Implementing Genomic Testing
LabCorp's Experience

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Hawazin Faruki, DrPH
Vice President, Clinical Development
Center for Molecular Biology & Pathology
Laboratory Corporation of America

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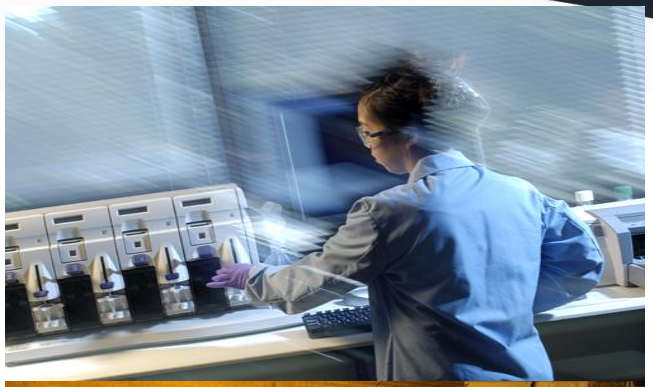
- 30,000 employees
- 220,000 customers
- 370,000 samples/day
- 1,500 patient centers
- 4,000 diagnostic tests
- >1M results per day

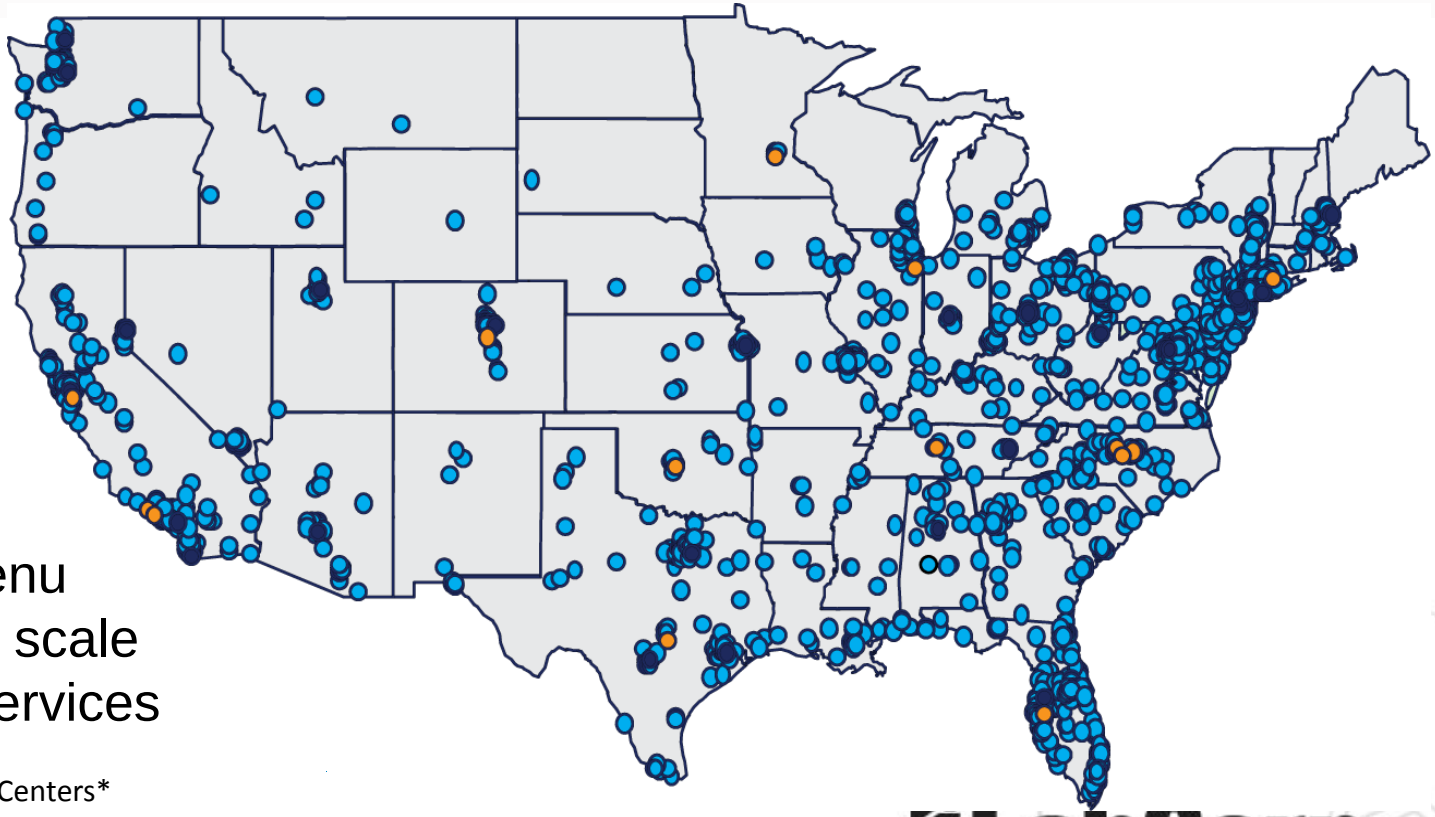
A leading provider of innovative, high quality diagnostic laboratory services that bring value to our customers and improve the delivery of patient care.

LabCorp US Operations

- >750 MD's/PhD's
- >150 Genetic Counselors
- 10 Centers of Excellence
- 38 Primary Testing locations
- > 270 STAT testing facilities
- >1,500 Patient Service Centers
- >8,000 phlebotomists
- >3,000 couriers



National Infrastructure



- Broad test menu
- Economies of scale
- Specialized services

- Patient Service Centers*
- Primary LabCorp Testing Locations*
- Centers of Excellence
  (CET, CMBP, Dianon, Esoterix, Monogram Biosciences, NGI, OTS, US Labs, Viromed, Integrated Genetics & Oncology)

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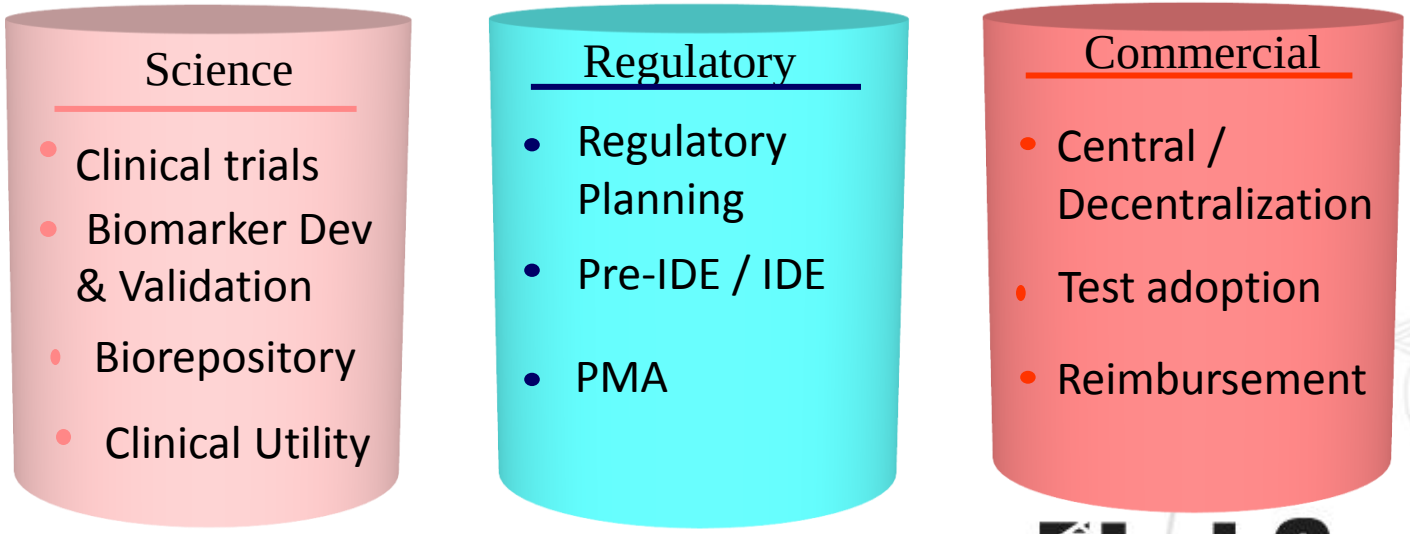
Global Clinical Trial Capabilities

- Global testing capabilities
- Strength in Europe, US and China
- First CAP-accredited clinical trial central lab in China (15+ years experience)

LabCorp's Companion Diagnostics Program

Development of a diagnostic test intended to select or monitor a new therapeutic



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Scientific Leadership in Diagnostics

- Review >400 opportunities/yr
- Introduce >130 new tests/yr
- Collaborations with pharma, biotech, and academic centers
- Genomic, proteomic, metabolomic, expression analysis, cell sorting

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New Diagnostic Opportunities

- Licensing opportunities
  - Academic institutions & Biotech companies
- Clinical trials/companion diagnostics
- Emerging clinical diagnostic applications
  - Scientific literature, meeting presentations, peers
- Acquisitions/Mergers
- Monitor send-out requests

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Evaluation of Diagnostic Opportunities
Scientific & Clinical Evaluation

- Analytical validity & clinical utility
  - Sensitivity, specificity, PPV/NPV
  - Improved outcomes, decreased costs, therapy guidance, toxicity avoidance
- Actionable result
- Reproducible study conclusions
- Evidence – publications, guidelines, professional society and DHHS/CMS endorsements

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Evaluation of Diagnostic Opportunities
Financial and Other Considerations

- Reimbursement outlook
- IP & Freedom to operate
- Cost to bring to market and return on investment
- Assay feasibility given our platform
- Regulatory landscape
- Market dynamics and competition

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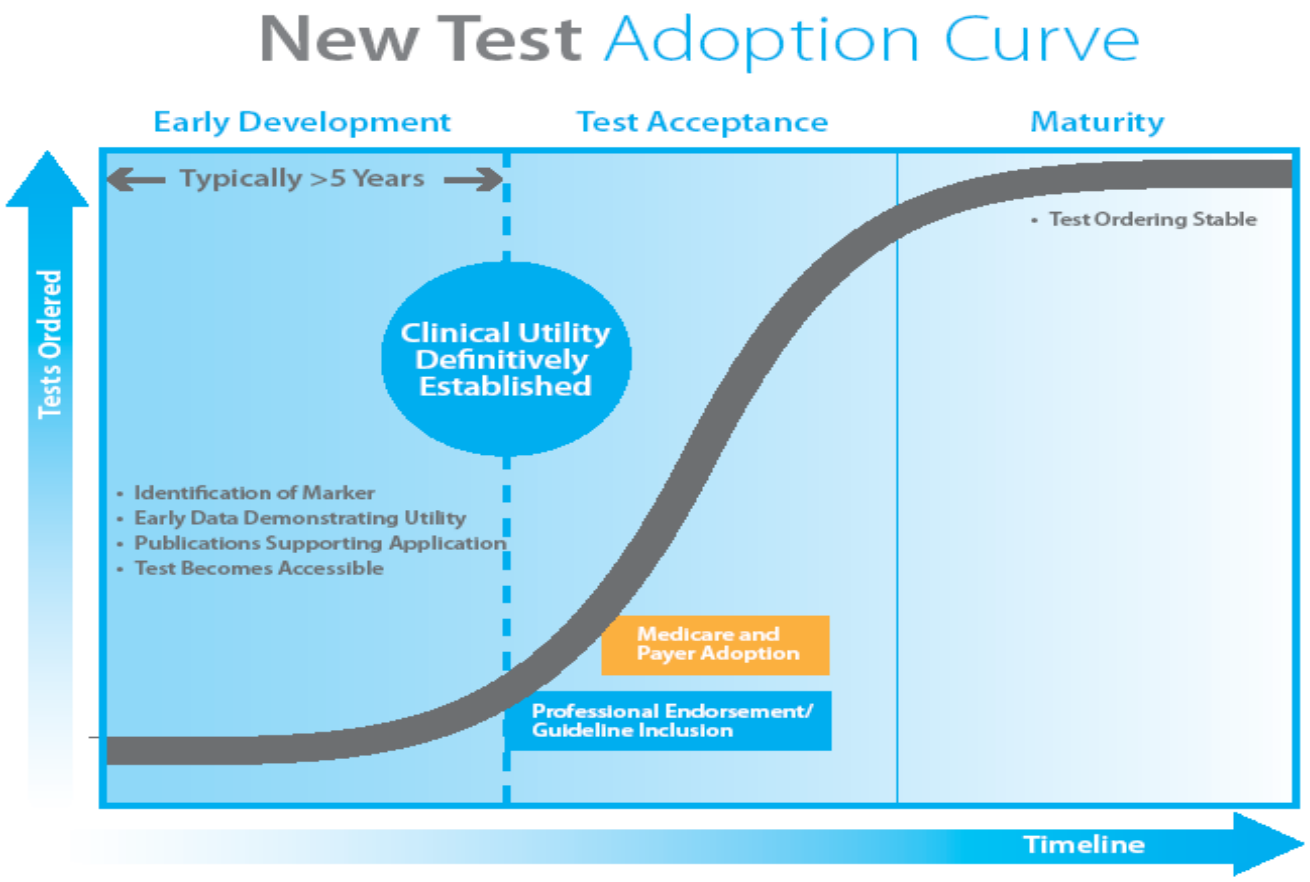
Modeling New Test Adoption



Faruki H. Genetics in Medicine Dec.2008.

Many Historic Examples in Molecular Diagnostic Test Adoption

- HIV Resistance testing adoption after DHHS guidelines in 2001
- HPV testing following ALTS study and updated guidelines in 2001-2002.
- HCV genotyping inclusion in treatment guidelines in 2001-2002 following INF/ribivirin trials
- Cystic Fibrosis carrier screening following ACOG/ACMG guidelines publication in 2001

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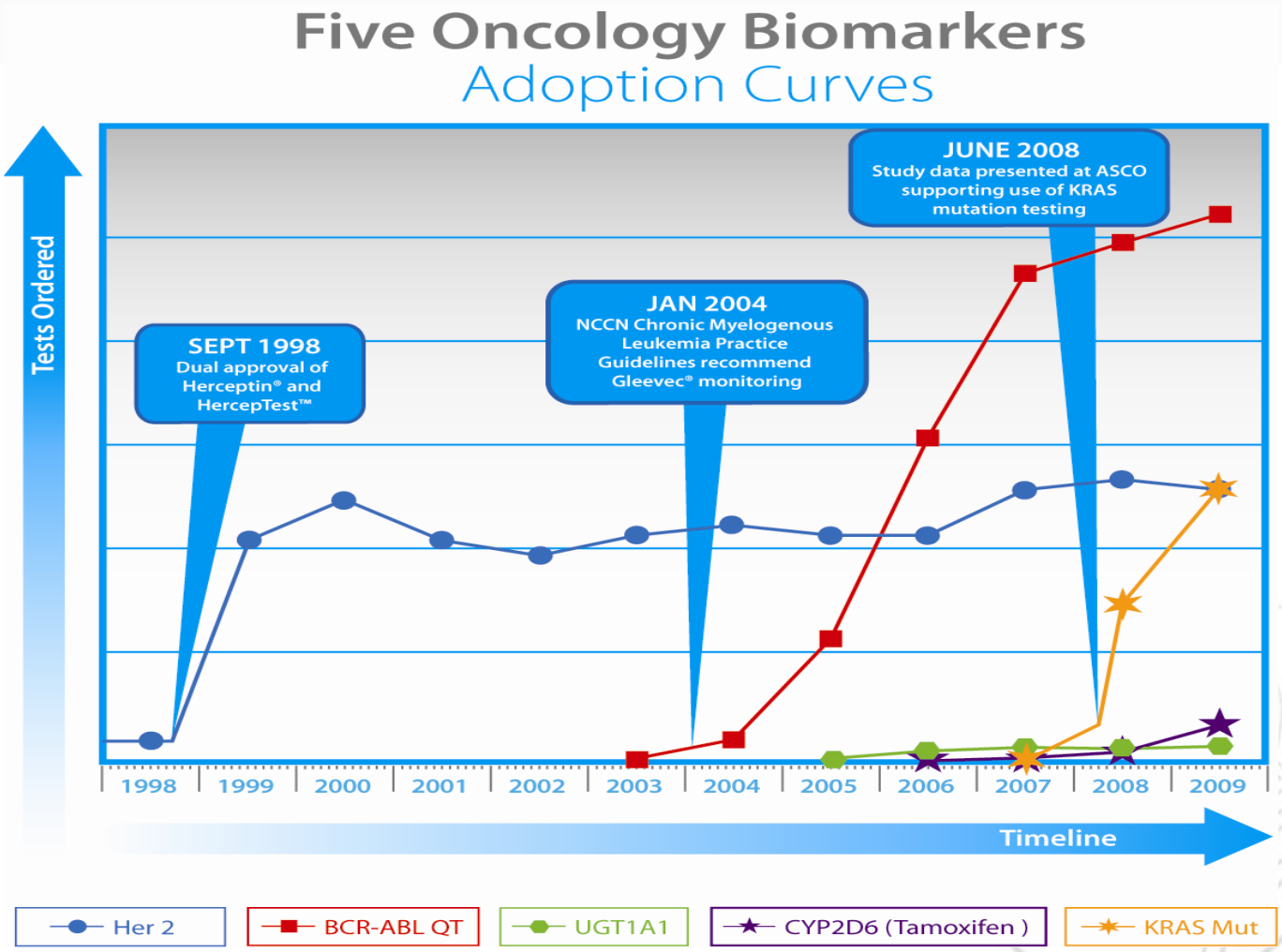
Test Adoption of Various Oncology Pharmacogenomic Markers



Faruki & Lai-Goldman.
Personalized Medicine 2010

Tests Where Adoption Has Not Yet Occurred

- Warfarin drug labeling (2007) and FDA cleared test kits (2008)
  - Clinical utility in question - Couma-Gen study
- UGTA1A FDA cleared test in 2006
  - Questions of utility depending on irinotecan dose
  - Variable performance in different racial and ethnic groups
- Cytochrome P450 2D6 amplichip FDA cleared in 2005
  - clinical utility not clearly established
  - SSRI drug application not validated (EGAPP)
  - Tamoxifen and CYP2D6 (clinical application emerging)

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Clinical Utility Impact

- Clinical utility not well established
  - Non-actionable result
  - Conflicting studies of clinical utility
  - Limited availability of well annotated samples

- Lack of endorsement
- Coverage & reimbursement denials
- Low utilization

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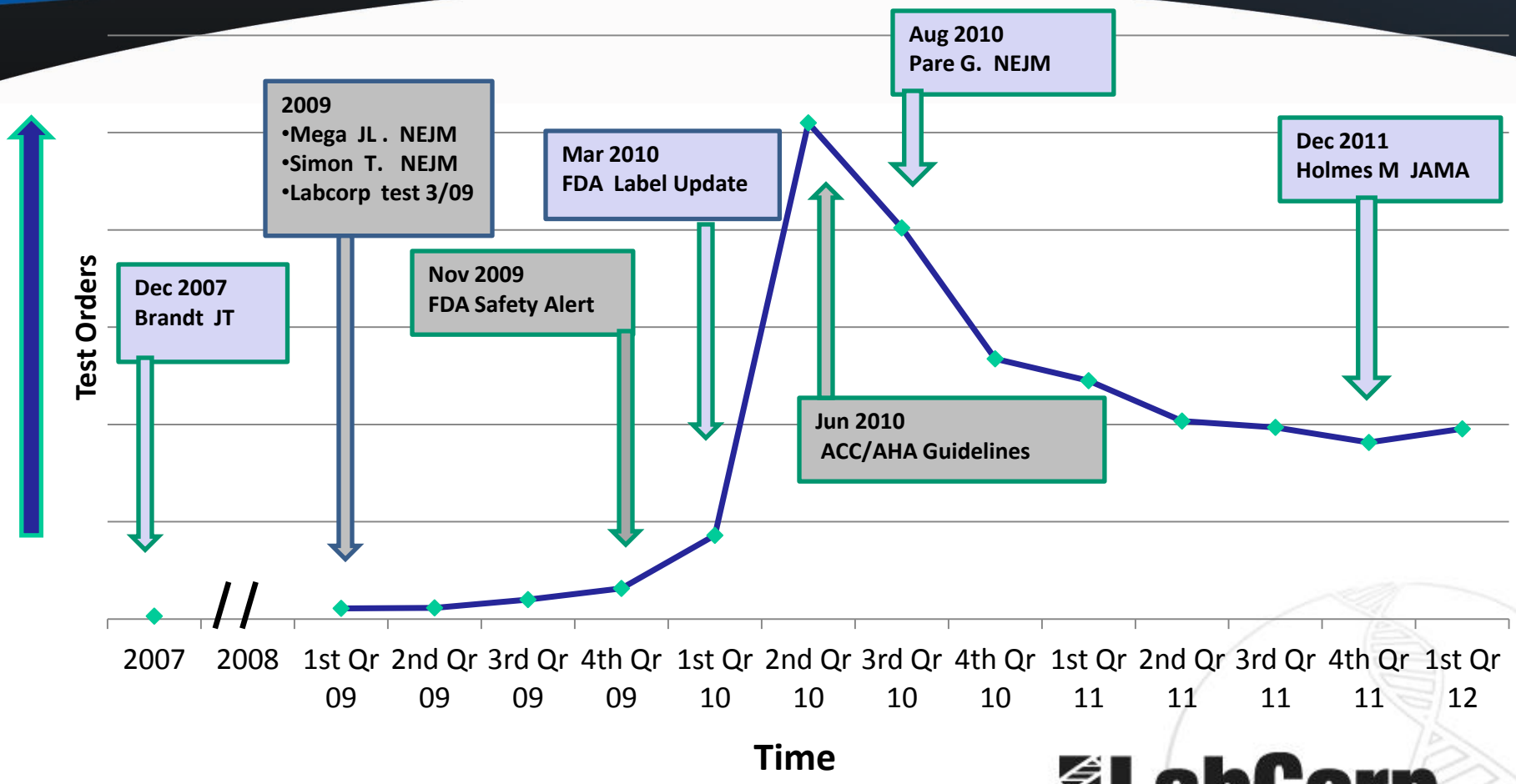
Clopidogrel CYP2C19 Orders



FDA clearance - Roche Amplichip in 2005
Autogenomics assay in 2010

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Payment Policies and Reimbursement

- Payer Adoption & Reimbursement
  - Scientific validity and clinical utility established
  - Practice Guidelines support
  - CMS, State, and Private Payer endorsement
  - Existing molecular CPT code stacking
- New coding in 2013

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Reimbursement Limitations

- New tiered CPT coding system (2013)
  - Greater transparency
- Most common assays assigned specific Tier 1 code
- Tier 2 complexity based codes – will payers deny Tier2 codes?
- New CPT code historically a multi year process
- Fee setting is separate from CPT coding
- Licensing and royalty burden

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Other Factors the Impact Market Adoption of Tests

- Specimen requirements (analyte stability, specimen transport, collection device)
- Access limitations
  - Global market – single lab access
- Physician related modulating factors
  - Economic conflicts
  - Physician specialty group involved
  - Physician education & practice change

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Conclusions

- Well controlled and adequately powered studies demonstrating analytical validity & clinical utility
- Clear actionable result
  - Prevent drug toxicity
  - Identify treatment path/ select for drug efficacy
  - Diagnose rare heritable disorders – carrier testing
- Path to fair reimbursement
- Freedom to operate

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