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Genomic Medicine Education Initiatives of the College of American Pathologists

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Information Requested by NHGRI

- Member needs assessments completed or planned
- State of genomic science & practice by members
- Short & long term pace of change in genomics use
- Current plans to address genomics literacy
- Process for genomics practice guidelines development for diagnosis and treatment
- Activities by associated specialty board to include genomics in certification procedures

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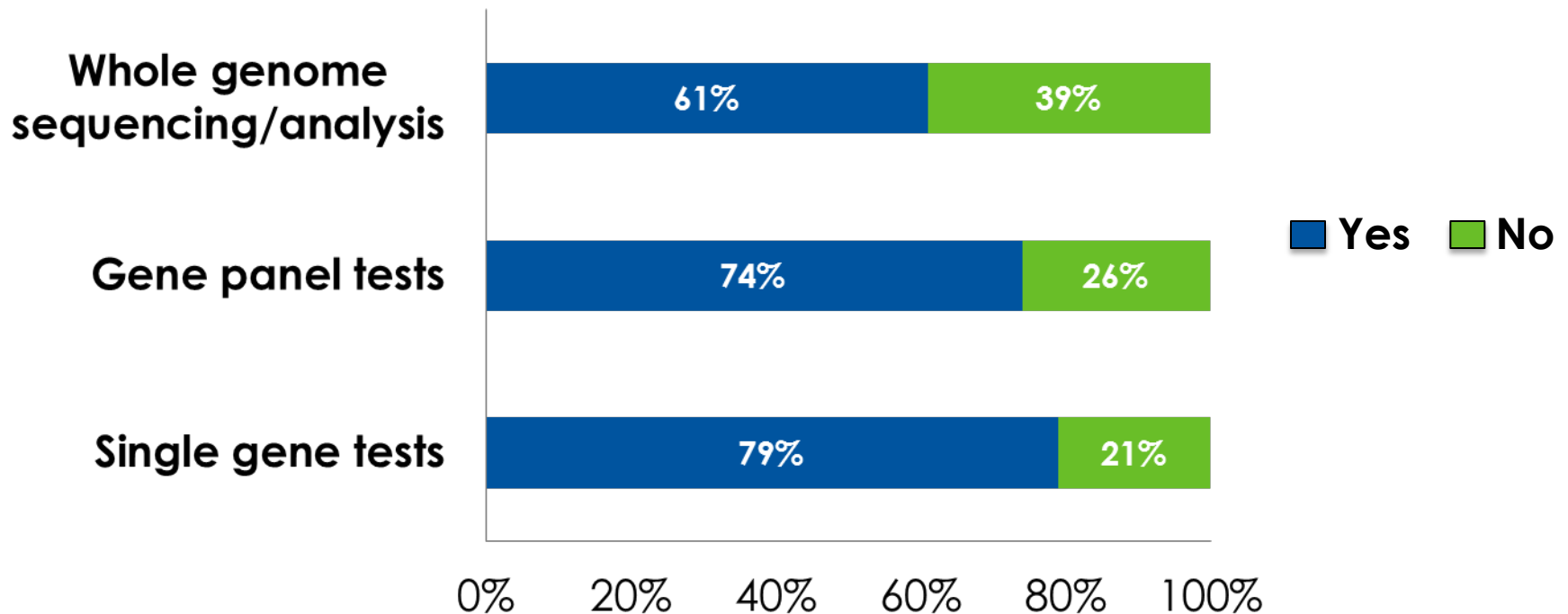
Pathologists' Genomics Needs Assessment

- >5 Yr Pathology Transformation Process (2008)
 - Changing pathologist demographics
 - Healthcare delivery reform
 - Personalized Healthcare / Genomic Medicine
- 2010 member survey of genomic knowledge

Pathologists Familiar with Molecular & Genomic Tests (CAP Member Survey, August 2010)

CAP Survey Question: Please indicate whether you are familiar with the technology (i.e., you can describe the technology to others including its potential use in medicine).

% of Respondents Familiar with Molecular Tests¹ (Total number of respondents = 1028)



¹Source: Case for Change Survey of members conducted by CAP, August 2010

Pathologists' Genomics Needs Assessment

- >5 Yr Pathology Transformation Process (2008)
- 2010 member survey of genomic knowledge
- Define Pathology Transformation Strategy (2009-2012)

CAP Pathologist Transformation Strategy

- Enable our members to control their professional economic destinies;
- Focus our support on pathology practices
- Help them create greater value, especially in **embedding new genomics** and informatics capabilities in their work, and
- Get paid for this
- In the context of coordinated care.

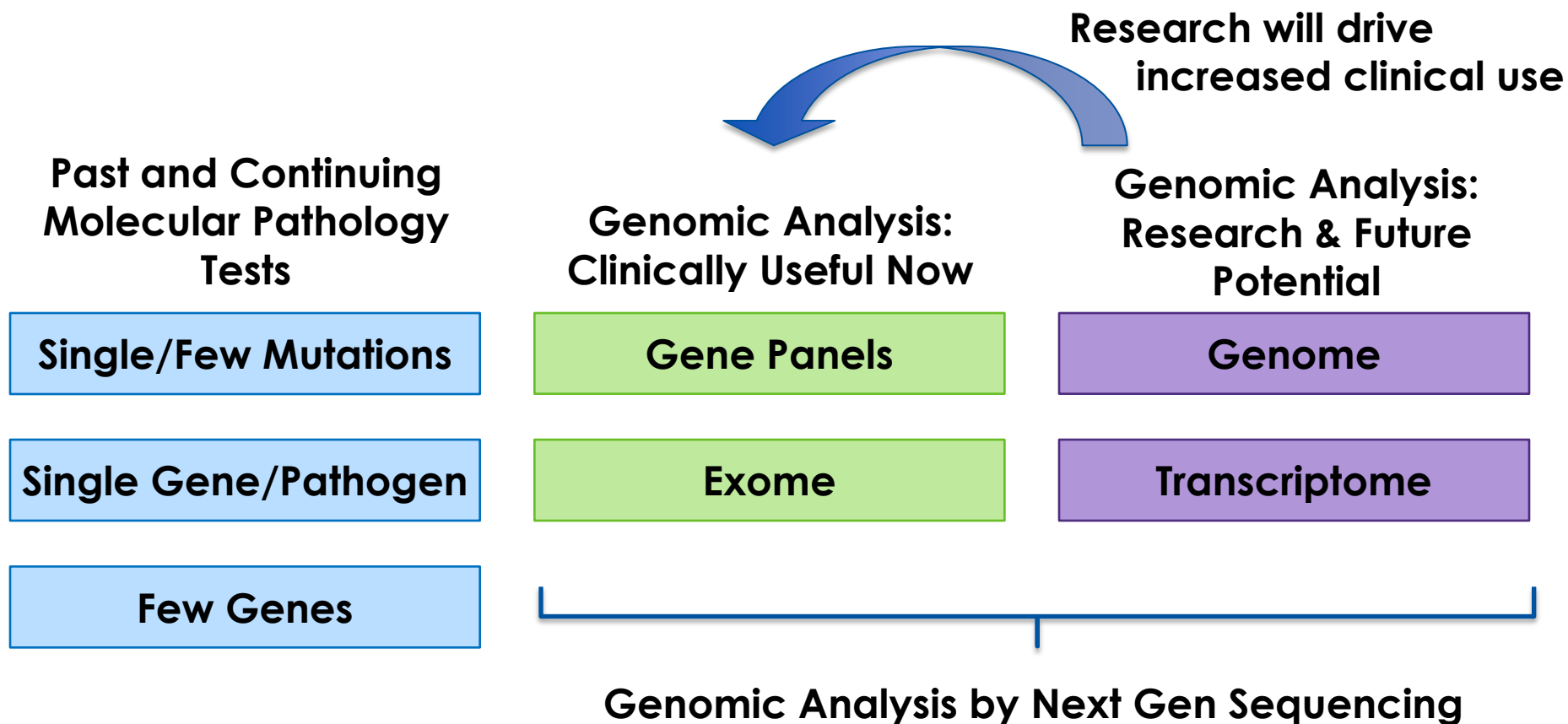
Pathologists' Genomics Needs Assessment

- >5 Yr Pathology Transformation Process (2008)
- 2010 member survey of genomic knowledge
- Define Pathology Transformation Strategy (2009-2012)
- Implement multi-year transformative initiatives (2013+)
 - Genomics strategic plan to support larger transformation

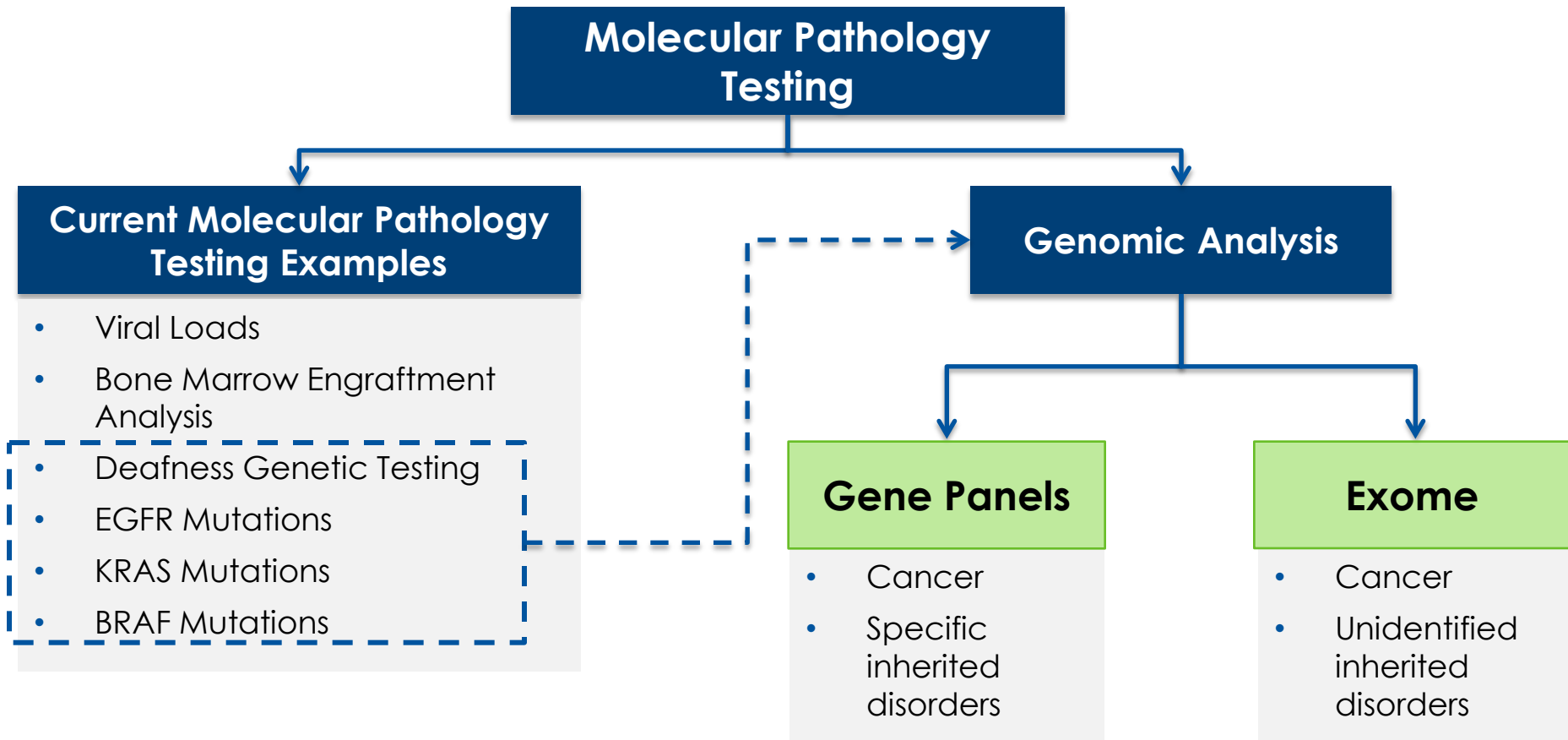
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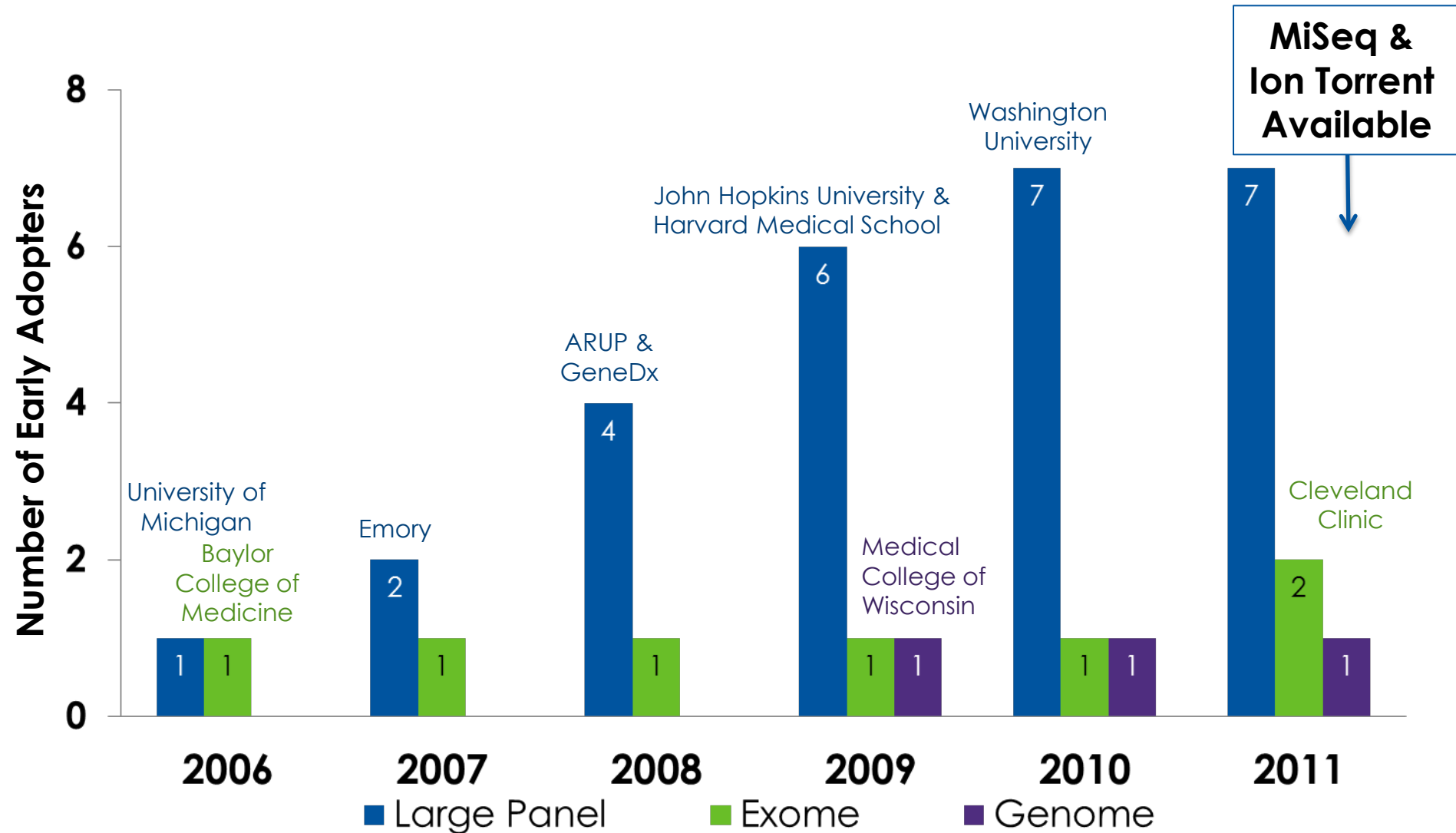
Genomic Analysis by Next Generation Sequencing Being Used in Molecular Pathology Practice Today



Some Molecular Pathology Tests Will Move to NGS While Others Will Remain on Current Platforms



Early Adopters of Clinical Genomic Testing



Note: In total, 10 responses were available for analysis; Year of adoption was not available for three universities (MD Anderson Cancer Center, Yale School of Medicine, and UCLA)

Advances in Sequencing Technology Driving Adoption of Genomic Testing in Molecular Pathology Laboratories

	1 st Genome	Research/ Clinical	Clinically Relevant Cost & TAT		
	ABI	HiSeq	MiSeq	Ion Torrent (Q1 2012)	Ion Proton (Q4 2012)
Sequencers	Hundreds	One	One	One	One
Instrument Price	\$ 250,000	\$ 750,000	\$ 125,000+	\$ 75,000	Unknown
Time	Years	Weeks	27 hours	8 hours	8 hours
Output	NA	~50 Gb	2 Gb	1 Gb	50 Gb
Genomic Analysis	Single Genes	Gene Panels, Exome, Genome	Gene Panels	Gene Panels	Gene Panels to Genome

TIME



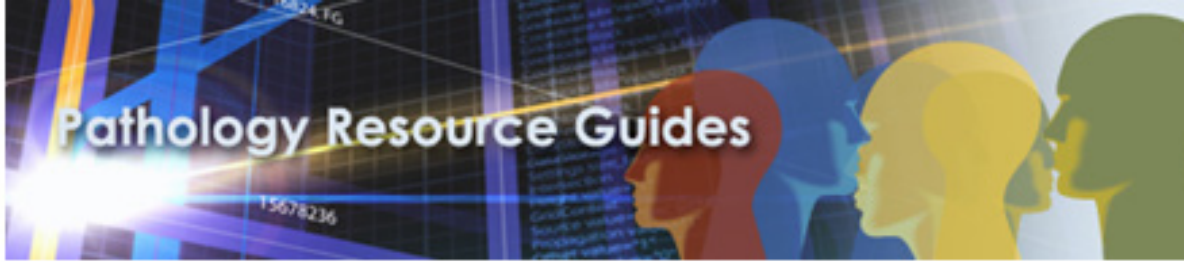
Clinical Genomic Testing possible today & rapidly being adopted

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Assuring the Quality of Genomic Tests

- **CAP's NGS Inspection Checklist Questions**
 - Sequence data generation (10 questions)
 - Bioinformatics analysis (8 questions)
 - Focus on validation & documentation
 - Applies to any instruments or tests
 - Released July 2012 with 2013 update planned
- **CAP's NGS Proficiency Testing Program**
 - Use characterized genome(s)
 - Each laboratory performs their specific test(s)
 - Assess both sequence data generation & bioinformatics



- **Resource Guides for:**
 - Genomic Analysis (gene panels, exome, genome)
 - Molecular Diagnosis
- **Genomic Analysis Resource Guide Table of Contents:**
 - Genomic Analysis: The Basics
 - Insights from Early Adopters
 - Genomic Analysis for Cancer
 - Genomic Analysis for Hereditary Diseases
 - Genomic Analysis for Infectious Diseases
 - Issues for the Practicing Pathologist
 - Standards & Accreditation
 - CAP Genomic Analysis Education Resources
 - Other Industry Resources and Conferences
 - New for 2013: Genomic Bioinformatics

CAP Molecular/Genomics Education

- 37 molecular/genomic courses at CAP'12

Selected 2012 CAP Meeting Sessions

- Next Generation Sequencing: Activities at CAP and Beyond
- Next Generation Sequencing for Inherited Disorders
- Advanced Testing in Colorectal Cancers: MSI, KRAS, BRAF and Beyond
- Molecular Testing Guidelines for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors
- Myeloid Neoplasms: Morphology to Molecular Genetics
- Molecular Classification of Multiple Myeloma using Genomic Profiling
- Molecular Hematopathology in the Era of Personalized Medicine
- Molecular Microbiology in the Community-Based Practice
- Direct to Consumer Genetic Testing: How Does It Affect Pathologists?

CAP Molecular/Genomics Education

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- CAP's Online Courses (16 CME/SAM courses)
 - Pharmacogenomics (3)
 - Molecular testing for specific types of cases

CAP Molecular/Genomics Education

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- Free Webinar Series: 3 Yrs Live & Archived
 - Genomic Testing: Panels, exome & genome
 - Molecular Pathology Testing: How To's
 - Organ-based Molecular Pathology

>4,500 CAP Members Attended ≥ 1 Webinar (2011)

Webinar Attendees: 5,022

CAP members: 4,069 (81.0%)

Archived Webinar Listeners: 1,481

CAP members: 1,106 (74.7%)

Total Audience: 6,503

CAP members: 5,175 (79.6%)

Upcoming Webinar Topics for 2013

- Molecular Microbiology in Community-Based Practice
- Pathologist's Role in Breast Cancer Diagnosis & Treatment
- Next Generation Sequencing (DNA Day 2013)
- NGS for Cancer: An Early Adopter Perspective
- Colon Cancer & Molecular Testing

Providing Tools to Practicing Pathologists: Short Presentations on Emerging Concepts (SPECs)

- Disease-specific PowerPoints on specific molecular testing with key role in patient management
- Key references
- CAP members can customize for local conference and health care leader presentations
- CAP tracks use & provides updated materials

SPECs Available at 2012 CAP Annual Meeting

- The Workup of Colorectal Cancer
- Colorectal Cancer: HNPCC & Lynch Syndrome
- Therapeutic Guidance for Metastatic Melanoma
- Diagnosis & Workup of Thyroid Cancer: *BRAF*
- Workup of Polycythemia & Thrombocytosis: *JAK2*

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CAP Pathology and Laboratory Quality Center

- Ensures quality in patient-centric diagnostic medicine through guideline development.
- Uses evidence to support development of practice guidelines and protocols.
- Employs a multidisciplinary approach with other organizations to ensure broad acceptance of guidelines.
- Facilitates the coordination of consensus activities in the absence of evidence-based practice guidelines.

The CAP Center Process



CAP Center Guidelines (selected)

Published: Guideline Recommendations

- ASCO/CAP: ER/PgR Testing in Breast Cancer
- ASCO/CAP: HER2 Testing in Breast Cancer

In Press (April 2013): Molecular Test Guidelines

- CAP/IASLC/AMP: Selection of Lung Cancer Patients for EGFR & ALK Tyrosine Kinase Inhibitors

In Development

- CAP/ASH Algorithm for Initial Work-up of Acute Leukemia
- ASCP/CAP/AMP/ASCO Molecular Markers for the Evaluation of Colorectal Cancer

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Pathology Training & Certification Requirements

- Residency Training Programs have 1-3 months molecular pathology training \pm genomics
- ABP Boards include molecular knowledge:
 - 7-9% of AP exam
 - 10-15% of CP exam
- Subspecialty Board Certification in Molecular Genetic Pathology jointly by ABP and ABMG
- CAP & Association of Pathology Chairs (APC) agreement to work together on Pathology Residency Training issues, including genomics

Training (Pathology) Residents in Genomics (TRIG)

- Intersociety initiative led by Dr. Richard Haspel (BID)
- NCI R25: A National Curriculum in Cancer Genomics for Pathology Residents (2012-2017)
 - Aim 1: Develop a pathology resident genomic medicine curriculum, with a major focus on cancer care, & tools for national implementation.
 - Aim 2: Evaluate the curriculum using a pre/post-test design at five pathology residency programs using validated assessment tools.
 - Aim 3: Promote curriculum implementation using the resources of major national pathology organizations so that by 2017, >90% of pathology residency programs nationwide have training in cancer genomics

Thank You for This Opportunity

Any Questions??

