Implementing Genomic Testing
LabCorp’s Experience

NHGRI Genomic Medicine III
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Laboratory Corporation of America
Laboratory Corporation of America

- 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)
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

Science
- Clinical trials
- Biomarker Dev & Validation
- Biorepository
- Clinical Utility

Regulatory
- Regulatory Planning
- Pre-IDE / IDE
- PMA

Commercial
- Central / Decentralization
- Test adoption
- Reimbursement
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
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
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
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
Modeling New Test Adoption

New Test Adoption Curve

Early Development
- Typically >5 Years
- Identification of Marker
- Early Data Demonstrating Utility
- Publications Supporting Application
- Test Becomes Accessible

Test Acceptance

Maturity
- Test Ordering Stable

Clinical Utility Definitively Established

Medicare and Payer Adoption

Professional Endorsement/Guideline Inclusion

Timeline

Tests Ordered

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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
Test Adoption of Various Oncology Pharmacogenomic Markers

Five Oncology Biomarkers
Adoption Curves

- **SEPT 1998**: Dual approval of Herceptin® and HercepTest™
- **JAN 2004**: NCCN Chronic Myelogenous Leukemia Practice Guidelines recommend Gleevec® monitoring
- **JUNE 2008**: Study data presented at ASCO supporting use of KRAS mutation testing

- **Her 2**
- **BCR-ABL QT**
- **UGT1A1**
- **CYP2D6 (Tamoxifen)**
- **KRAS Mut**

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)
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
Clopidogrel CYP2C19 Orders

FDA clearance - Roche Amplichip in 2005
Autogenomics assay in 2010
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
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
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
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