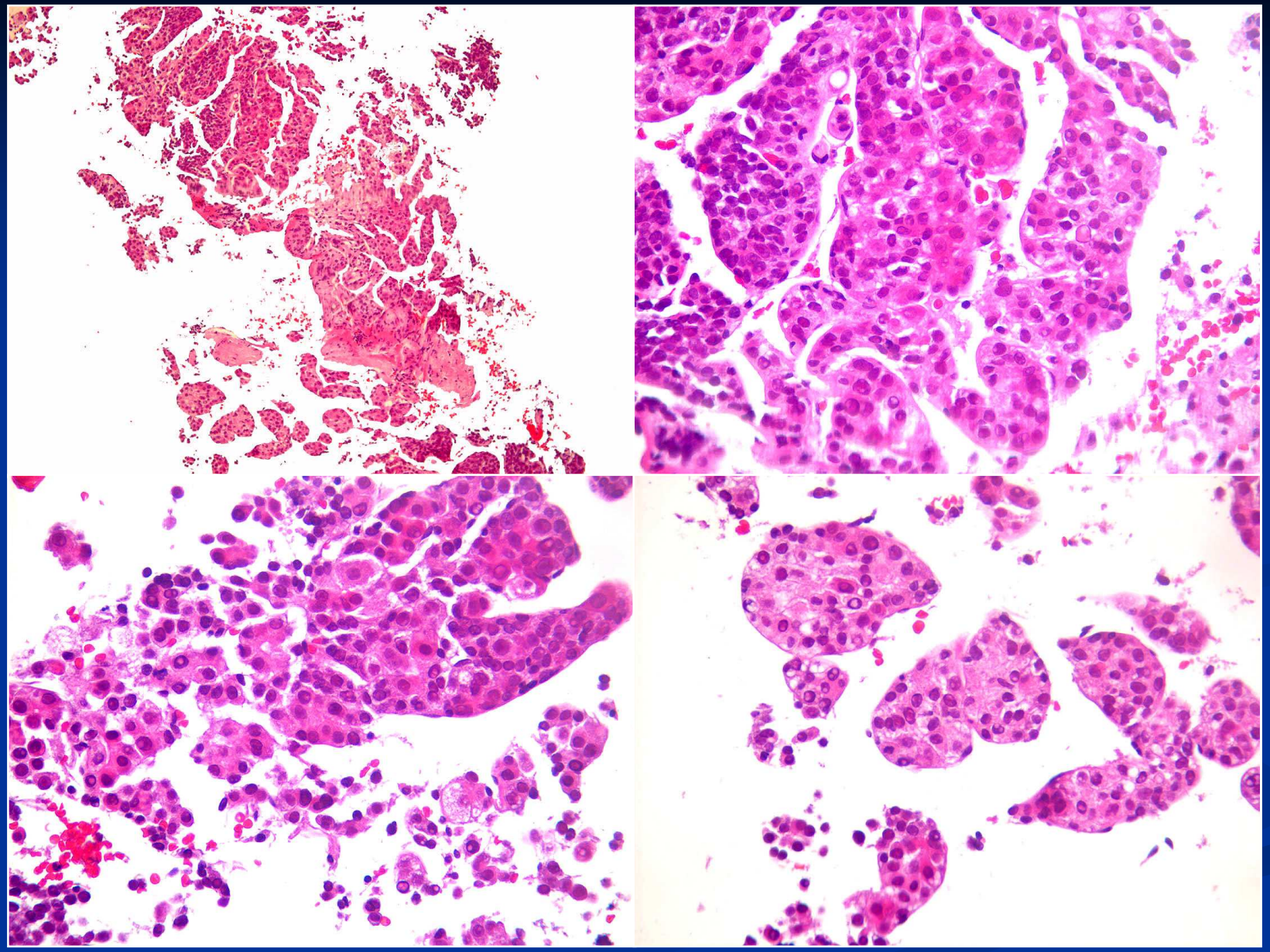
- Rapid consultation on cases
- Provide capability to have subspecialty experts review challenging cases (added value)
- Provide a peer review capability for single/isolated pathologist

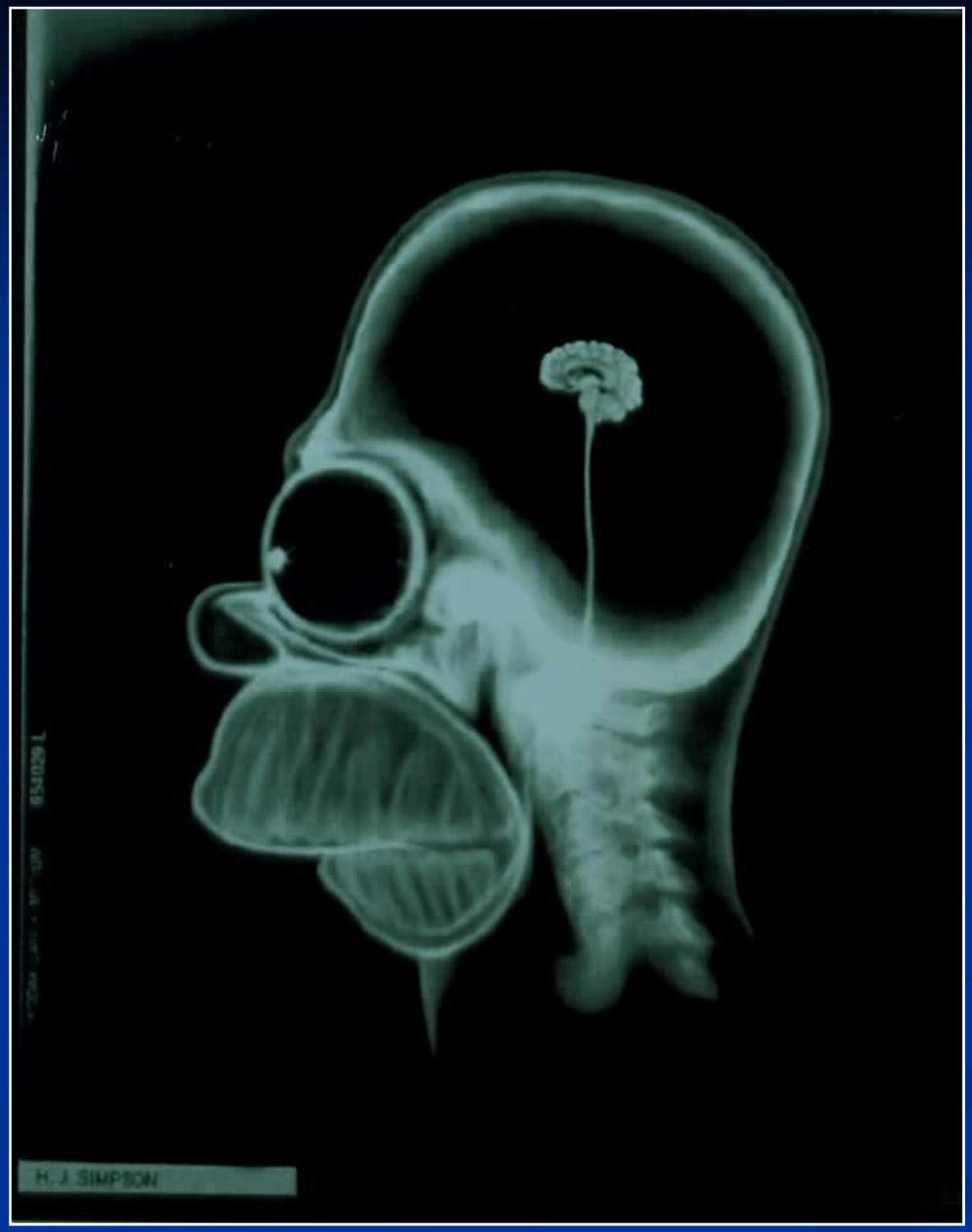
Established Practices

- Frozen section
- Routine surgical pathology
- Consultation (second, expert, QA/QC)
- GME/CME (ABP, USCAP, CAP, ASC)

Provisional Practices

- Cytopathology (Z-stack focusing)
- ~~Special stains – IHC;ISH~~
- Clinical microscopy




H. J. SIMPSON

1/25/08

Outside conventional radiograph of the right knee dated 1/16/08 (3 films).
Lucent, slightly bubbly lesion in the cortex of the proximal medial tibial metaphysis,
with a well defined border. Adjacent, approximately 3-4cm, focus of mature appearing calcification.
Small bubbly lesion in the posterior aspect of the medial supracondylar ridge.

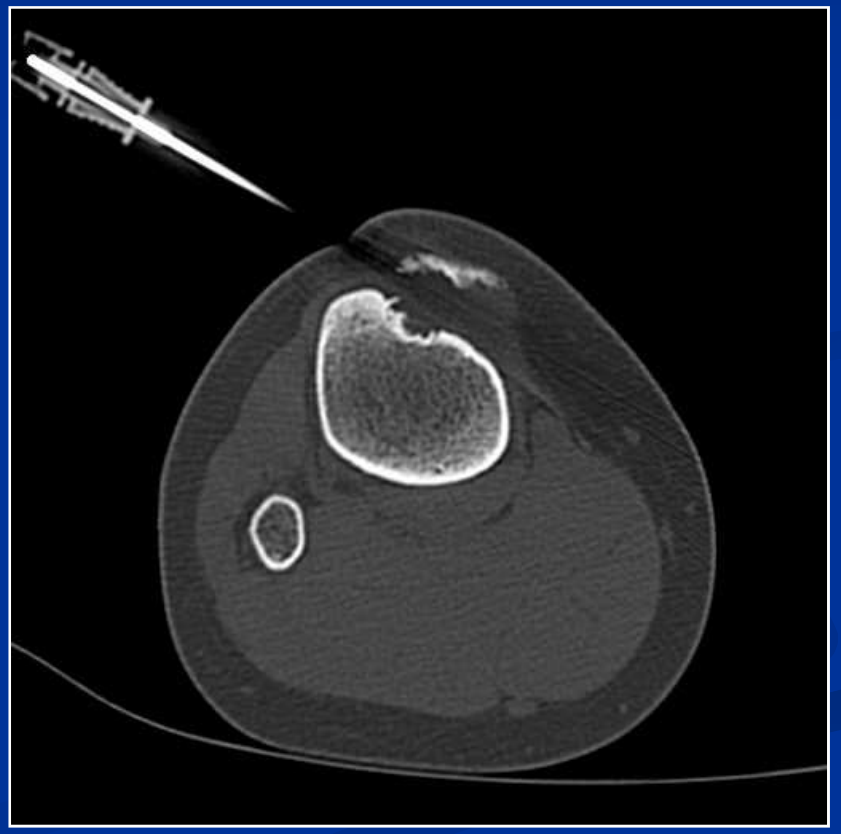
Outside MRI of the right leg dated 1/23/08 (14 films). Expansile lesion in the anterior cortex of the proximal medial tibia adjacent to the tibial tubercle. and pes tendons insertions. This measures approximately 3-4cm in greatest oblique transverse dimension and is associated heterogeneous signal consistent with calcification as noted on the outside conventional radiographs. Apart from the calcification, it has relatively uniform signal, which is bright on T2, and dark on T1, with diffuse enhancement after IV gadolinium.
The posterior border of the mass is well defined, with a sclerotic margin. The anterior soft tissue border is irregular.

Overall, this tibial lesion has a more benign appearance. Differential considerations include a benign fibro-osseous lesion, MFD, avulsive cortical irregularity, with myositis ossificans related to trauma, or a soft tissue chondroma. A sarcoma is thought less likely but cannot be excluded. The lesion in the distal femur was not included on the MRI but may represent a benign MFD or avulsive cortical irregularity

1/30/08

Right Tibia Fibula 2vw AP/Lat:
Right Knee 3vw/STDG w/Patella:

There are no prior examinations available for comparison. There is a lytic lesion in the proximal right tibial metaphysis, medial and anterior. The overall matrix is lucent, but there is dense calcification in the extraosseous soft tissues medial and anterior to the center of the lesion in the bone. The bony margins of the lesion are well defined, partially sclerotic, suggesting a benign process. The calcification in the soft tissues may represent avulsed fragments, potentially from a pathologic fracture, but osteoid matrix cannot be entirely excluded. If the extraosseous finding is related to fracture or myositis ossificans, biopsy of this specific area may complicate the diagnosis.



Barriers

- Cultural
  - Generation gap
  - If it ain't broke….
  - Workflow
- Technical
  - Support staff/professional colleagues
  - Interoperability/lack of standards

Barriers

- Licensure and credentialing
  - Malpractice liability
  - HIPAA
- Fiscal barriers

Human Pathology (2009) 40, 1070–1081

ELSEVIER

Human
PATHOLOGY

www.elsevier.com/locate/humpath

Special Section on Telepathology

Primary frozen section diagnosis by robotic microscopy and virtual slide telepathology: the University Health Network experience

Andrew J. Evans MD, PhD*, Runjan Chetty MB, BCh, DPhil, Blaise A. Clarke MB, ChB, Sidney Croul MD, Danny M. Ghazarian MD, PhD, Tim-Rasmus Kiehl MD, Bayardo Perez Ordonez MD, Suganthi Ilaalagan BSc, MLT, Sylvia L. Asa MD, PhD

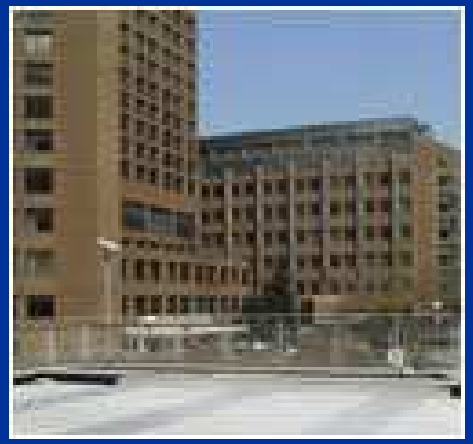
Department of Pathology Laboratory Medicine Program, University Health Network, Toronto, Ontario, Canada M5G 2C4

University Health Network – Toronto, Canada

Princess Margaret

~ 1.5 miles

Toronto Western



Toronto General

Why Telepathology at UHN?

- No on-site at AP frozen section service at TWH for ~10 years
- Tissue sent to TGH – up 1 hour TAT
- Lack of timely intra-operative frozen section support.
- Small volume frozen section requirement

Telepathology QS Procedure

- Surgeon communicates with pathologist
- Surgeon defines tissue of interest
- PA/histotechnologist at TWH generate frozen section slide
- PA generates overview scan and connects TWH "server" to PMH/TGH "client"
- Pathologist controls microscope and reports result to surgeon in TWH OR

UHN Telepathology Experience/Outcomes

- 674 primary FS diagnoses (350 by RM and 314 by WSI)
- 95% of which were for neurosurgical cases.
- Average of 9.98 minutes RM decreased to 2.71 minutes with WSI
  - 26% of cases requiring < 1 minute/slide and
  - 43% of cases < 2 minutes/slide.
  - Smears were examined in addition to FS slides in 30% of the WSI cases.
- Diagnostic accuracy was 98% for both WSI and RM, however the use of WSI has markedly improved pathologist satisfaction.

UHN Telepathology: Due Diligence Before Going Live

- Medical Malpractice Insurance Provider
  - Canadian Medical Protective Association (CMPA)
  - Telepathology will not affect coverage
- UHN Medical Advisory Committee
  - SOP presented for approval
- Federal Health Protection Branch - Ottawa
  - Telepathology does not involve "medical devices" (no direct contact between instrument and patient) – no HPB approval required
- Surgeon Education
  - Demonstrating the robotic microscope/slide scanner
    - Essential to get surgeon buy-in!

From the conventional microscope to the digital slide scanner in routine diagnostic histopathology

Sten Thorstenson, MD
Medical Director
Department of Pathology and Cytology
Kalmar County Hospital
Kalmar, Sweden

Presented @ Pathology Visions 2009, San Diego

Kalmar, Sweden

Kalmar: 62,000 pop.

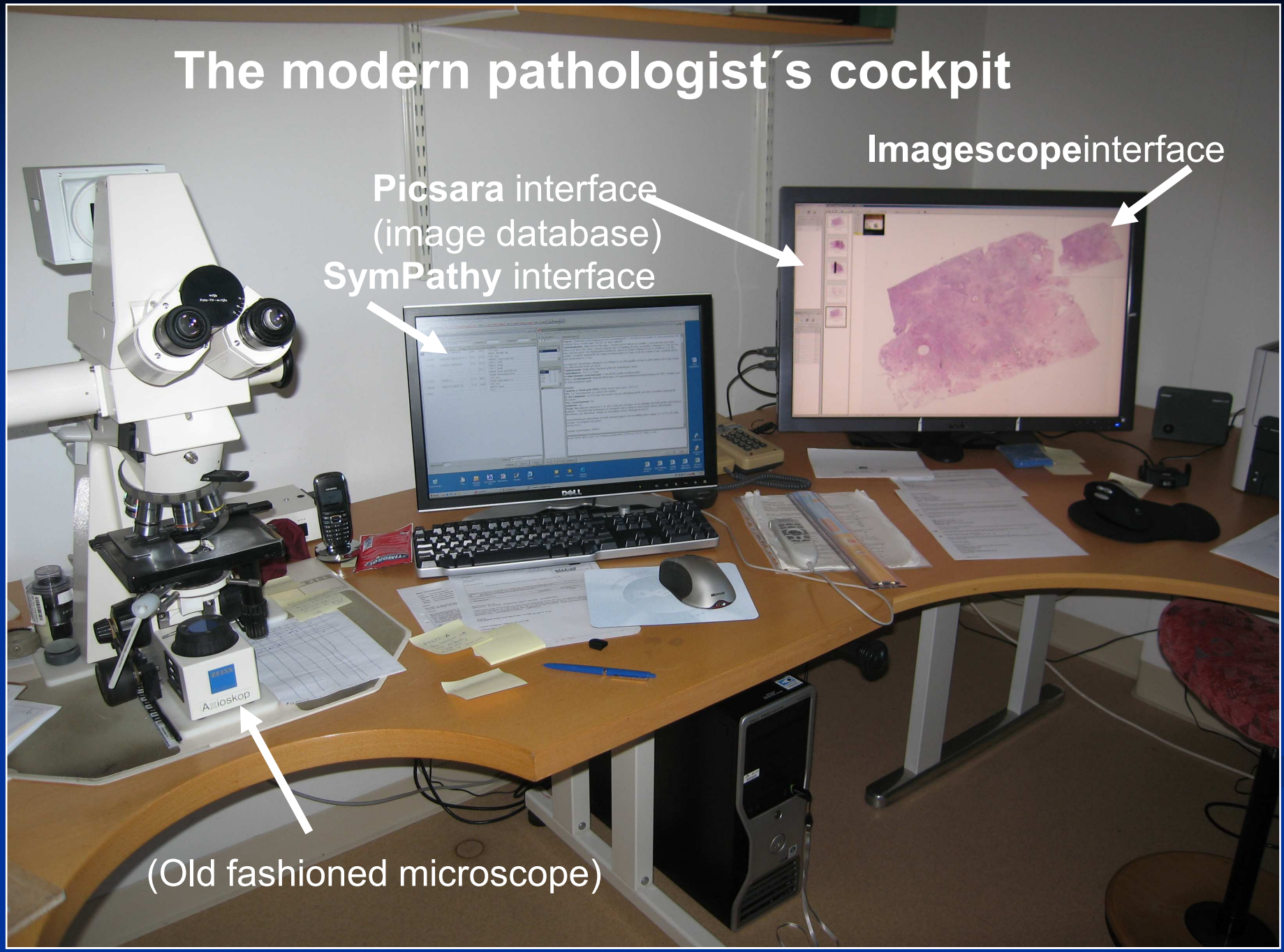
Kalmar county: 235,000 pop. and 3 hospitals

Pathology departments: 1

Kalmar today

- >60000 histopathology slides have been scanned
- 24 hr scanning (2 Aperio Scanscope XT)
- 1.5 years of routine histopathology diagnostics
- >75% of the routine histopathology is diagnosed digitally
- 10 years experience of digital telepathology frozen section service.
- Some clinicopathological conferences digitally
- Individual digital slide conferencing (on demand from clinicians)

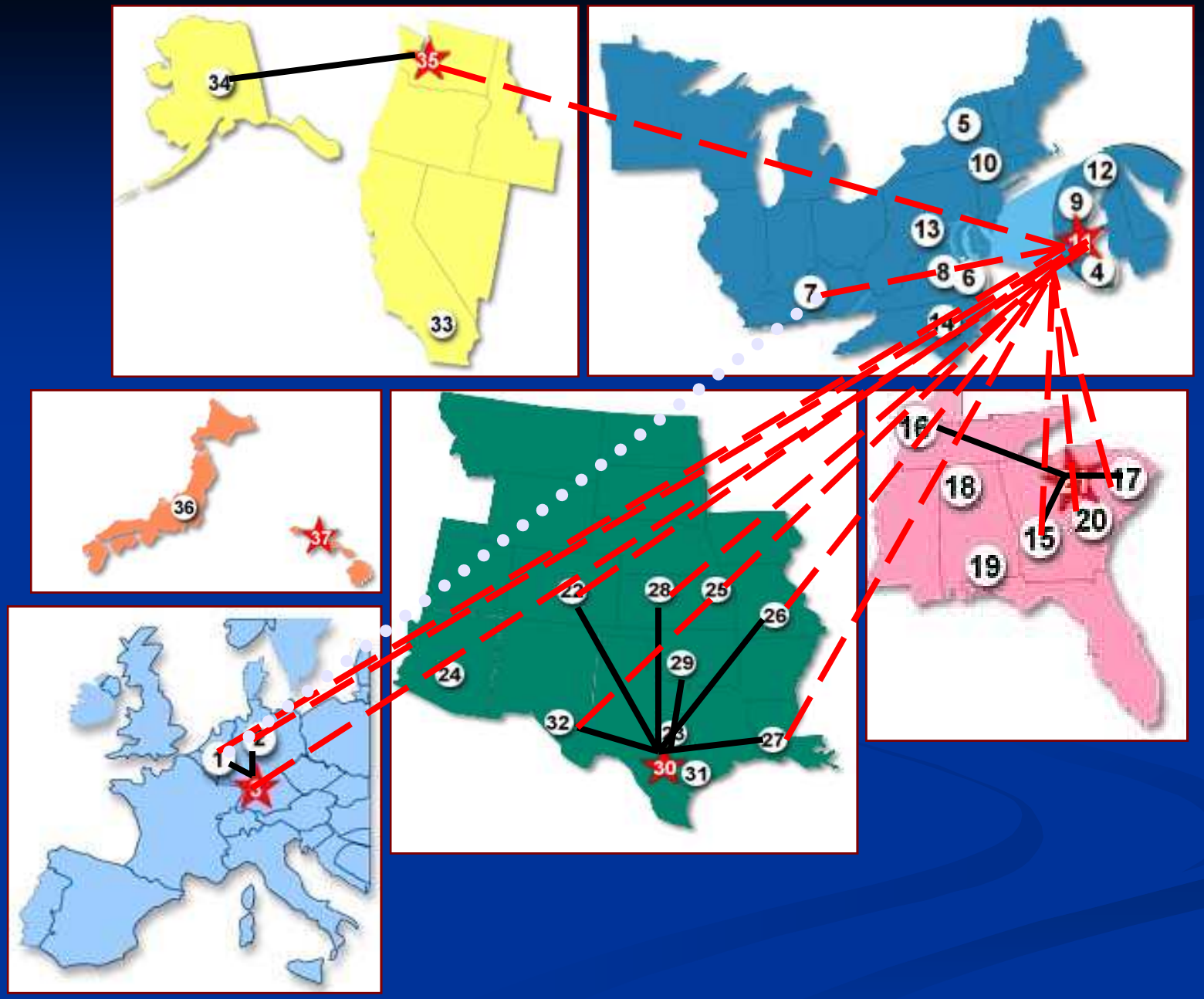
The modern pathologist´s cockpit



Clearly improved ergonomics!
Coffee!
The modernpatholo gist
Anyone wants to work as a pathologist in Kalmar ? Phone +46 480 448019

Army Telemedicine Program

- Walter Reed AMC (6/01)
- WRAMC CBCP (6/01)
- Ft. Knox (IACH) (8/01)
- Ft. Bragg (WAMC) (11/01)
- Landstuhl RMC (12/01)
- Tripler AMC (4/02)
- Heidelberg AH (1/03)
- Wuerzberg AH (1/03)
- Ft. Benning (MACH) (1/03)
- Ft. Hood (DACH) (2/03)
- Brooke AMC (2/03)
- Korea (EACH) (2/03)
- Ft. Riley (IACH) (10/03)
- Ft. Sill (RACH) (10/03)
- Ft. Carson (EACH) (2/04)
- Eisenhower AMC (3/04)
- Ft. Campbell (BACH) (3/04)
- Ft. Jackson (MACH) (3/04)
- Ft. Stewart (WACH) (3/04)
- Ft. Leonard Wood (GLWACH) (3/04)
- Iraq (31st CSH) (11/04)
- Ft. Eustis (MACH) (5/05)
- Air Force Academy (5/05)
- Ft. Belvoir (DACH) (9/05)
- Madigan AMC (10/05)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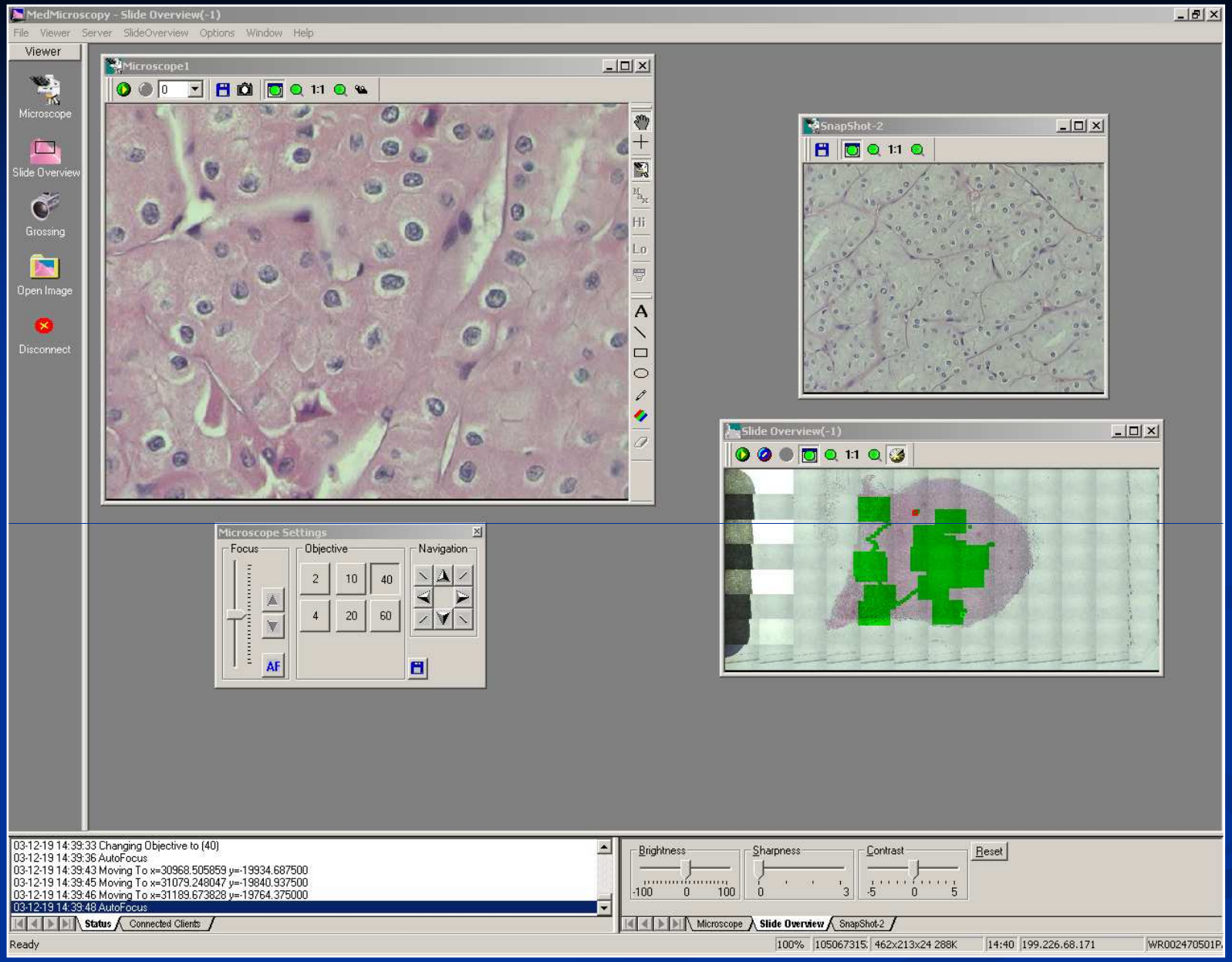
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SnapShot-2
Slide Overview(-1)
Microscope Settings
Focus
Objective
Navigation
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10
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03-12-19 14:39:33 Changing Objective to (40)
03-12-19 14:39:36 AutoFocus
03-12-19 14:39:43 Moving To x=30968.505859 y=-19934.687500
03-12-19 14:39:45 Moving To x=31079.248047 y=-19840.937500
03-12-19 14:39:46 Moving To x=31189.673828 y=-19764.375000
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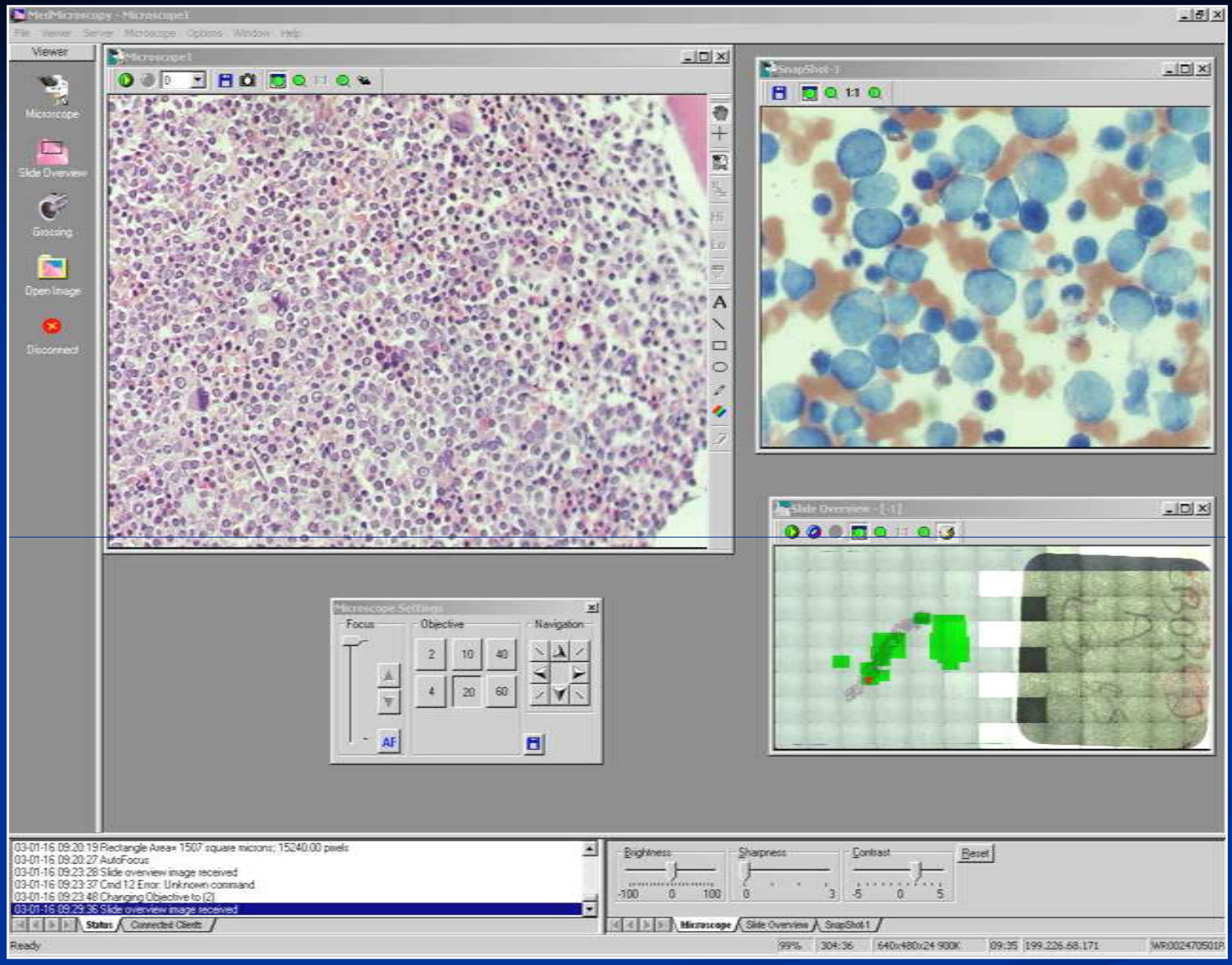
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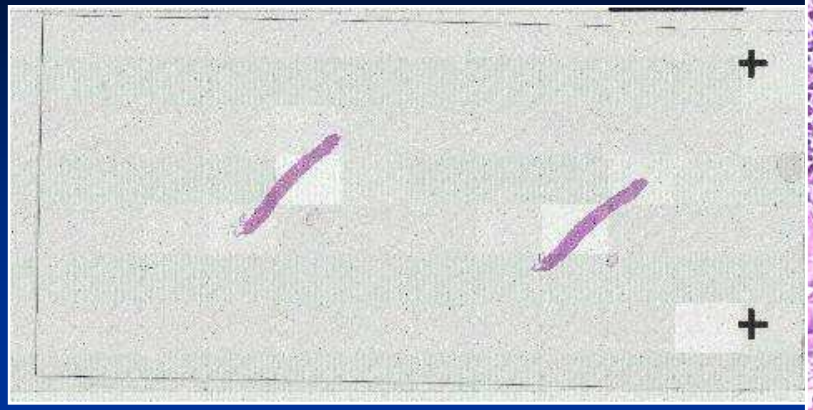

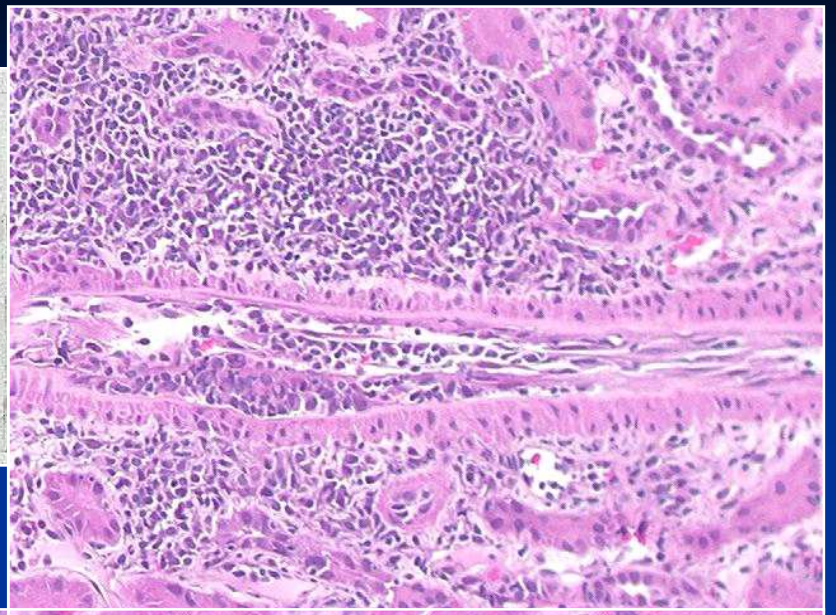

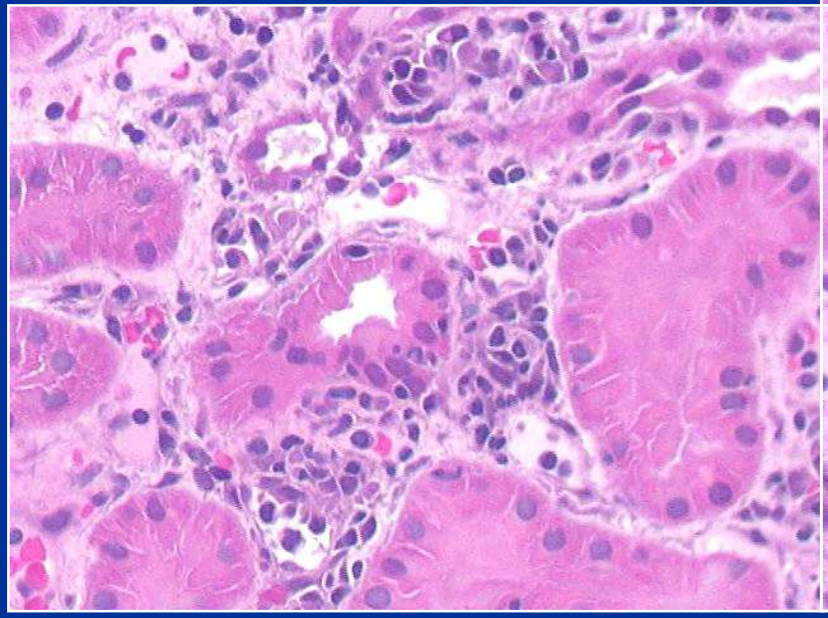

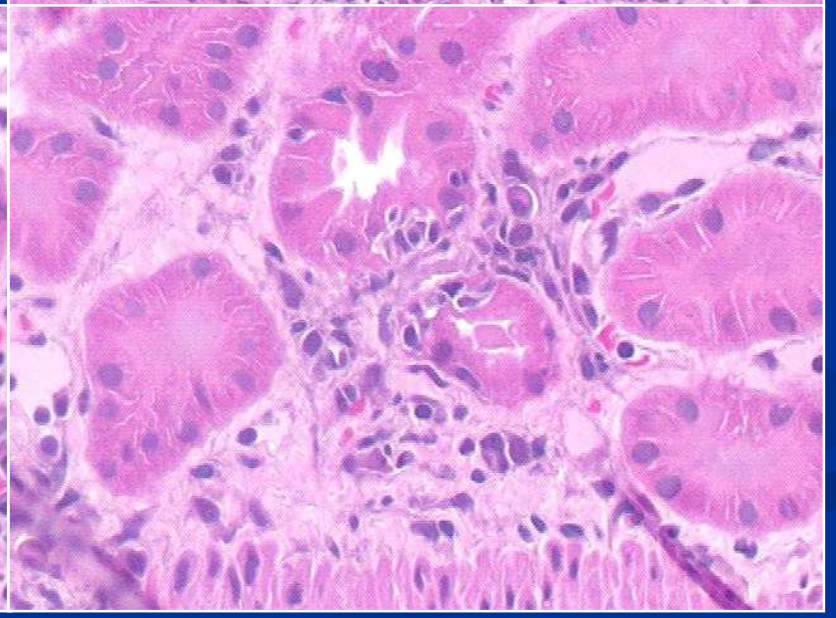

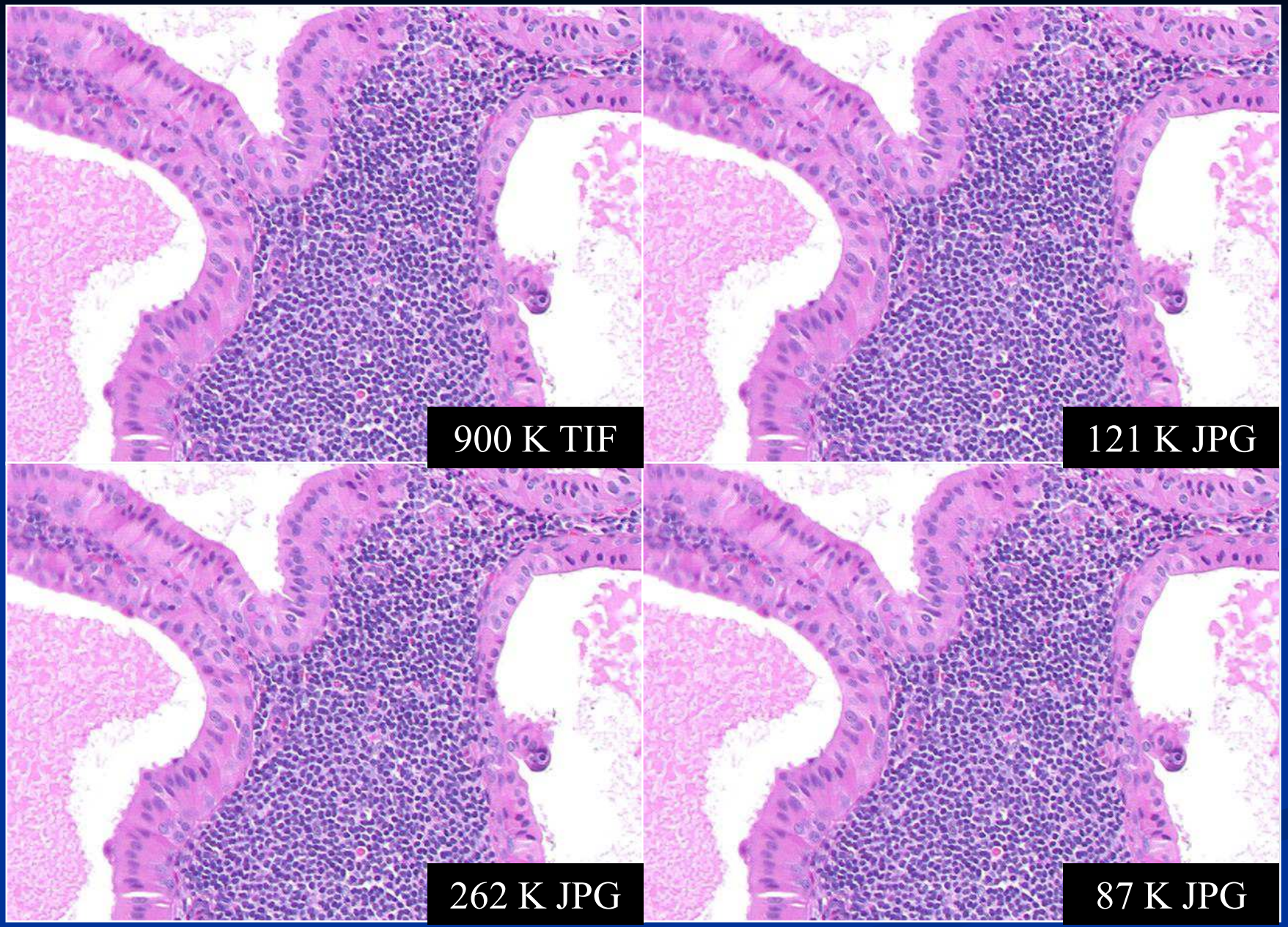
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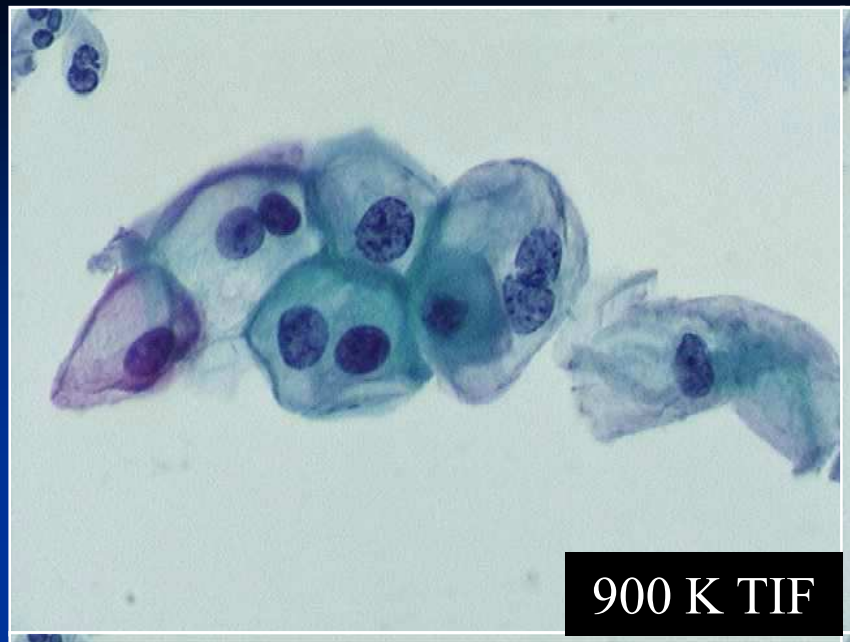
87 K JPG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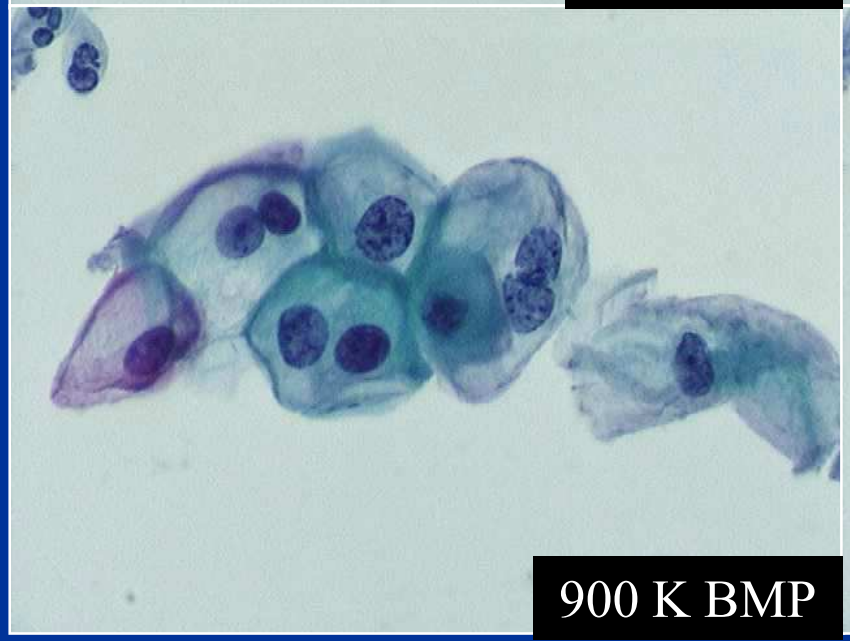
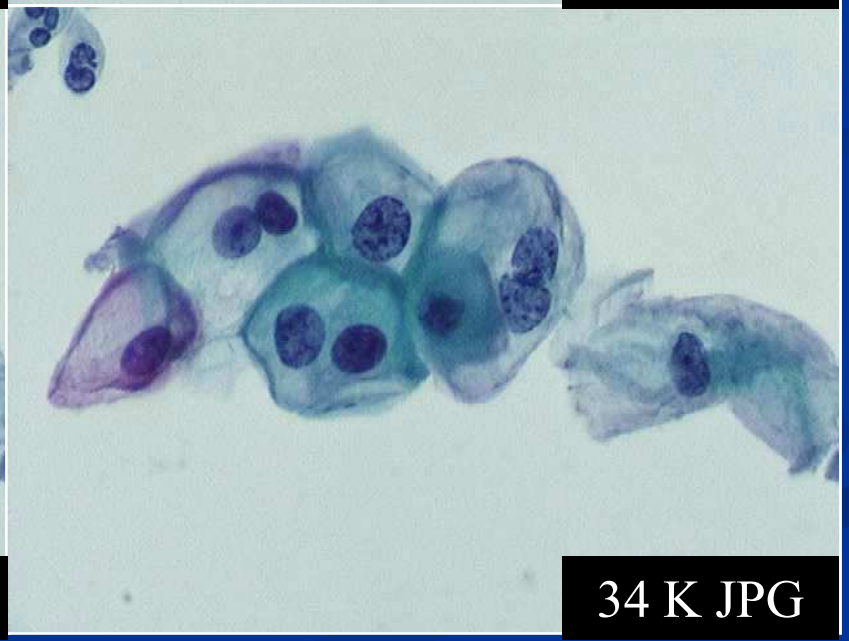

900 K BMP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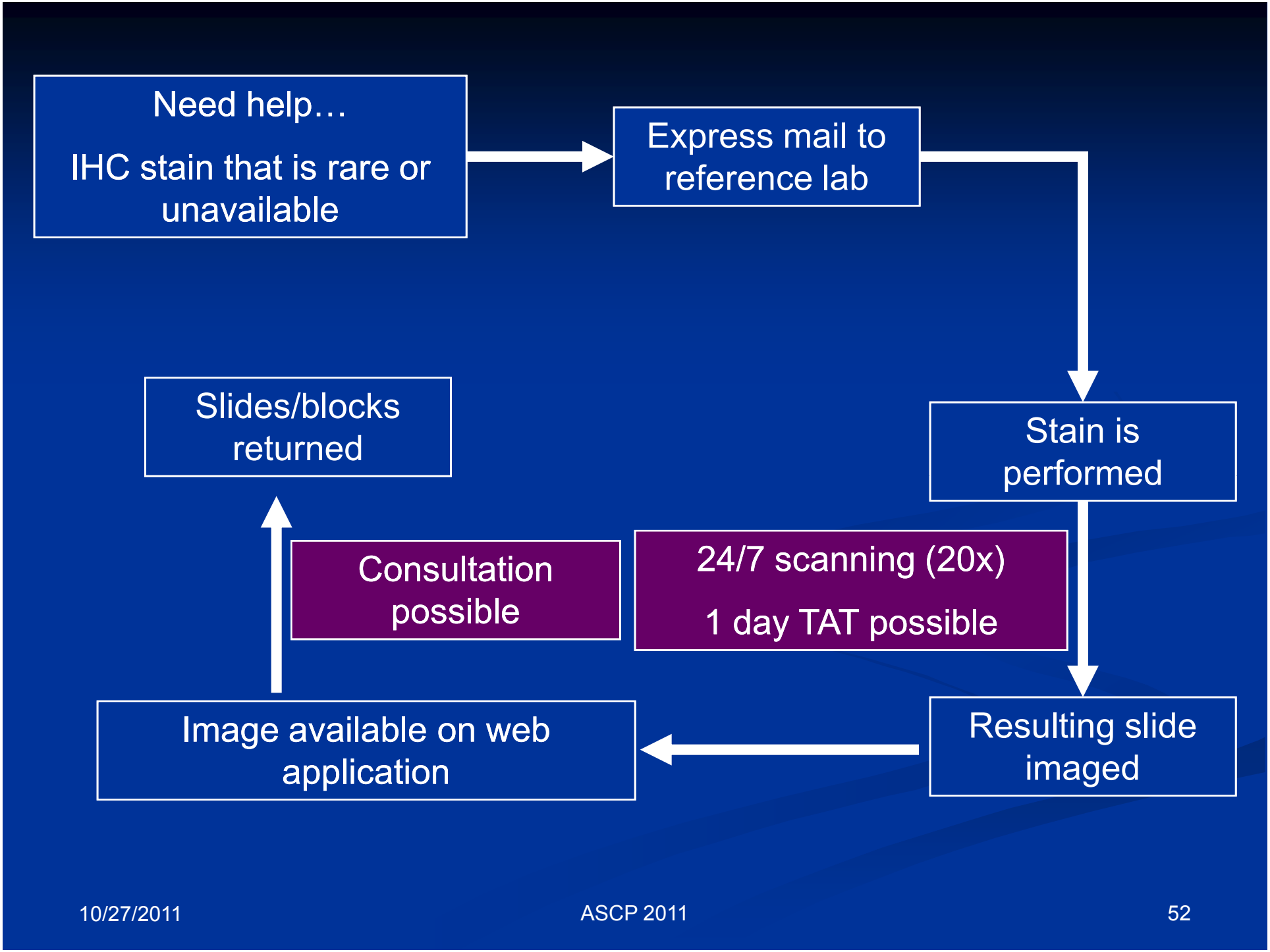
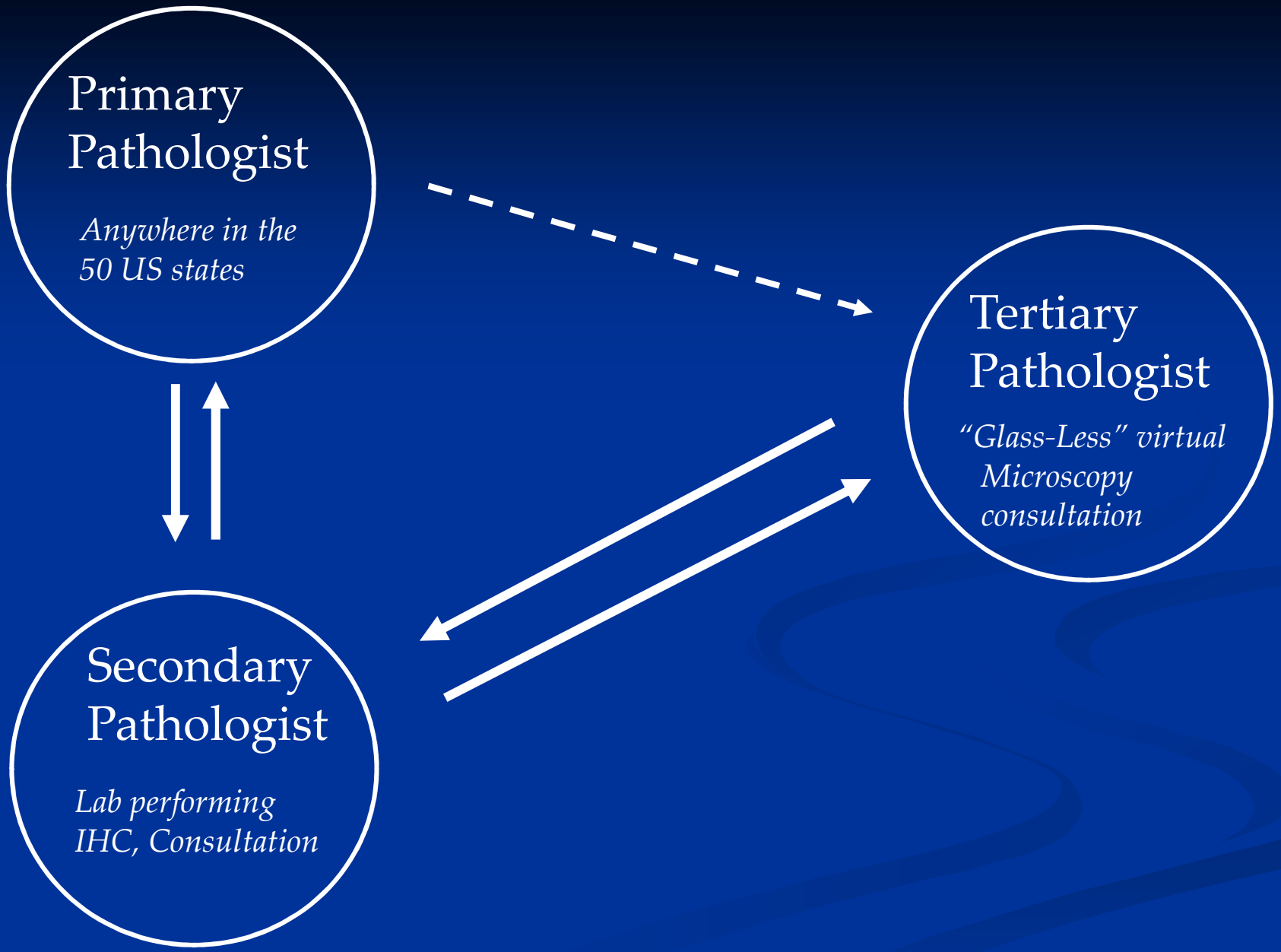
Virtual IHC Business Model

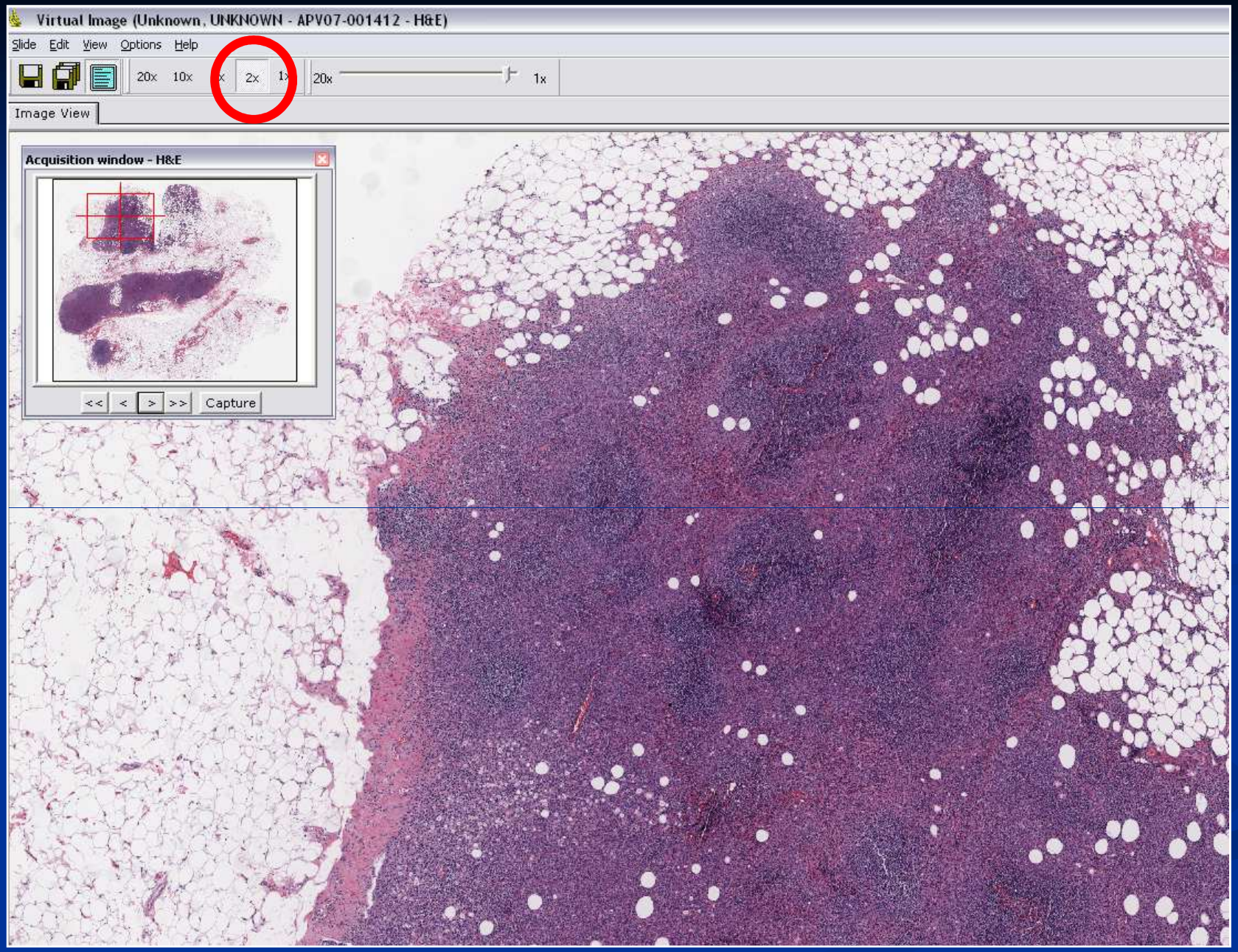
- Large laboratories partnering with pathologists or pathology groups
- Large laboratory performs technical component
- Pathologists performs professional component


Need help…
IHC stain that is rare or unavailable
Express mail to reference lab
Stain is performed
Resulting slide imaged
Image available on web application
Slides/blocks returned
Consultation possible
24/7 scanning (20x)
1 day TAT possible

	Central Lab	Referring Pathologist
Technical performance	Yes	
Professional Interpretation		Yes
Technical Billing	Yes	
Professional Billing		Yes

	Central Lab	Referring Pathologist
Capital investment	Yes	
Large menu		Yes
Research and Development	Yes	


Primary Pathologist
Anywhere in the 50 US states
Tertiary Pathologist
"Glass-Less" virtual Microscopy consultation
Secondary Pathologist
Lab performing IHC, Consultation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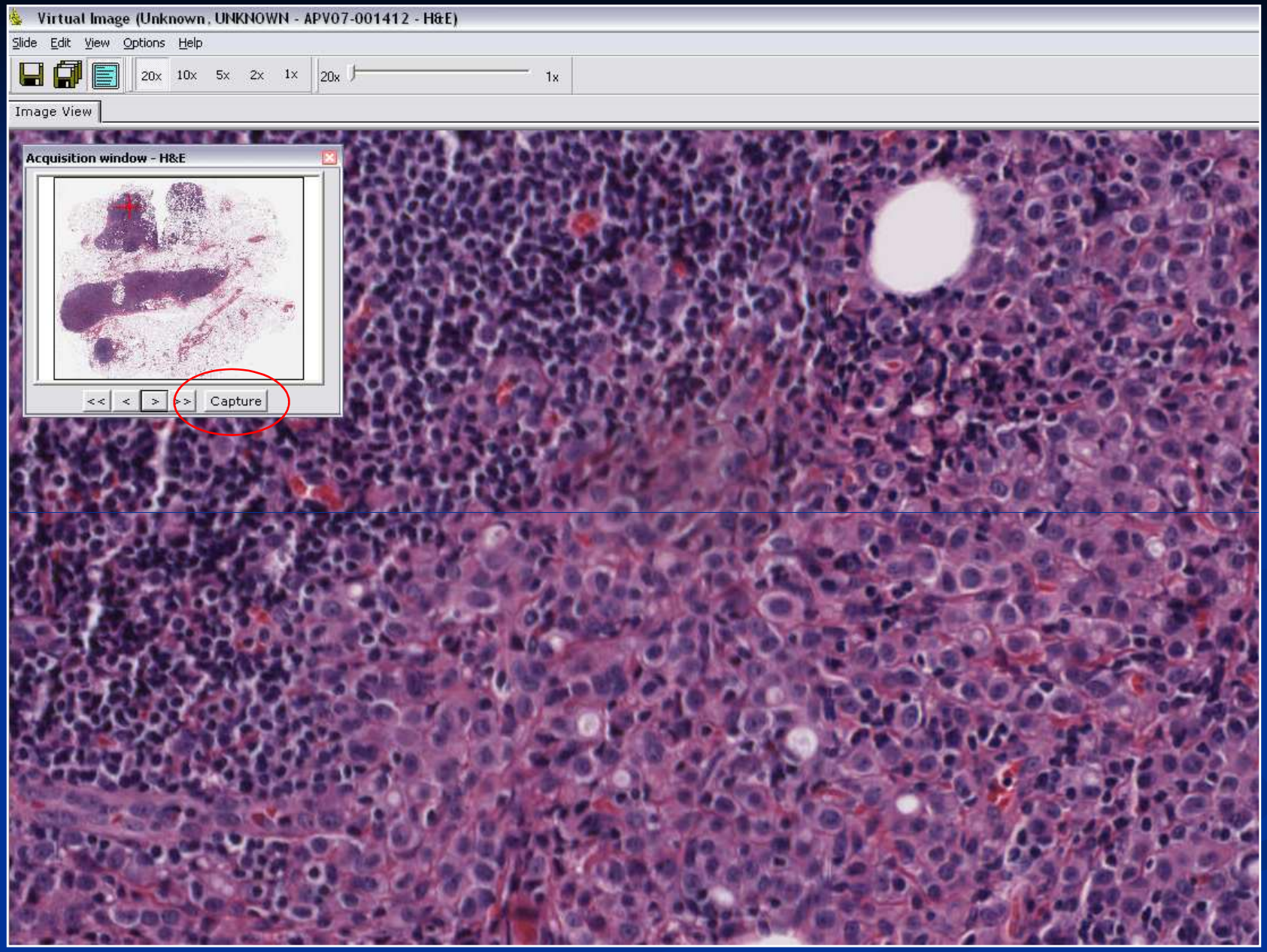
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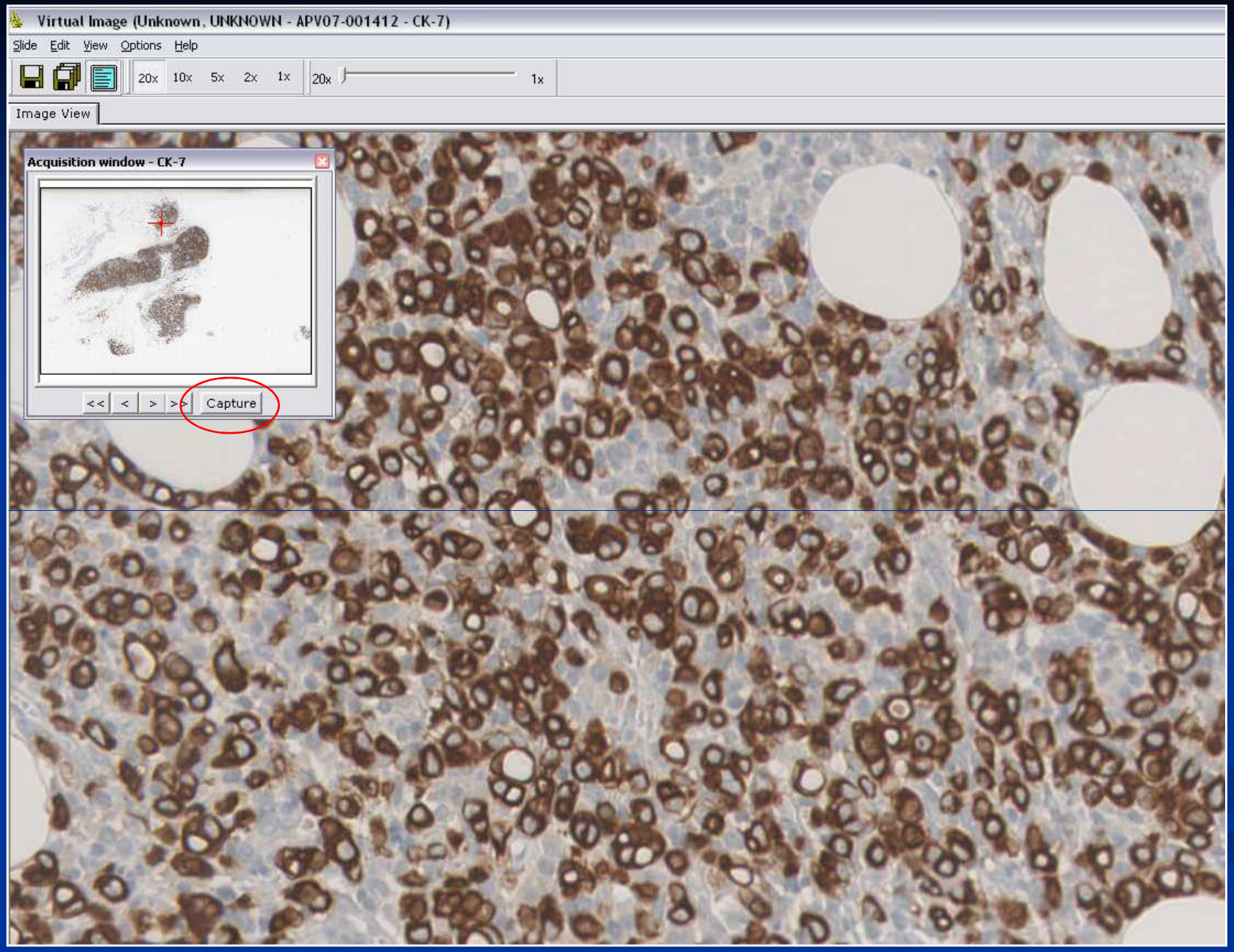
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Acquisition window - CK-7
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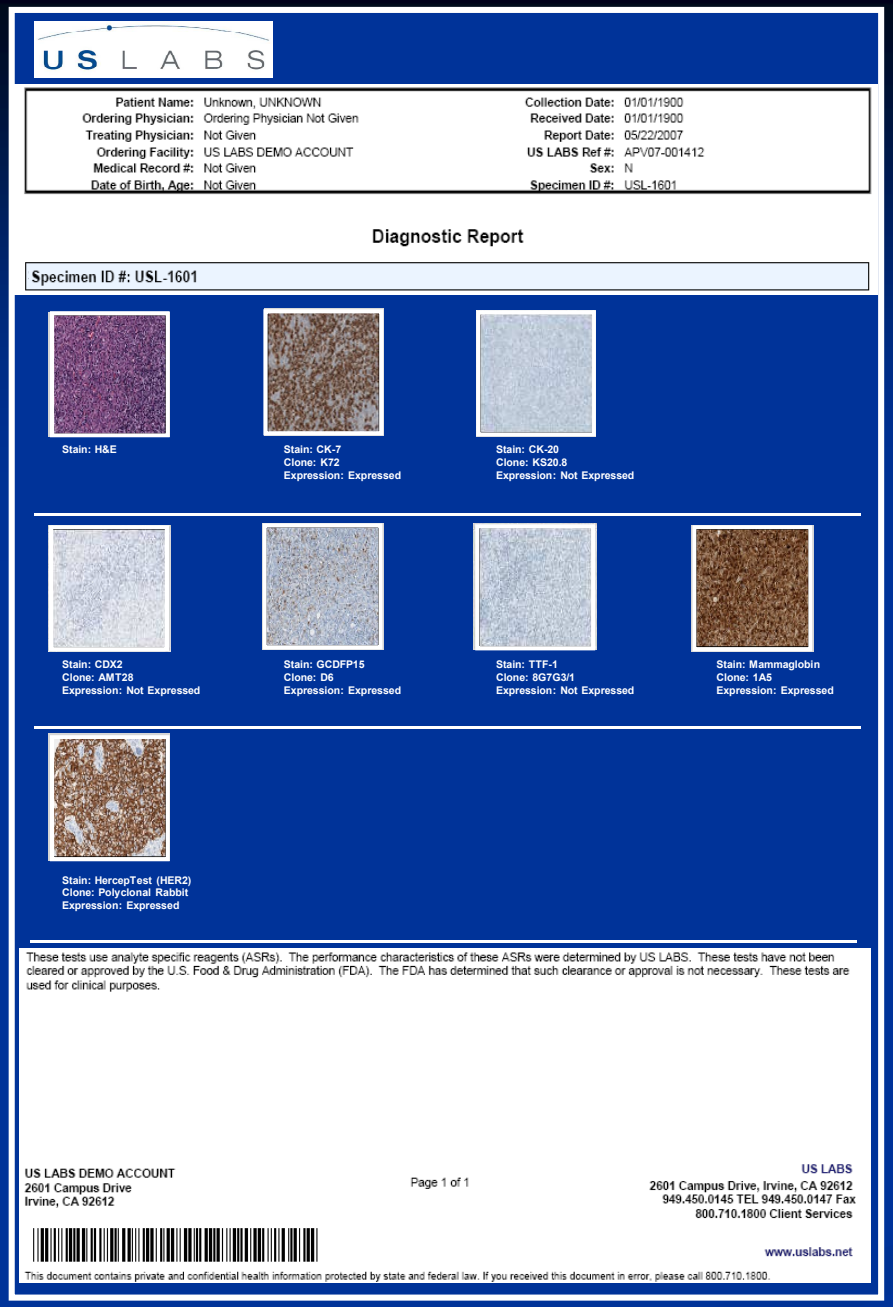

USLABS

Patient Name:	Unknown, UNKNOWN	Collection Date:	01/01/1900
Ordering Physician:	Ordering Physician Not Given	Received Date:	01/01/1900
Treating Physician:	Not Given	Report Date:	05/22/2007
Ordering Facility:	US LABS DEMO ACCOUNT	US LABS Ref #:	APV07-001412
Medical Record #:	Not Given	Sex:	N
Date of Birth, Age:	Not Given	Specimen ID #:	USL-1601

Diagnostic Report

Specimen ID #: USL-1601

Stain: H&E

Stain: CK-7
Clone: K72
Expression: Expressed

Stain: CK-20
Clone: KS20.8
Expression: Not Expressed

Stain: CDX2
Clone: AMT28
Expression: Not Expressed

Stain: GCDFP15
Clone: D6
Expression: Expressed

Stain: TTF-1
Clone: 8G7G3/1
Expression: Not Expressed

Stain: Mammaglobin
Clone: 1A5
Expression: Expressed

Stain: HercepTest (HER2)
Clone: Polyclonal Rabbit
Expression: Expressed

These tests use analyte specific reagents (ASRs). The performance characteristics of these ASRs were determined by US LABS. These tests have not been cleared or approved by the U.S. Food & Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. These tests are used for clinical purposes.

US LABS DEMO ACCOUNT
2601 Campus Drive
Irvine, CA 92612

Page 1 of 1

US LABS
2601 Campus Drive, Irvine, CA 92612
949.450.0145 TEL 949.450.0147 Fax
800.710.1800 Client Services

www.uslabs.net

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- EMR compatibility?

Image Analysis

- Image analysis for quantitative immunohistochemical stains
  - Machines are good at counting
  - They are not very good at thinking
  - Good reproducibility
  - Better information
  - Associated increase in billing codes relative to manual IHC

American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer

Antonio C. Wolff, M. Elizabeth H. Hammond, Jared N. Schwartz, Karen L. Hagerty, D. Craig Allred, Richard J. Cote, Mitchell Dowsett, Patrick L. Fitzgibbons, Wedad M. Hanna, Amy Langer, Lisa M. McShane, Soonmyung Paik, Mark D. Pegram, Edith A. Perez, Michael F. Press, Anthony Rhodes, Catharine Sturgeon, Sheila E. Taube, Raymond Tubbs, Gail H. Vance, Marc van de Vijver, Thomas M. Wheeler, Daniel F. Hayes

Archives of Pathology and Laboratory Medicine: **Vol. 131, No. 1, pp. 18–43.**

Inconsistency of HER2 Test Raises Questions

J Natl Cancer Inst 2007;99(14)1064-1065.

The tests that determine who gets the powerful breast cancer drug trastuzumab (Herceptin) may not be as reliable as previously thought, researchers reported at the annual meeting of the American Society of Clinical Oncology. That means some women who should be getting trastuzumab treatment are not, while other women who will not benefit are unnecessarily exposed to a drug that can cause heart problems.

Bad Cancer Tests Drawing Scrutiny - WSJ.com - Windows Internet Explorer
http://online.wsj.com/article/SB119941325367266813.html
THE WALL STREET JOURNAL.
THE WALL STREET JOURNAL. Digital Network
WSJ.com
MarketWatch
BARRON'S
All Things Digital.
More
SEARCH
The Online Journal GET 2 WEEKS FREE
The Print Journal GET 2 WEEKS FREE
SUBSCRIBE NOW
Remember Me
Log In
As of Friday, January 4, 2008
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AIDS Parley
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BLOGS
Most Popular Posts
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2. Starting Today, No More Free Water on US Air
3. Obama Agrees to Three Debates, No Town-Halls
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MORE FREE CONTENT
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Leisure
Markets Data Center
Video
Blogs
Forums
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Autos
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A Daily Political Newsletter from WSJ.com's Opinion Editors
SIGN UP NOW
Bad Cancer Tests Drawing Scrutiny
By ANNA WILDE MATHEWS
January 4, 2008
Thousands of breast-cancer patients may be getting the wrong treatment because of errors in two laboratory tests widely used to determine which drugs are prescribed.
The tests are used to help determine whether women with invasive breast cancer will receive drugs such as Genentech Inc.'s Herceptin, GlaxoSmithKline PLC's Tykerb and a number of antihormone medications, including the generic tamoxifen and newer treatments such as AstraZeneca PLC's Arimidex and Faslodex.
The pharmaceuticals industry is trying to develop more medicines tailored to the individual characteristics of patients and their diseases. Herceptin, which went on the market in 1998, has been hailed as a breakthrough because it is designed for a certain subset of breast-cancer patients rather than everyone who has the disease.
But recent studies that turned up problems in testing point to a potential snag for such drugs: They depend on accurate lab results.
"We all make the assumption that every test is done well. It turns out it's not a correct assumption," says Lee Newcomer, a cancer doctor who is senior vice president at insurer UnitedHealth Group Inc. Several major private insurers, including UnitedHealth, Aetna Inc. and WellPoint Inc., say they will generally pay for second-opinion breast-cancer tests. However, Dr. Newcomer says that even though UnitedHealth covers a second test, few doctors order them.
In 2007, around 178,000 patients were expected to be diagnosed with invasive breast cancer in the U.S., according to the American Cancer Society.
An oral exam can help with early detection of:
a) diabetes
b) heart disease
c) cancer
d) all of the above
Click on the correct answer
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Internet
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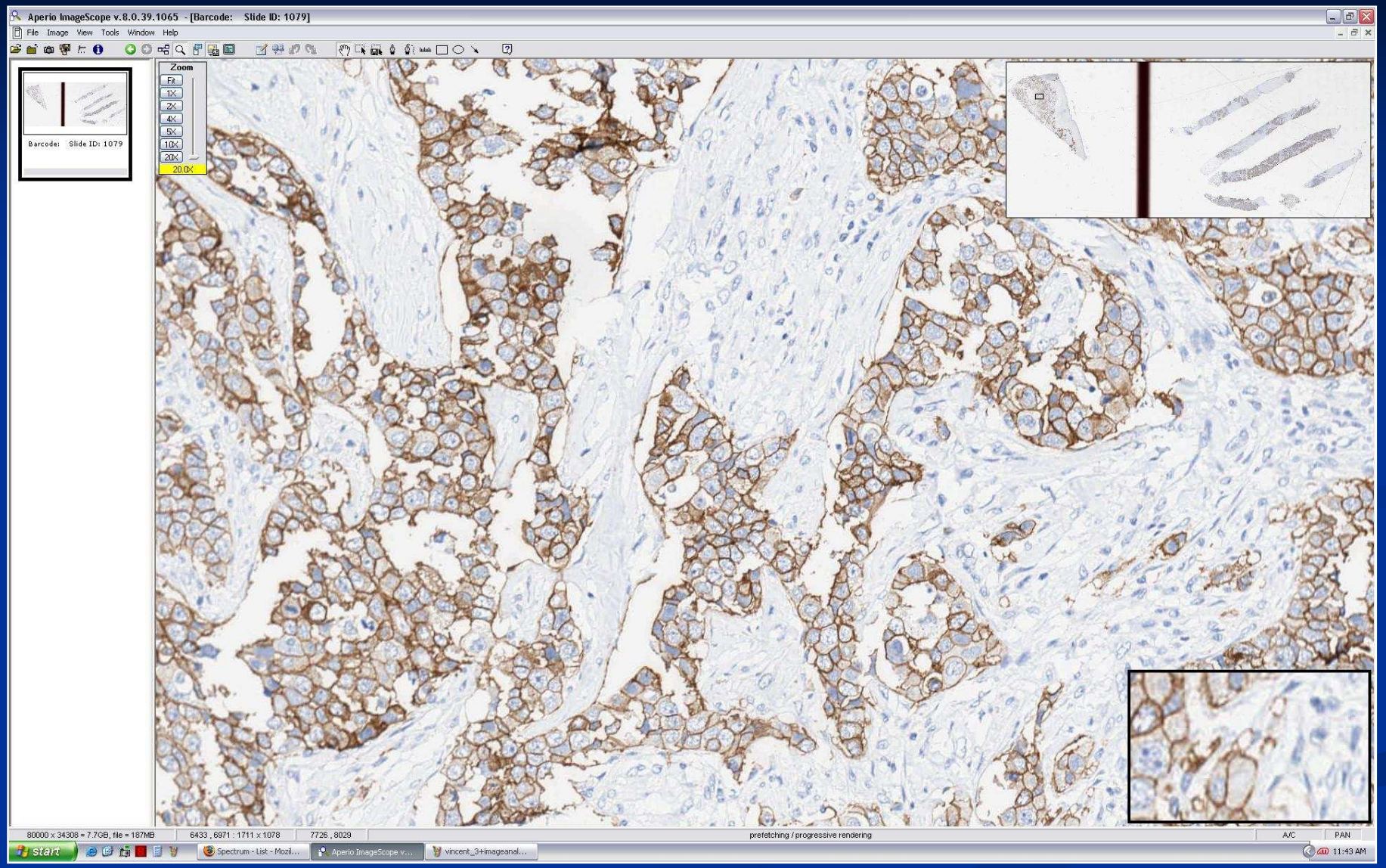
Preanalytic
Time to fixation
Method of tissue processing
Time of fixation
Type of fixation
Analytic
Assay validation
Equipment calibration
Use of standardized laboratory procedures
Training and competency assessment of staff
Type of antigen retrieval
Test reagents
Use of standardized control materials
Use of automated laboratory methods
Postanalytic
Interpretation criteria
Use of image analysis
Reporting elements
Quality assurance procedures
Laboratory accreditation
Proficiency testing
Pathologist competency assessment

Abbreviation: HER2, human epidermal growth factor receptor 2.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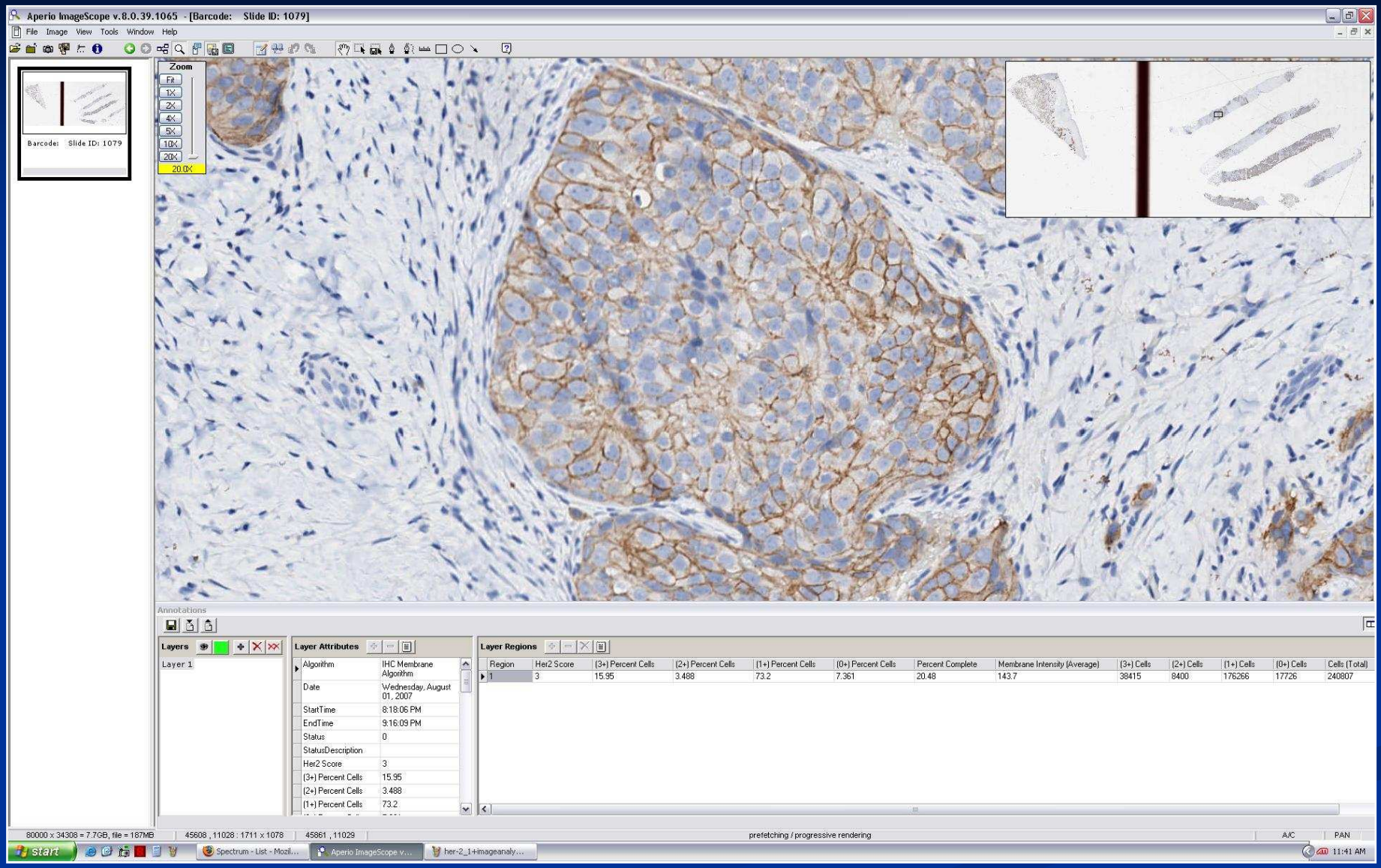
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Barcode: Slide ID: 1079
Annotations
Layers
Layer 1
Layer Attributes
Algorithm IHC Membrane Algorithm
Date Wednesday, August 01, 2007
StartTime 8:18:06 PM
EndTime 9:16:09 PM
Status 0
StatusDescription
Her2 Score 3
(3+) Percent Cells 15.95
(2+) Percent Cells 3.488
(1+) Percent Cells 73.2
Layer Regions
Region Her2 Score (3+) Percent Cells (2+) Percent Cells (1+) Percent Cells (0+) Percent Cells Percent Complete Membrane Intensity (Average) (3+) Cells (2+) Cells (1+) Cells (0+) Cells Cells (Total)
1 3 15.95 3.488 73.2 7.361 20.48 143.7 38415 8400 176266 17726 240807
80000 x 34308 = 7.7GB, file = 187MB
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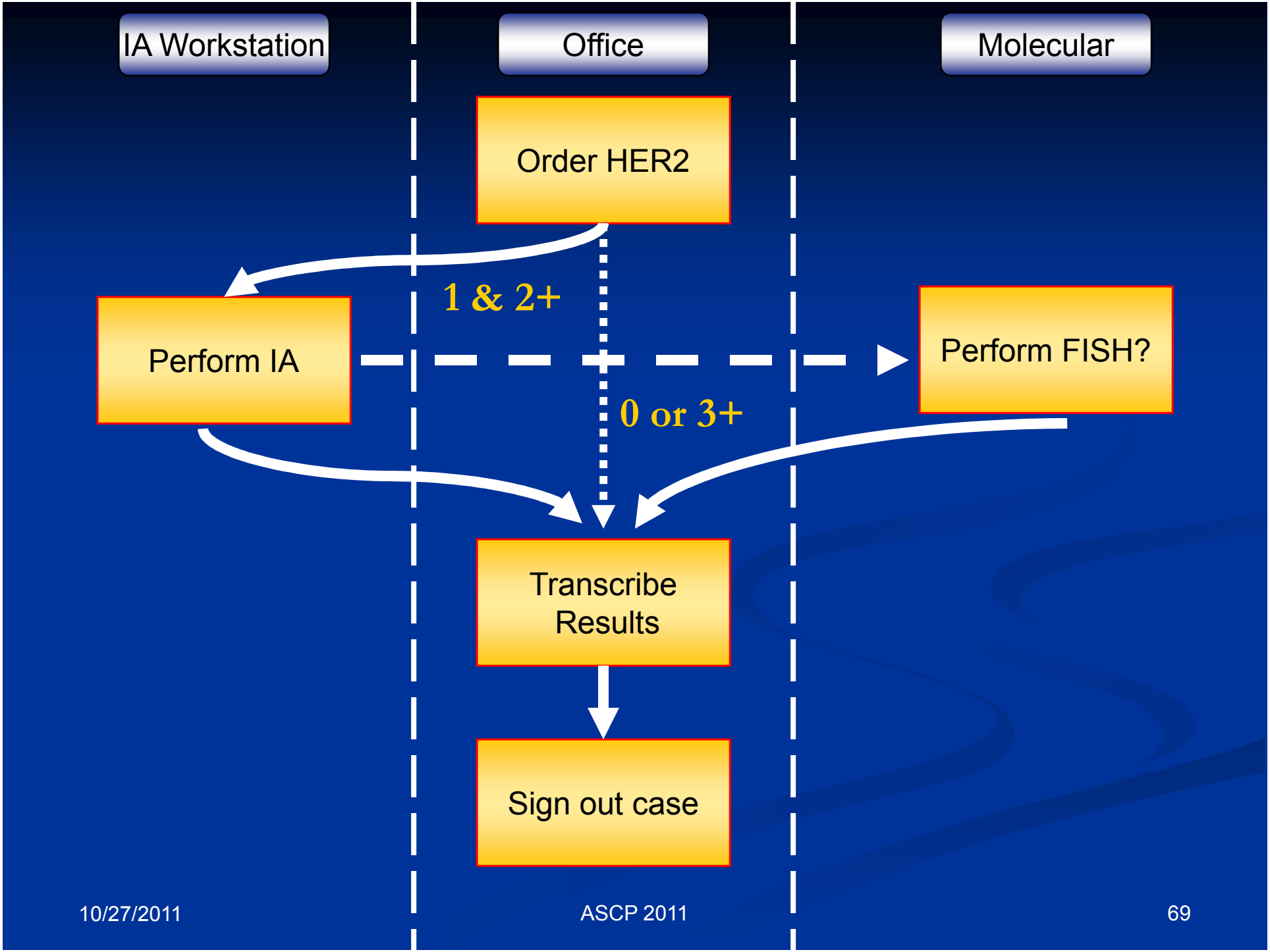
Conclusions

- IA appears to be more accurate than MA in HER2 IHC, particularly for 2+ cases (FISH non-amplified)
- Algorithms appeared to overscore or underscore a minority of cases, particularly 1+ IHC cases (FISH non-amplified)
- Pilot study suggests a role for IA in 2+ cases to avoid unnecessary FISH testing in overscored cases
- Cost and time required for WSI analysis may still be prohibitive for routine clinical use without added resources in the laboratory for IA.

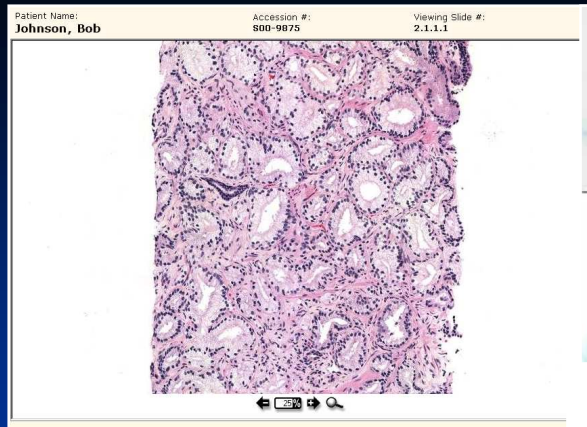
Conclusions

- CPT 88360 – Morphometric analysis, tumor immunohistochemistry (e.g. HER2, estrogen/ progesterone receptor), quantitative, semiquantitative, each antibody; manual
  - PC+TC=$147.95
- CPT 88361 – Morphometric analysis, tumor immunohistochemistry (e.g., HER2 estrogen/ progesterone receptor), quantitative, semiquantitative, each antibody; using computer assisted technology
  - 88361 PC+TC=$229.16 Δ(TC+PC)=$81.21


IA Workstation
Office
Molecular
Order HER2
1 & 2+
Perform IA
Perform FISH?
0 or 3+
Transcribe Results
Sign out case

Reimbursement

- CPT 88360 – Morphometric analysis, tumor immunohistochemistry (e.g., Her2/neu, estrogen/progesterone receptor), quantitative, semiquantitative, each antibody; manual
  - PC+TC=$147.95
- CPT 88361 – Morphometric analysis, tumor immunohistochemistry (e.g., Her2/neu, estrogen/progesterone receptor), quantitative, semiquantitative, each antibody; using computer assisted technology
  - 88361 PC+TC=$229.16 Δ(TC+PC)=$81.21
- HER2 FISH
  - 88368 PC+TC=$710.00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Johnson, Bob
Accession #:
S00-9875
Viewing Slide #:
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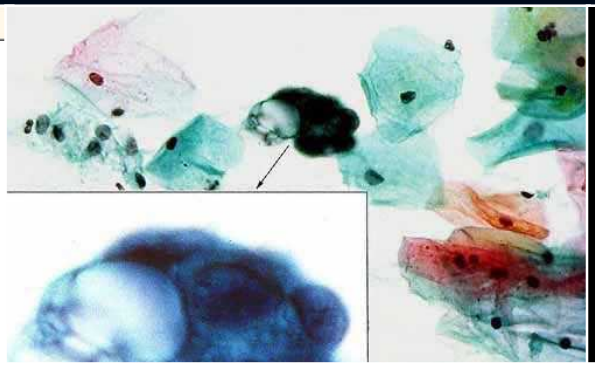

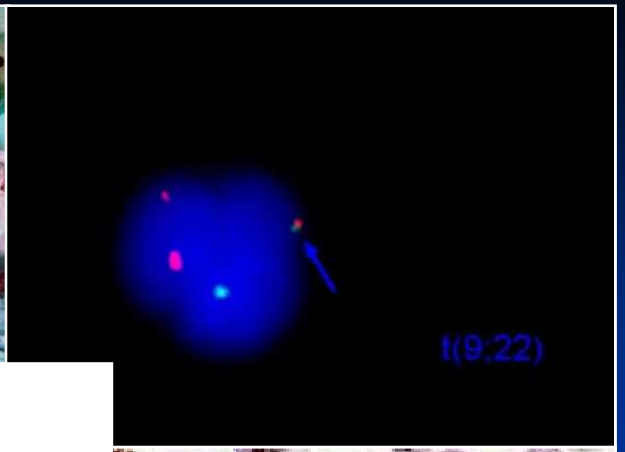
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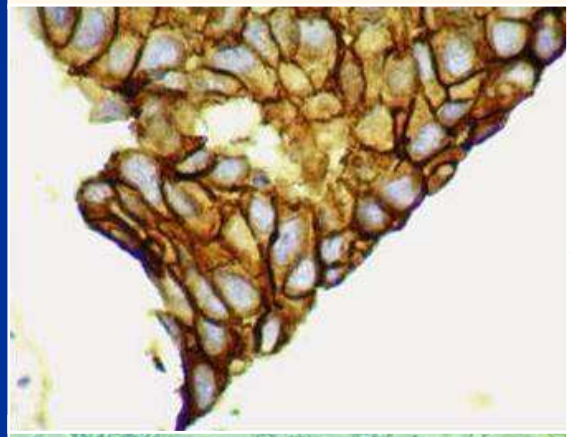

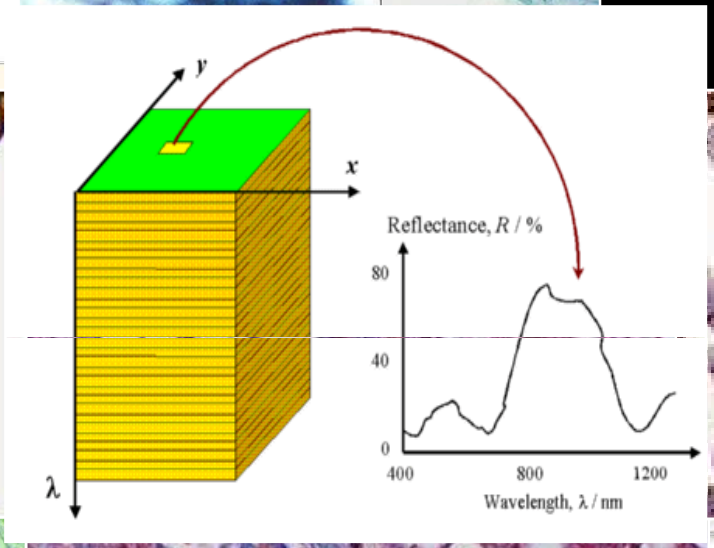
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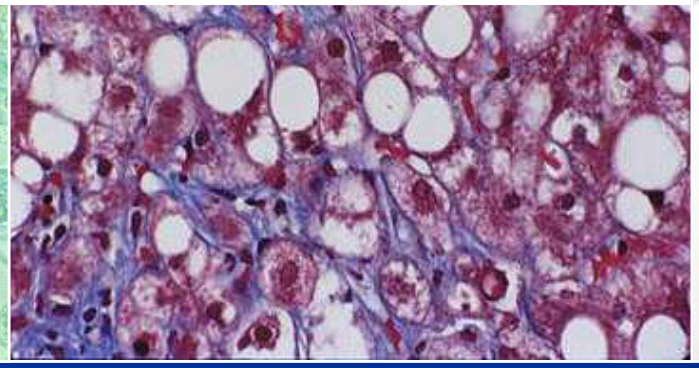
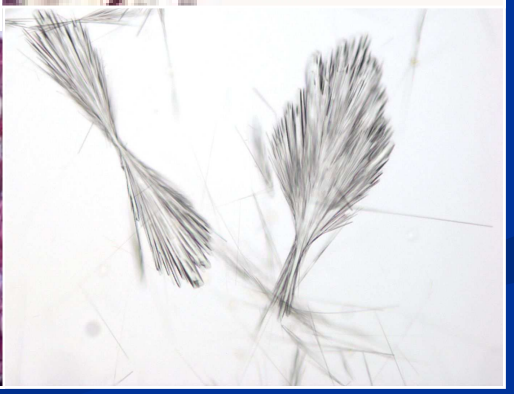
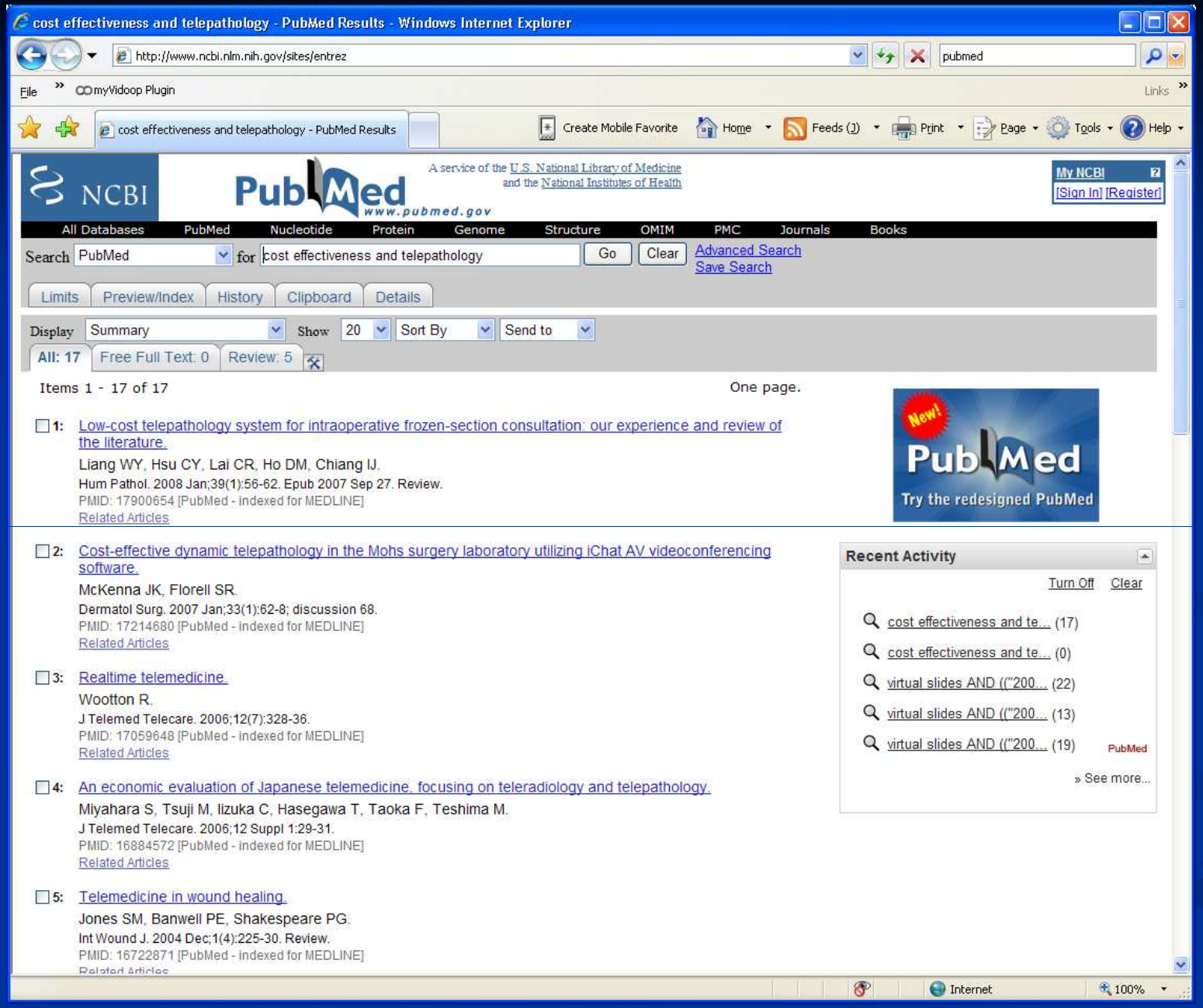




Is it worth it?

Fiscal Barriers

- Most health care organizations are not notorious risk-takers.
- How to justify?
- Is it cost-effective?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Limits
Preview/Index
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Clipboard
Details
Display Summary
Show 20
Sort By
Send to
All: 17
Free Full Text: 0
Review: 5
Items 1 - 17 of 17
One page.
1: Low-cost telepathology system for intraoperative frozen-section consultation: our experience and review of the literature.
Liang WY, Hsu CY, Lai CR, Ho DM, Chiang IJ.
Hum Pathol. 2008 Jan;39(1):56-62. Epub 2007 Sep 27. Review.
PMID: 17900654 [PubMed - indexed for MEDLINE]
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2: Cost-effective dynamic telepathology in the Mohs surgery laboratory utilizing iChat AV videoconferencing software.
McKenna JK, Florell SR.
Dermatol Surg. 2007 Jan;33(1):62-8; discussion 68.
PMID: 17214680 [PubMed - indexed for MEDLINE]
Related Articles
3: Realtime telemedicine.
Wootton R.
J Telemed Telecare. 2006;12(7):328-36.
PMID: 17059648 [PubMed - indexed for MEDLINE]
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4: An economic evaluation of Japanese telemedicine, focusing on teleradiology and telepathology.
Miyahara S, Tsuji M, Iizuka C, Hasegawa T, Taoka F, Teshima M.
J Telemed Telecare. 2006;12 Suppl 1:29-31.
PMID: 16884572 [PubMed - indexed for MEDLINE]
Related Articles
5: Telemedicine in wound healing.
Jones SM, Banwell PE, Shakespeare PG.
Int Wound J. 2004 Dec;1(4):225-30. Review.
PMID: 16722871 [PubMed - indexed for MEDLINE]
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cost effectiveness and te... (0)
virtual slides AND (("200... (22)
virtual slides AND (("200... (13)
virtual slides AND (("200... (19)
PubMed
» See more...
Internet
100%

Cost Justification in Telepathology Comparison of services by three models

	On-site pathologist	Tele-pathology	Courier
Frozen section diagnosis	Yes	Yes	No
TAT	Days*	Minutes*	Days
Live consults w/ clinicians & slides	Yes	Yes	No
Second pathology opinions	Delayed	Immediate	Delayed

Agha Z, Weinstein RS, Dunn BE. Cost minimization analysis of telepathology. Am J Clin Pathol 1999 Oct;112:470-8.

Linda Dao, M.D.

Paul Lappinga, M.D.

Robert Ridenour III, M.D.

David Durnick, M.D.

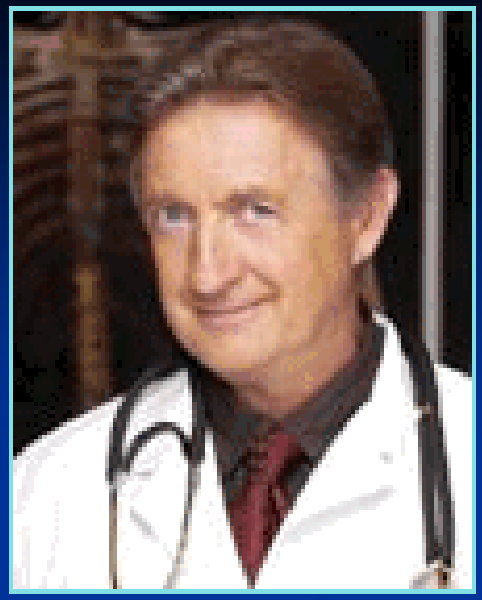
Sacred Heart Pathology, LLC

Angela Wood, M.D.

The 'Stage'

- Pathology practice
  - 5 pathologists
  - Sacred Heart Hospital
    - 300 beds
  - Willmar, MN
    - Rural practice
  - Hospital and Outpatient Procedure Clinic
    - 20,000 surgicals/year
    - Bone marrows, pap smears, FNAs
  - Fully staffed histology lab (IHCs)
  - Pathology assistant

The 'Scenario'



- Watertown, SD
  - Solo pathologist retiring
  - 110 miles away
  - Low frozen section volume
    - 5,000 surgicals/year
    - 20 frozen section slides/week
  - Histology lab fully staffed (No IHC)
  - Pathology assistant

Everything at Your Fingertips

Mopec

+

MASTER ON/OFF

LEICA
3050 S
Leica

+

Capital Expenditures

- Histology Lab
  - Tissue processor $40,000
  - Tissue embedding center $7,500
  - Paraffin dispenser $2,000
  - Microtome $10,000
  - Tissue floating bath $500
  - Slide stainer $10,000
  - Coverslipper $10,000
  - Total $80,000
- Frozen Section Lab
  - Cryostat $10,000

Cost Scenario 1: Hire Pathologist

- Fixed cost
  - Pathologist $230,000
  - Pathology assistant $65,000
  - Histotech $36,000
  - Secretary $30,000
  - Courier service $6,000
  - Histology lab $8,000
  - Frozen section lab $1,000
- Variable cost
  - Frozen section supp $5,000
  - Histology supplies $50,000
- Total $431,000

Cost Scenario 2: Driving

- Gas $9,000
- Loss of productivity $115,000
- Time lost *priceless*

- Total = #2 + (#1 – pathologist's salary)
  = $124,000 + $201,000
  = $325,000

Cost Scenario 3: Buy Scanner

- Fixed cost
  - Scanner $24,000
  - Pathologist assistant $65,000
  - Courier service $12,000
  - Frozen section lab $1,000
- Variable cost
  - Frozen section supplies $5,000
- Total $107,000

Savings

Hire Pathologist

- Fixed cost
  - Pathologist $230,000
  - PA $65,000
  - Histotech $36,000
  - Secretary $30,000
  - Courier service $6,000
  - Histology lab $8,000
  - Frozen section lab $1,000
- Variable cost
  - Frozen section supp $5,000
  - Histology supplies $50,000
- Total $431,000

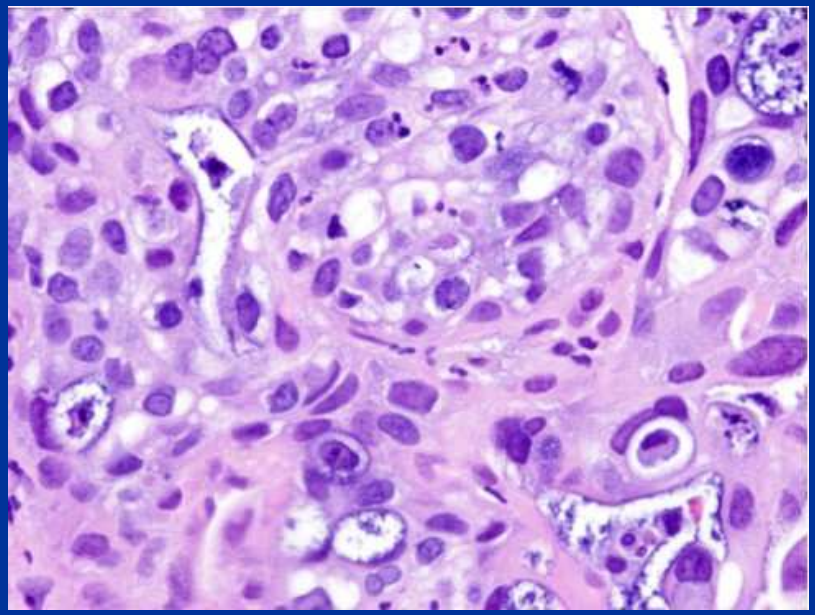
Buy Scanner

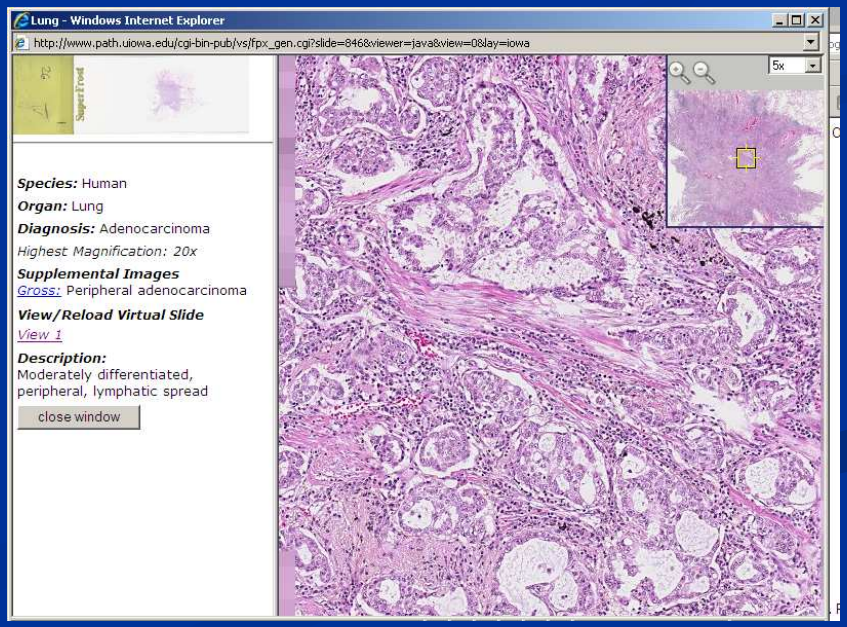
- Fixed cost
  - Scanner $24,000
  - PA $65,000
  - Courier service $12,000
  - Frozen section lab $1,000
- Variable cost
  - Frozen section supp $5,000
- Total $107,000

Savings: $324,000

Additional Benefits to Integrating Digital Pathology into Practice

- Review old cases
  - Adenocarcinoma metastatic to brain . . .
  - But history of lung cancer





Additional Benefits to Integrating Digital Pathology into Practice

- Tumor boards/Conferences/Teaching

Additional Benefits to Integrating Digital Pathology into Practice

- Model for further expansion/acquisitions

Additional Benefits to Integrating Digital Pathology into Practice

- Consults
  - No slides sent through mail
  - Possibly faster TAT
  - However, additional stains = old way

Versus

Quick Review of Groups Goals

- Provide excellent service to clinicians
  - Frozen section interpretation
  - Quick turn around time
- Harness combined knowledge of staff
- Use pathologists' time efficiently
- Use technology to improve service
    - Additional tests
    - Faster TAT
    - Expansion

↑Value

↑Quality

- Frozen section
  - Faster TAT
  - Combined knowledge
- Permanent section
  - Centralized processing
  - Uniform histology

↓Cost

- Consolidated histo lab
- Increased efficiency
- One less pathologist

Telepathology as a Cost Effective Tool

- Reduce costs without impairing turnaround time
- Save travel time
  - Improve resource utilization
    - MD and technical personnel
    - ⇓ courier/travel costs
- Create added value
- Return on investment (ROI)
- Value on investment (VOI)

Real-life example

- 10 pathologists/3 hospitals
- 6/1/1- FS/surgicals/cytologies/outreach
- 1 DP and 1 HP for consultation cases
- Centralized histology
- Replace 1 man shop(s) with idealized telepathology/virtual slide system
  - Rapid scan/high-resolution/dynamic
  - PACS/LIS

- Real–life analysis
  - Cost per System $50,000
  - Monthly Cost (using market 3 year lease rates) $1,750
- Pathologist Time
  - Frozen Sections per Month requiring coverage/travel 40
  - Hours Saved per Frozen Section with System 1
  - Hours Saved per Month 40
  - Value of Pathologist Hour $400
  - Value Created per Month $16,000
  - Value Created per Year $192,000
- Patient Costs
  - Patient Stays per Month extended due to slow path response 0
  - Average Days Extended 0
  - Total Extra Hospital Days 0
  - Cost per Patient Day $2,000
  - Value Created per Month $0
  - Value Created per Year $0
- Courier Costs
  - Consulations per Month using System 0
  - Average Courier Cost $0
  - Value Created per Month $0
  - Value Created per Year $0
- Total Value Creation
  - Value Created per Month $16,000
  - Value Created per Year $192,000

Limitations/Weaknesses

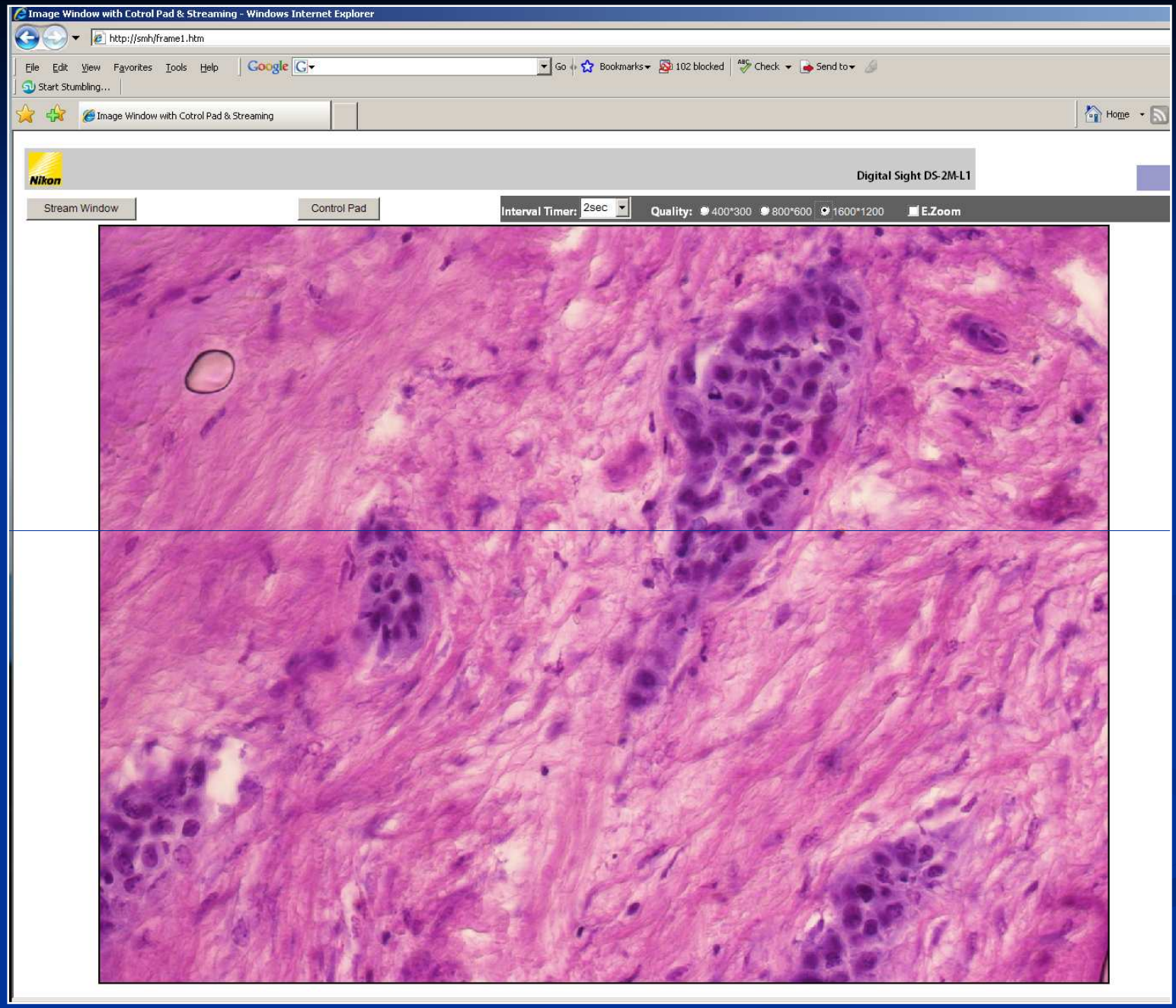
- Fewer (same) people doing more
- Technical cost considerations
- Use may not justify expense (# of FS)
- Back up plan
  - A difficult case is a difficult case
  - Technical problems
- Intangible benefits
  - Face on the lab/Morale
  - Clinical laboratory functions
  - Direct communication/interaction with clinicians

Is it worth it?

- It depends – volume/cost & time of travel
- Utilize existing personnel to manage risk
  - Negate solo-pathologist/risk management
  - Consult with colleagues
  - Rapid subspecialty consultation
- Lose intangible benefits
  - PR – Face-to-face discussion with clinicians
  - Morale

Is it worth it?

- Leverage technology into clinical business practice
- Transplant services
- Toronto General Hospital brain frozens
- DOD/VA
- Europe
- Emerging markets - Asia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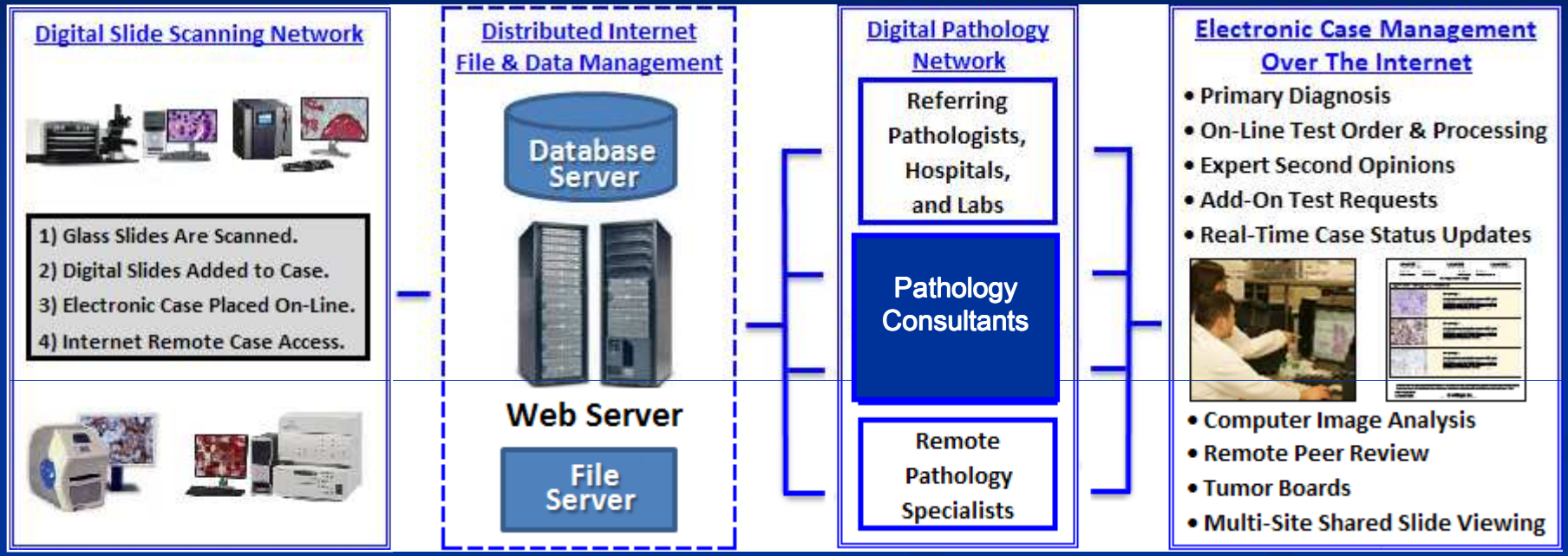
Nikon
Digital Sight DS-2M-L1
Stream Window
Control Pad
Interval Timer: 2sec
Quality: 400*300 800*600 1600*1200
E.Zoom

Felt head
Insert carrier this end up
Leather skirt
Do not send specimen without insert
NOTICE
AFTER 10:00 pm SEND EXTRA EMPTY TUBES TO STATION 50. DIALING 00 WILL NOT WORK. 00 WILL WORK AT 7:00 am - PLEASE USE AT THAT TIME.
THANK YOU
CONVEYANCE
Ortho
Cultures
To St. 64
Cytology
To St. 66
1 2 3 F1
4 5 6 F2
7 8 9 F3
CLEAR 0 SEND F4

ProposedConsultation Network Schema

Digital Pathology & Electronic Case Management Over The Internet

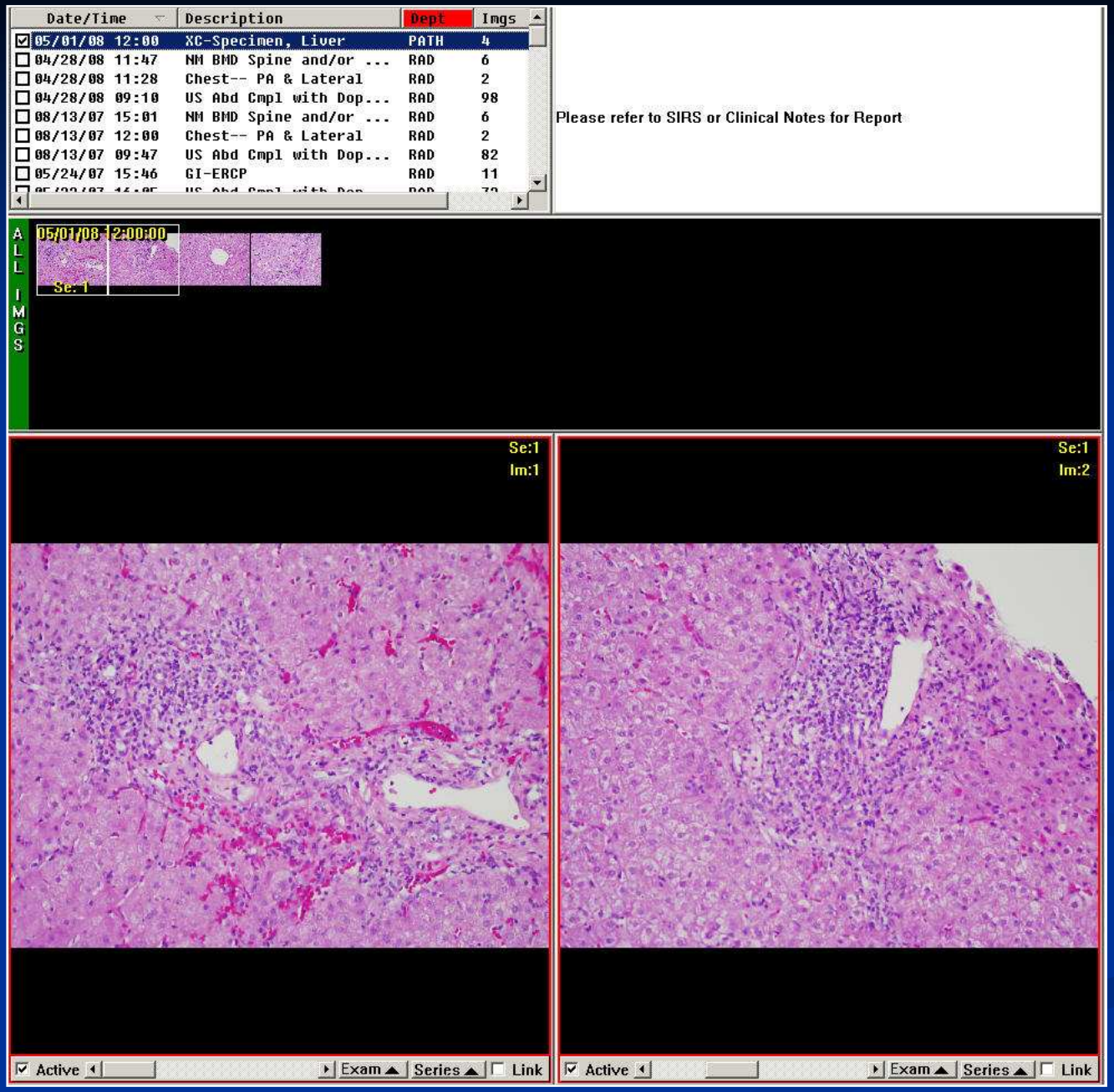


- Faster Turn Around Times
- Distributed Case Work-Load Volumes Across Pathologist within the Network
- Access to Leading Experts Across The Pathology Sub-Specialties
- Instant, Real Time Second Opinions
- Online Internet Case-Access Simplifies Peer Collaboration and Slide Consultation
- Pathologist can log-on from anywhere, at anytime and read cases over the Internet

Differentiated Service Model

- Secure access; shared expertise
- Improved consultation and turnaround time
- Elimination of slide shipping & handling
- Extensive/searchable image results database
- Connectivity to colleagues/clients/hospitals
- Image analysis applications
  - Better consistency; CPT code with Δ

Consulting Pathologist	Referring Pathologist	Patient	IT/ Admin
❑Offer faster TAT to foster better relationships with clients ❑Retain record of case slides (more effective answering questions regarding cases, reduce liability) ❑Render consults from anywhere/anytime ❑Eliminates dealing with glass slides ❑Grow consulting business ❑Stay on the leading-edge by offering flexibility	❑Receive faster TAT (especially if they own a scanner) ❑Access to sub-specialty experts ❑Gain competitive advantage ❑Opportunity for a digital slide conference ❑Reduce glass slide overhead (if have own scanner); ensure that glass slides are returned, and not lost or broken ❑Eliminate need to prepare additional slides ❑Send blocks only when necessary	❑Faster TAT ❑Easier to get a secondary consult ❑Better control over patient care experience	❑Easy to implement ❑Avoids cost, challenge of maintaining internal IT infrastructure ❑Cloud computing facilitates image sharing


Date/Time
Description
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Imgs
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04/28/08 11:47 NM BMD Spine and/or ... RAD 6
04/28/08 11:28 Chest-- PA & Lateral RAD 2
04/28/08 09:10 US Abd Cmpl with Dop... RAD 98
08/13/07 15:01 NM BMD Spine and/or ... RAD 6
08/13/07 12:00 Chest-- PA & Lateral RAD 2
08/13/07 09:47 US Abd Cmpl with Dop... RAD 82
05/24/07 15:46 GI-ERCP RAD 11
Please refer to SIRS or Clinical Notes for Report
ALL IMGS
05/01/08 12:00:00
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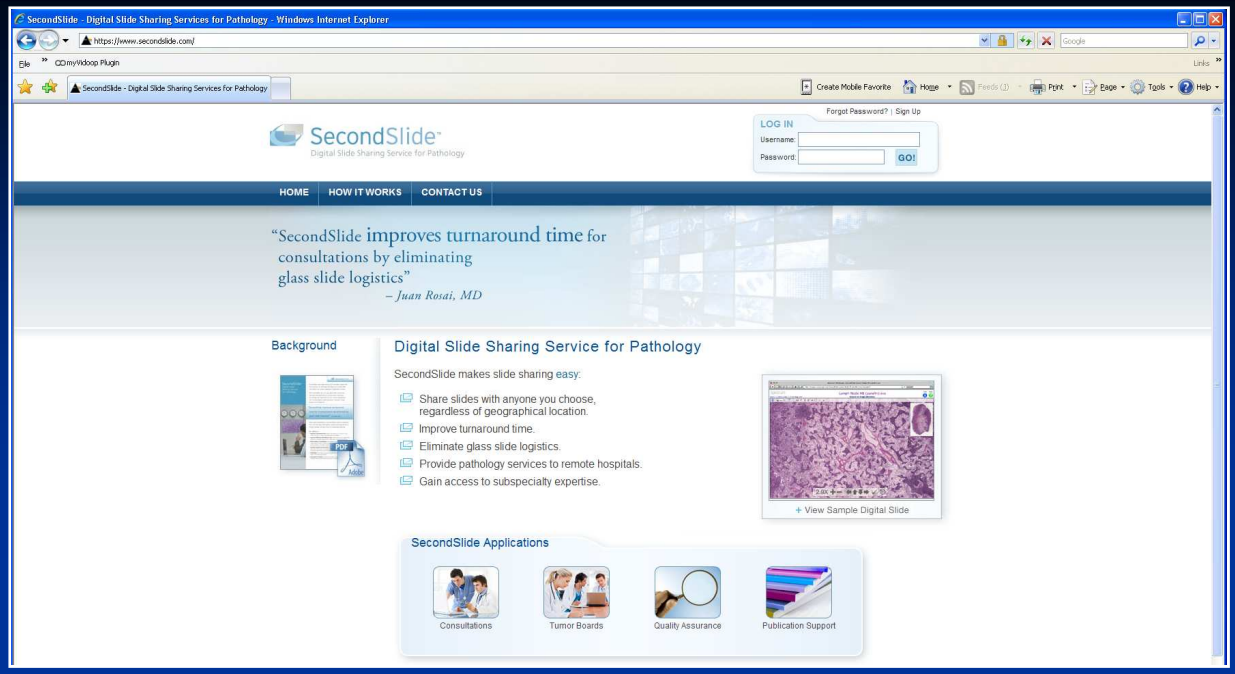
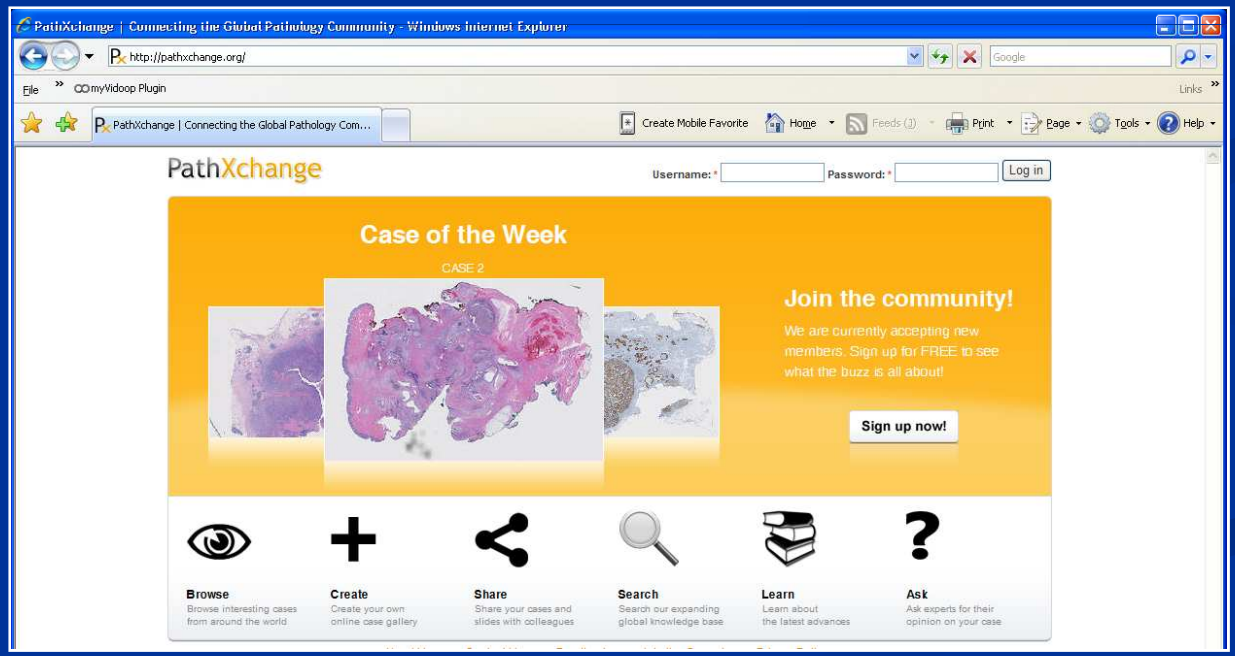
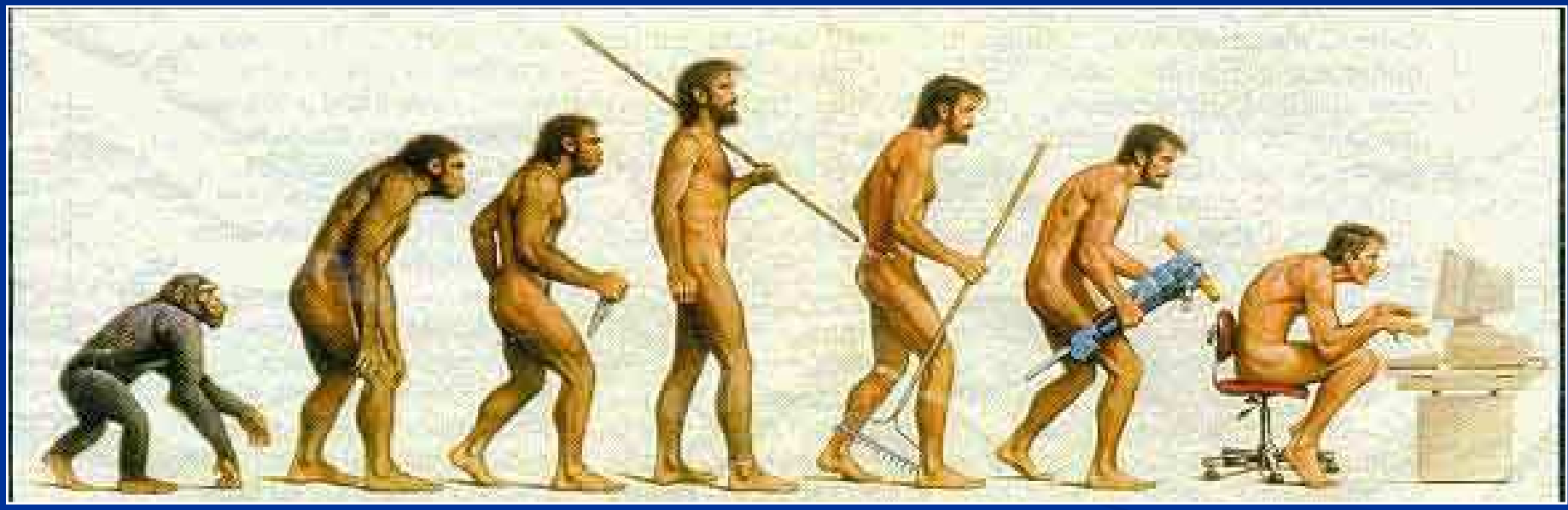

SecondSlide - Digital Slide Sharing Services for Pathology - Windows Internet Explorer
SecondSlide
Digital Slide Sharing Service for Pathology
LOG IN
Username:
Password:
GO!
HOME
HOW IT WORKS
CONTACT US
"SecondSlide improves turnaround time for consultations by eliminating glass slide logistics"
– Juan Rosai, MD
Background
Digital Slide Sharing Service for Pathology
SecondSlide makes slide sharing easy:
Share slides with anyone you choose, regardless of geographical location.
Improve turnaround time.
Eliminate glass slide logistics.
Provide pathology services to remote hospitals.
Gain access to subspecialty expertise.
+ View Sample Digital Slide
SecondSlide Applications
Consultations
Tumor Boards
Quality Assurance
Publication Support


PathXchange | Connecting the Global Pathology Community - Windows Internet Explorer
http://pathxchange.org/
PathXchange
Username: *
Password: *
Log in
Case of the Week
CASE 2
Join the community!
We are currently accepting new members. Sign up for FREE to see what the buzz is all about!
Sign up now!
Browse
Browse interesting cases from around the world
Create
Create your own online case gallery
Share
Share your cases and slides with colleagues
Search
Search our expanding global knowledge base
Learn
Learn about the latest advances
Ask
Ask experts for their opinion on your case

Lessons learned



General

- Technology diffusion & adaptation
  - "Technology is the easy part, changing hearts and minds is the hard part."
- IT issues - firewalls
- Human resources/personnel
- Sustainability
  - "~~Almost~~ as good as light microscopy"
  - Not exactly the same – human user interface

Effectiveness vs. Implementation

- Highly effective technology can be implemented that limits success
- Users can choose not to use new technology
  - Challenge of change
- Implement to meet your needs

Laboratory General

OUTLINE

SUMMARY OF CHANGES....3
INSPECTION TECHNIQUES – KEY POINTS....6
PROFICIENCY TESTING....8
QUALITY MANAGEMENT....10
SPECIMEN COLLECTION, DATA HANDLING, AND REPORTING....21
COLLECTION MANUAL AND OTHER DOCUMENTATION....21
SPECIMEN COLLECTION....24
TRANSPORT SERVICES....28
REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/ASSESSMENT....30
REPORTING OF RESULTS....33
DIRECT- TO- CONSUMER TESTING....41
QUALITY OF WATER AND GLASSWARE WASHING....42
TEST METHOD VALIDATION....45
METHOD PERFORMANCE SPECIFICATIONS....45
REFERENCE INTERVALS....49
LABORATORY COMPUTER SERVICES....49
COMPUTER FACILITY....50
LIS/COMPUTER PROCEDURE MANUAL....51
HARDWARE AND SOFTWARE....52
SYSTEM MAINTENANCE....54
SYSTEM SECURITY....54
PATIENT DATA....55
AUTOVERIFICATION....57
DATA RETRIEVAL AND PRESERVATION....59
INTERFACES....60
NETWORKS....62
TELEPATHOLOGY....62
PERSONNEL....64
TECHNICAL SUPERVISORS....64
GENERAL SUPERVISORS....65
ALL PERSONNEL....66
PHYSICAL FACILITIES....69
SPACE....69
ENVIRONMENT....70
COMMUNICATIONS....71
INVENTORY AND STORAGE OF SUPPLIES....71
POWER....72
LABORATORY SAFETY....72
MANUALS AND RECORDS....72
PHYSICAL INSPECTION OF THE LABORATORY....84

- Network equipment (accessible, labeled, well maintained)

GEN.49000 Network Performance **Phase I**

There is periodic monitoring of network performance and availability to all sites.

NOTE: Networks are the medium of data transport. Periodic review of collision rates, throughput, and downtimes should be conducted to assist in network maintenance and design.

Evidence of Compliance:
✓ Records of monitoring

GEN.49500 Network Maintenance **Phase I**

The network equipment is accessible, well-maintained and adequately labeled, showing which devices are using a specific port.

NOTE: Cables and ports should be monitored so that a device can be found quickly in case of network failure.

TELEPATHOLOGY

This section applies to telepathology. Telepathology is the practice of pathology, in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record.

Telepathology modes include:
- *Static telepathology – interpretation based on pre-selected still image(s)*
- *Dynamic telepathology - viewing real-time images*
- *Virtual slides/whole slide imaging*

This checklist section applies to:
- *Primary diagnoses made by telepathology*
- *Frozen section diagnoses*
- *Formal second-opinion consultations*
- *Ancillary techniques in which the pathologist participates in interpretation of images*

This checklist section is NOT applicable to:
- *Informal reviews without formal reporting*
- *Image analysis, in which the image is not interpreted by a pathologist, such as urine analysis*
- *Educational or research use of these systems*

Inspector Instructions:

- Sampling of telepathology policies and procedures

GEN.50057 Slide/Image ID **Phase II**

There is a method for the telepathologist to ensure that correct patient identification and slides/images are submitted for review.

NOTE: There are multiple ways to accomplish positive patient identification, including verbal communications, images of slide identifier, etc.

Evidence of Compliance:
✓ Written procedure defining mechanism to positively identify slides/images

GEN.50614 Clinical Information Access **Phase I**

The telepathologist has access to pertinent clinical information at the time of slide/image(s) review.

NOTE: Typically this information includes at least the information on the surgical pathology requisition form.

GEN.51171 Telepathology Appropriate Use **Phase I**

The methods and systems in place ensure that the system used for telepathology is appropriate for its intended clinical use.

NOTE: There should be a policy statement in the procedure manual that identifies appropriate and inappropriate use cases. For example, if a dynamic telemicroscopy system is installed on a microscope in the frozen section suite, the manual might state that this system is intended for use in intra-operative consultation and is not intended for second opinion consultation from pathologists at outside institutions.

GEN.51728 Telepathology Training **Phase I**

The lab has a procedure addressing training requirements for all users of the telepathology system.

Evidence of Compliance:
✓ Records for telepathology training in personnel files

GEN.52285 Telepathology QM **Phase I**

Telepathology is included in the laboratory's quality management program.

NOTE: For example, the laboratory might monitor the frequency of deferrals of frozen section diagnoses, including comparison to frozen sections diagnosed by traditional microscopy.

GEN.52842 Telepathology and HIPAA **Phase II**

There are procedures in place to ensure that sites engaging in telepathology provide reasonable confidentiality, security and conformance to HIPAA requirements.

NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions.

Approach to Determine Potential Future Scenarios for DP
Steps A–F

WIP

A	**Define Digital Pathology Applications**	1. What are the boundaries of the scenario, e.g. Impact of Whole Slide Imaging on the specialty of pathology?
B	**Define Practice Settings**	1. What are the practice settings where Digital Pathology is expected to be adopted for its different applications?
C	**Identify Key Assumptions for Digital Pathology Scenarios**	1. Certainties: What are the trends that will define future certainties and what are the assumptions around these? What do we believe to be true regardless of the scenario (e.g. Cost of Digital Pathology expected to rapidly decrease)? 2. Uncertainties: What are the key assumptions related to uncertainties that are likely to shape/alter the future are we unsure of?
D	**a) Identify the Adoption of Digital Pathology Applications in Different Practice Settings in Current State, 3–5 Years, and 7–10 Years** **b) Identify the "Impetus for Adoption" Applications**	1. What is the degree of adoption (Low, Medium, or High) of each application on the different practice settings for different time stamps? Which are the applications that will act as the Impetus for Adoption? 2. Which are the core applications for a practice setting? Which of these are the initial applications and the evolved applications in 3–5 years and 7–10 years time horizon? Define scenarios based on these initial and evolved applications
E	**Define Pathology Practice Parameters that could be affected by Digital Pathology**	1. What will be the areas and magnitude of impact that further define a scenario (e.g., time for testing, revenue) for each practice setting?
F	**Calculate FTE and Revenue for the Model, based on the Inputs of Interpretation Time, Adoption, CPT codes, etc.**	1. What will be the impact on FTEs and Economics for these scenarios? 2. Which are the service factors that can be mapped with applications? What is the broad distribution of applications across these factors?

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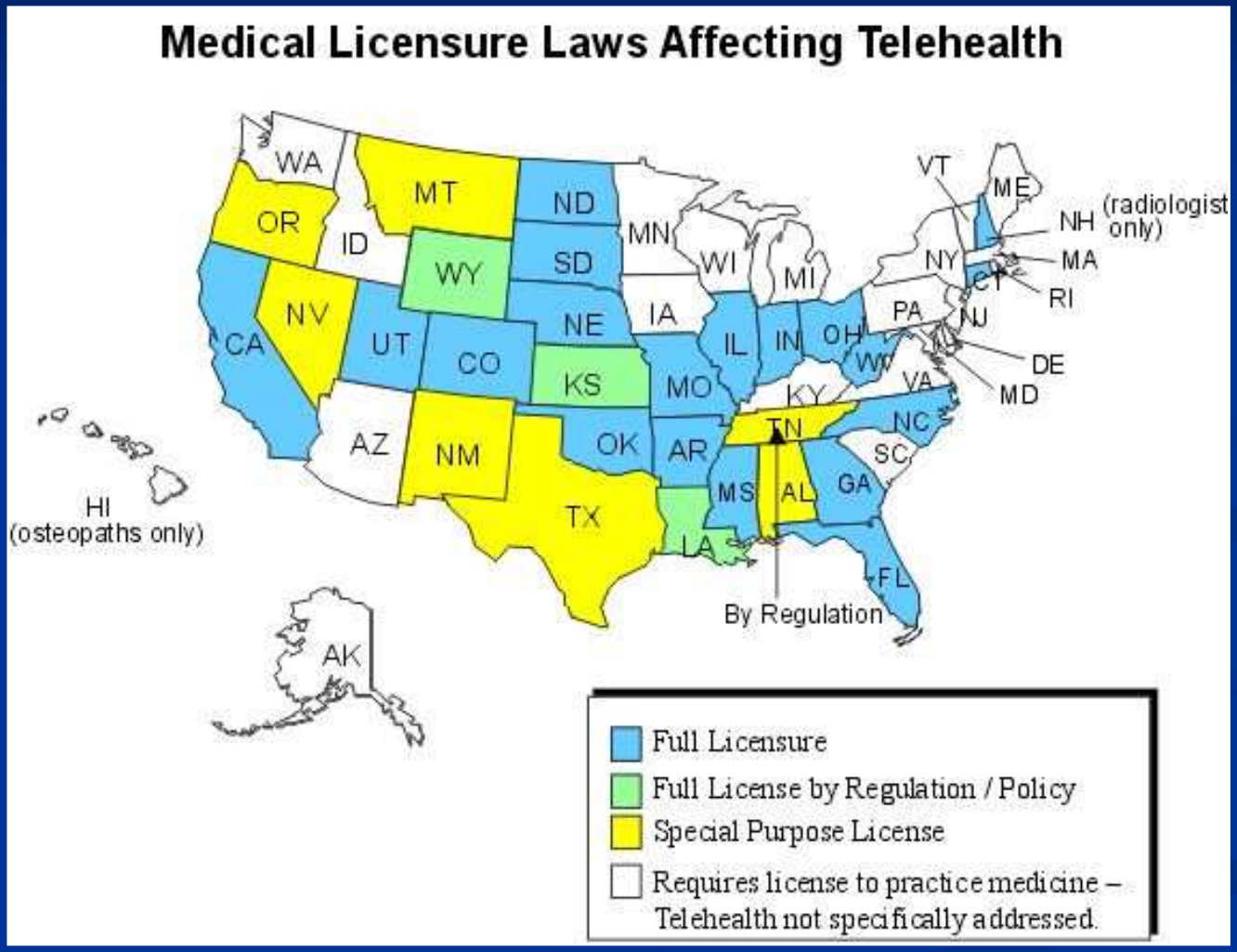
Licensure Issues

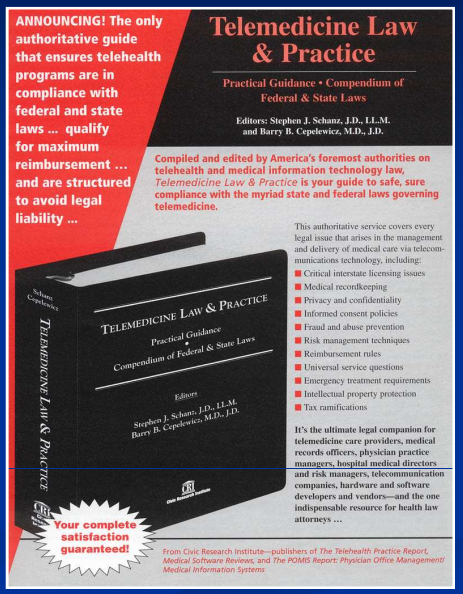


JCAHO: Telemedicine Credentialing Standards

"If a telemedicine practitioner prescribes, renders a diagnosis, or otherwise provides clinical treatment to a patient, the telemedicine practitioner is credentialed and privileged by the organization receiving the telemedicine service."

Insurance & Medicolegal Issues

- Check with local carriers and providers
- Telemedicine law and lawyers
- Nuances of clinical practice will dictate



Medicolegal standards

- Market forces are changing and insurers are responding to the market
- Assistance in working with insurers to meet standards of care
- Risk of using technology vs. Not using technology

It is agreed that no coverage is provided for liability arising out of the insured's activities performed for or in conjunction with Walter Reed Army Medical Center, telepathology, or the State of Pennsylvania.

Regulatory standards

- FDA panel Oct 2009
- Medicolegal implication

Technical standards

- DICOM standard facilitates interoperability between scanners, image storage systems and viewers
- Image compression that would not compromise pathologists' ability to diagnose
- Image fidelity from scanner to monitor
- Storage standards – HIPAA, redundancy, back up
- Storage standards – length of storage

Factors for consideration

- Quality of equipment (PCs, monitors, scanners)
- Quality of monitor images (resolution, color, contrast)

A 1
BUNNY, BUGS
B 1
BUNNY, BUGS

Human Pathology (2009) **40**, 1137–1142

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Human PATHOLOGY

www.elsevier.com/locate/humpath

Special Section on Telepathology

Medicolegal aspects of telepathology

Stanley T. Leung MD, JD*, Keith J. Kaplan MD

Received 10 November 2008; revised 14 January 2009; accepted 16 January 2009

3. Malpractice and liability

There is little case law that addresses the unique liability issues that could arise in telemedicine. Indeed, the state regulation of torts and medical malpractice usually leads to administrative remedies prior to adjudication by the courts. Thus, it is unlikely that a case would rise to the level of an appellate court in order to establish such case law.

The traditional tort or malpractice analysis should be performed in evaluating telemedicine liability:

- Duty
  - (Is there a PPR? Foreseeable plaintiff?)
- Breech of the duty
  - (Has *standard of care* been met?)
- Damage caused by Breech
  - (Is there a remedy at law or equity?)
- Proximate Cause
  - (1. Actual "but for…", substantial factor? 2. Foreseeable injury?)

Seven states have general exceptions to their state licensure laws that applied specifically to telemedicine. Alabama, Indiana, and Minnesota do not require out-of-state physicians to obtain a license to practice medicine from their home states if the physician does not practice in their state frequently. However, only Alabama provides a definition of "frequent" in its regulations:

> if such practice occurs less than ten (10) times in a calendar year or involves fewer than ten (10) patients in a calendar year or comprises less than one percent (1%) of the physician's diagnostic or therapeutic practice [11].

Illinois and Tennessee do not require a license if the physician is merely providing a second opinion. New Jersey and Washington do not require a license if the physician does not open a physical practice in the state or accept calls in the state. Thus, it would seem that in Illinois, Tennessee, New Jersey, or Washington state, the practice of telepathology, in an exclusively consultative role as a pathologist providing a second opinion to another pathologist in the state where the patient resides, would fall under such exceptions. However, all 7 states require that the out-of-state physician has an unrestricted license to practice medicine in the location of the distant physician in order to qualify for these exceptions.

Resources

- VIC Telepathology& Whole Slide Imaging course released March 2008 – updated 2010
- CAP Futurescape series
- Digital Pathology Association
- Pathology Visions/Pathology Informatics
- keithjkaplanmd@gmail.com

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An educational and informative weblog about the digital pathology community

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Meyer INSTRUMENTS

October 20, 2011

Invitation for Upcoming LLTech Webinar -- October 21

listen now

LLTech is creating innovative techniques for cellular imaging of fresh tissue. Recommend looking at this if you are involved with frozen sections, tissue banking, tissue mining, research and biobanking.

A reminder about our Light-CT webinar presentation - October 21st!

Dear Industry Colleague,

You are invited to join our webinar

Friday, October 21, beginning 11:30 am EDT.

Your host for this webinar: Lisa Minor, Ph.D.

REGISTER HERE

"Three-dimensional Osteogenic Differentiation on Polystyrene Scaffolds Imaged with the Light-CT Imaging System"

Presented by:

Carlos E. Caicedo-Carvajal, Ph.D. of 3D Biotek

The Light-CTTM is a unique, novel imaging system capable of performing 2-D and 3-D cellular digital imaging on fresh tissue without sacrificing the sample (even live animals), with a ~1 micron resolution in 2-D and 3-D.

Several references to the technology are available on the links to left of this mail (see Application notes).

Dr. Caicedo-Carvajal completed his Doctorate in Biomedical Engineering from the Rutgers University/UMDNJ Graduate Program in Biomedical Sciences.

He currently holds a position at 3D Biotek, characterizing and developing 3-dimensional (3-D) cell-based platforms using precision micro-fabricated polymer scaffolds. Dr. Caicedo-Carvajal is currently working on several projects, from 3-D perfusion bioreactor applications to development of Cancer Tissue Engineering applications using 3-D polymer scaffolds.

We sincerely think you will be interested in speaking with us next week or at a forthcoming webinar session!

Lisa

Lisa Minor, Ph.D.

Scientific and Application Leader

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indica labs — informed pathology

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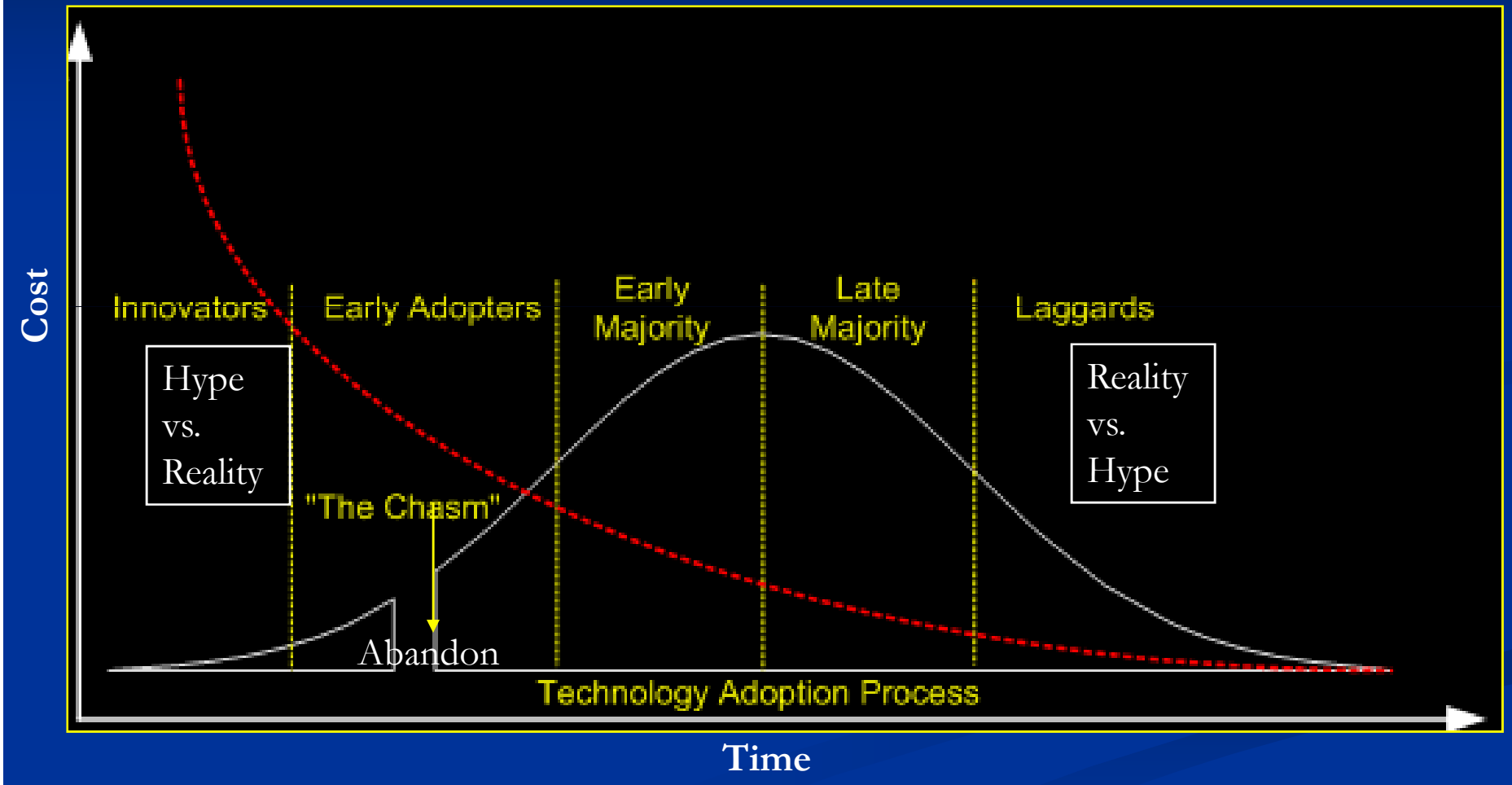
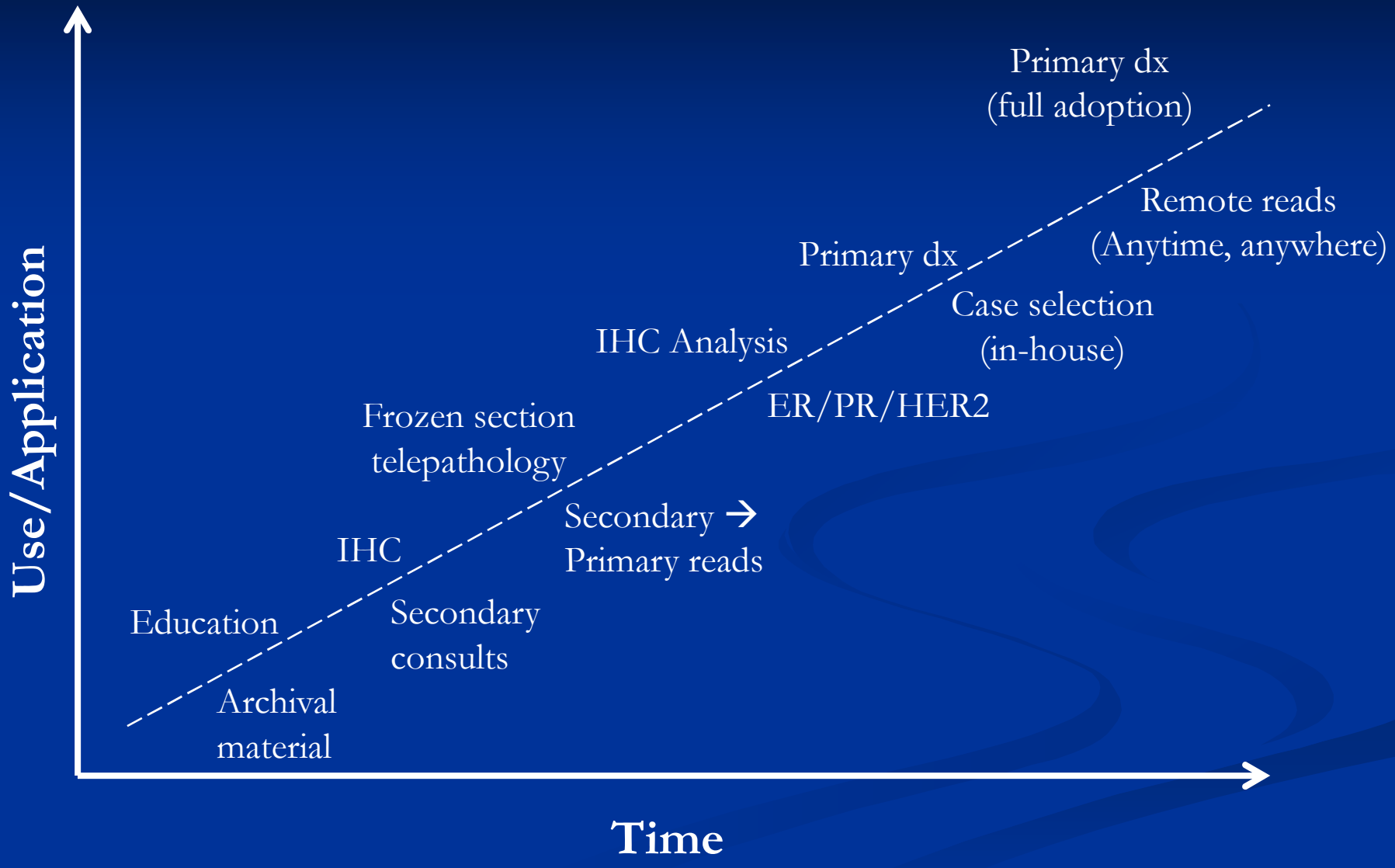
ACCELPATH — ACCELERATED DIGITAL TELEPATHOLOGY

Niche Adoption

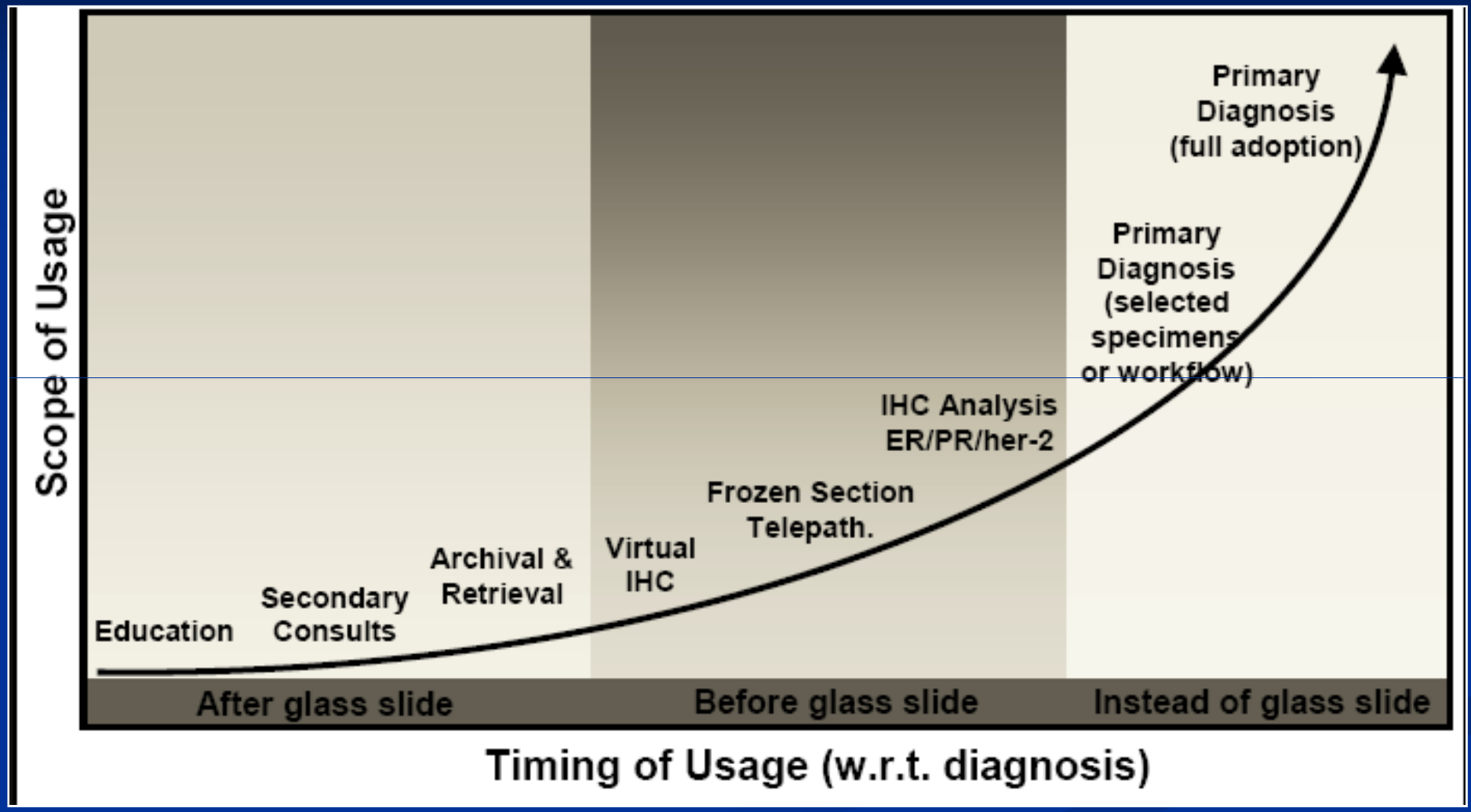
Technology adoption curve vs. Cost



Niche Adoption – Whole Slide



Adoption is occurring in niches



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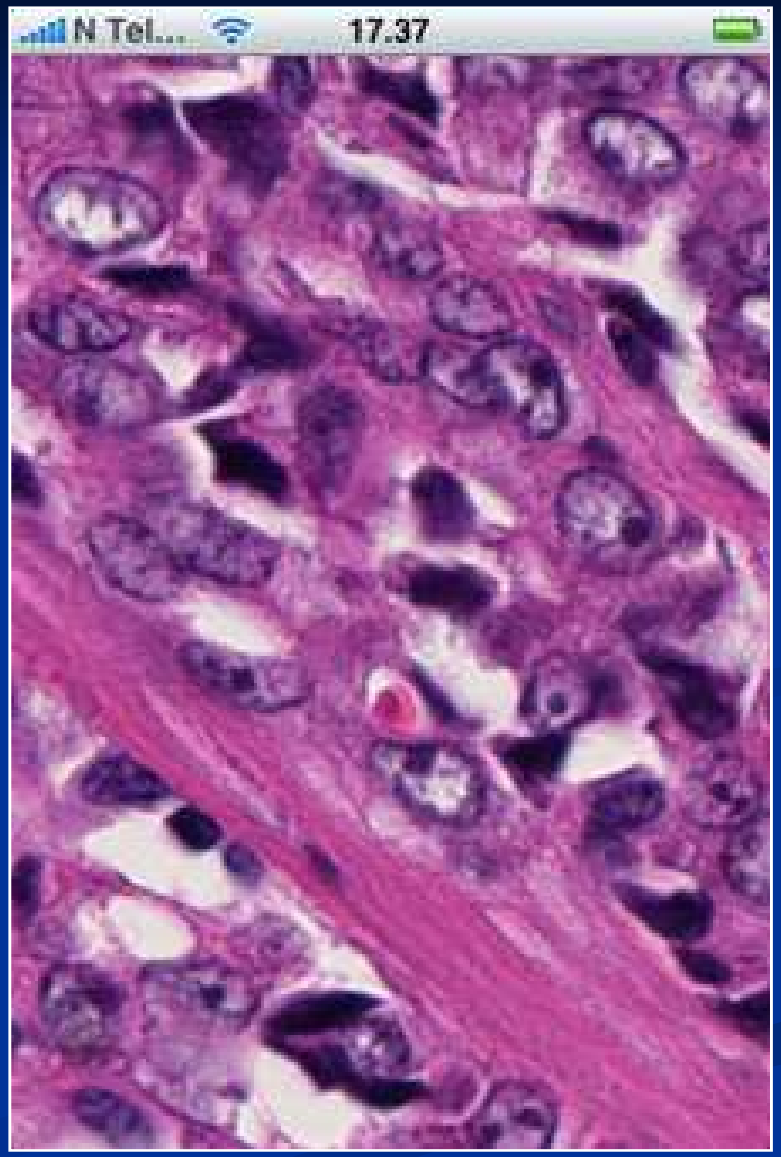
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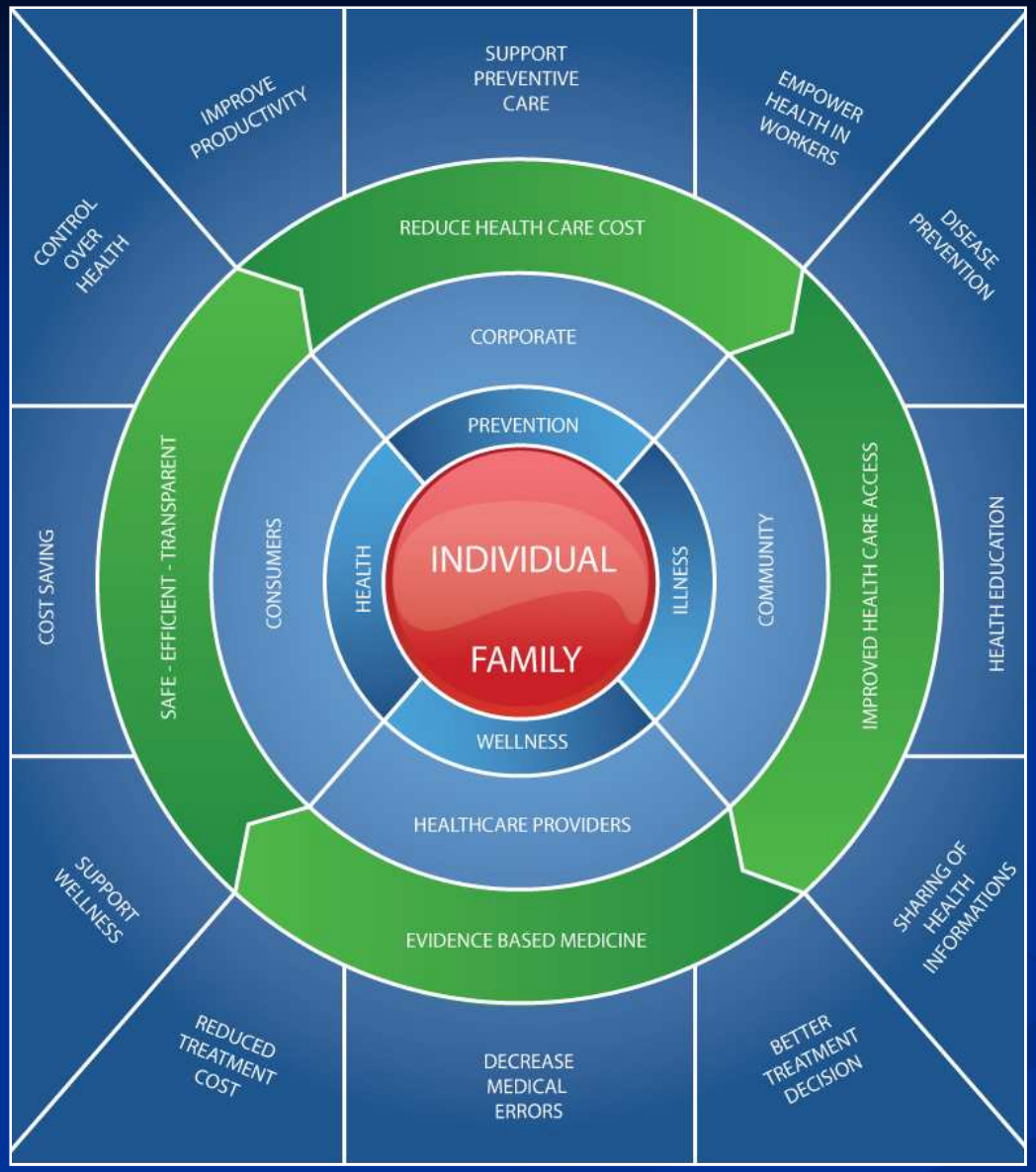
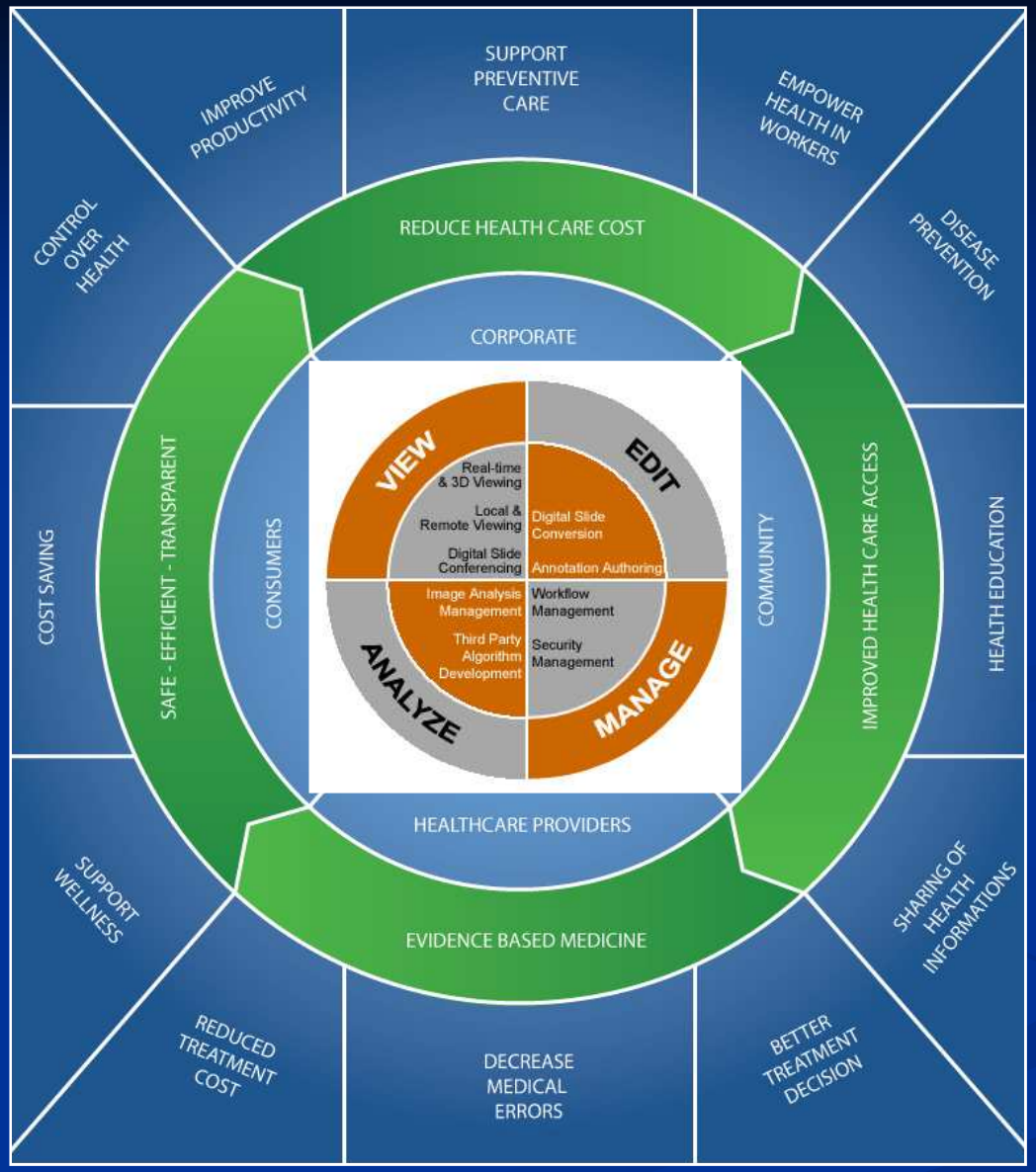

IMPROVE PRODUCTIVITY
SUPPORT PREVENTIVE CARE
EMPOWER HEALTH IN WORKERS
CONTROL OVER HEALTH
DISEASE PREVENTION
REDUCE HEALTH CARE COST
CORPORATE
PREVENTION
COST SAVING
SAFE - EFFICIENT - TRANSPARENT
CONSUMERS
HEALTH
INDIVIDUAL
FAMILY
ILLNESS
COMMUNITY
IMPROVED HEALTH CARE ACCESS
HEALTH EDUCATION
WELLNESS
HEALTHCARE PROVIDERS
SUPPORT WELLNESS
SHARING OF HEALTH INFORMATIONS
EVIDENCE BASED MEDICINE
REDUCED TREATMENT COST
DECREASE MEDICAL ERRORS
BETTER TREATMENT DECISION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CONSUMERS
VIEW
EDIT
Real-time & 3D Viewing
Local & Remote Viewing
Digital Slide Conferencing
Digital Slide Conversion
Annotation Authoring
Image Analysis Management
Third Party Algorithm Development
Workflow Management
Security Management
ANALYZE
MANAGE
COMMUNITY
IMPROVED HEALTH CARE ACCESS
HEALTH EDUCATION
HEALTHCARE PROVIDERS
SUPPORT WELLNESS
SHARING OF HEALTH INFORMATIONS
EVIDENCE BASED MEDICINE
REDUCED TREATMENT COST
DECREASE MEDICAL ERRORS
BETTER TREATMENT DECISION

Conclusions

- Digital pathology functional performance is adequate and improving
- Those who gain entry now are less likely to fall behind
- Gain a competitive advantage

Bene diagnoscitur, bene curatur.

"Something that is well diagnosed can be cured well."

www.virtualpathology.leeds.ac.uk

Thank you

SO YOU'RE SAYING PEOPLE WILL "TWEET" WHAT THEY'RE EATING FOR BREAKFAST?
AND "UPLOAD" PICTURES OF THEIR BREAKFASTS TO A "FACEBOOK"?
AND OTHER PEOPLE WILL LOOK AT THE BREAKFASTS AND MAKE COMMENTS?
SORRY TO BURST YOUR BUBBLE, DUDES, BUT YOU ASKED. YES, THAT'S THE FUTURE.
NO OFFENSE FUTURE MAN BUT IS EVERYONE IN YOUR TIME STUPID?