

From Resilience To Growth:

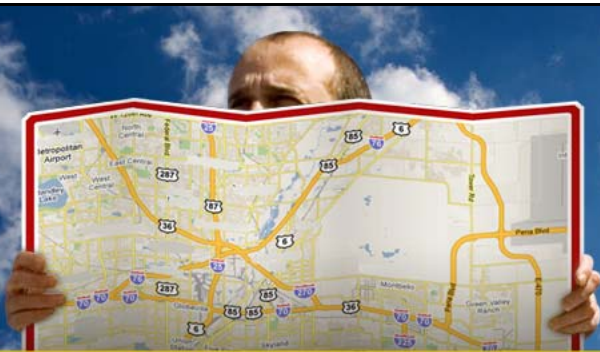
Mapping a New Direction for Life Sciences & Medical Devices



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Mapping the Way: Opportunities in Diagnostics



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Panelists:

- Ronald Eppen, Partner, *Foley & Lardner*
- Lucy Lu, Vice President of Business Development, *Crescendo Bioscience*
- Natasha Paul, Ph.D., Scientific Investigator, *TriLink Biotechnologies*
- Jon Vance, Director, *Avondale Partners*

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IN VITRO DIAGNOSTICS MARKET AND TRENDS

November 3, 2010

Foley Life Sciences and Medical Device Conference

Lucy Lu

Crescendo Bioscience Inc.



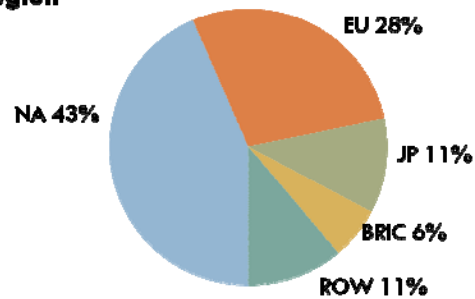
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In Vitro Dx Industry at a Glance

- Include laboratory/ hospital-based products, POC and OTC
- The world IVD market was \$44.4 billion in 2009 and is expected to grow at 6% CAGR to \$58.6 billion by 2014

Sales By Region



Source: Kalorama Information, 2010 The world wide market for in vitro diagnostics

Dx and Healthcare Costs

“The public needs to understand the 3%, 80% rule. Meaning the overall cost of healthcare is 3% in terms of the laboratory and the testing...yet it affects nearly 80% of all clinical decisions being made. “

Dr. Bill Frist, Former Senate Majority Leader, 2010 AACC

IVD Products WW Sales and Growth

Product Category	2009 Sales(\$B)	CAGR
Immunoassay	9.86	5%
Clinical Chemistry	6.41	2%
Hematology	2.36	2%
Coagulation	1.06	4%
Microbiology (ID/AST)	2.96	5%
Diabetes Care (BGM)	7.14	6%
Blood Bank Screening	2.55	3%
Nucleic Acid Testing (Molecular Dx)	3.12	15%
Point of Care Testing	5.92	6%
Anatomical Pathology/Cytology/FC	3.45	7%

Source: Kalorama Information, 2010 The world wide market for in vitro diagnostics

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IVD Companies and Varying Business Models

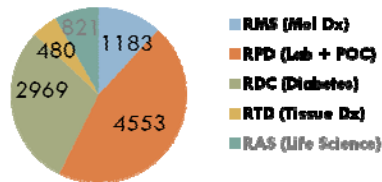
Broad Menu IVD	2009 IVD Rev./ Total Rev (\$M)	Specialty IVD	2009 IVD Rev./ Total Rev (\$M)
Roche Diagnostics	\$9,235/\$10,055	Gen-Probe	\$498
Abbott Diagnostics	\$4,981	Cepheid	\$116
Siemens Medical	\$4,766	Quidel	\$164
J&J-Ortho -Lifescan	\$4,403	Genomic Health	\$149
Beckman Coulter	\$2,789	Sequenom	\$38
Becton Dickinson	\$2,226/\$7,261	Prometheus	\$85/\$341
		Genoptix	\$184
bioMérieux	\$1,416	Qiagen	\$475/\$1,009
Bio-Rad	\$1,150/\$1,780	Illumina	small/\$662
		Life Technologies	\$30+/\$3,300
Alere	\$1,537	Luminex	\$33/\$120

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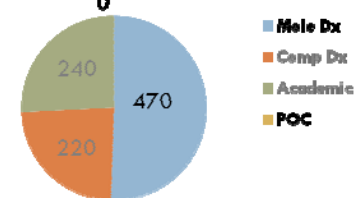
Examples of IVD Business Models

Roche Dx (\$10,055M)



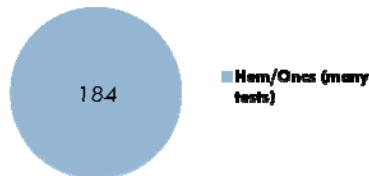
Broad IVD products to labs and clinics

Qiagen (\$1,009M)



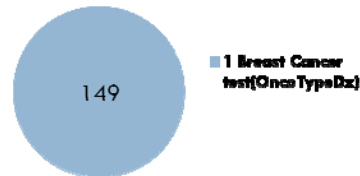
IVD products leverage its research tools

Genoptix Med Lab (\$184M)



Complex test services with results interpretation

Genomic Health (\$149M)



Lab services with unique product

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Evolving IVD Player Landscape

- Traditional IVD players actively acquiring to broaden offering (**Roche**/Ventana, **BD**/Handylab/GeneOhm/TriPath, **BC**/Olympus)
- Specialty Labs focus on just a few disease areas with novel LDTs or better services (Genoptix, Prometheus, Genomic Health, Crescendo...)
- Life science tools companies move into IVD (**Qiagen**/Digene/DxS/ESE, **Life Technologies**, Illumina, Luminex, Agilent, Millipore)
- Reference Labs moving toward novel LDTs/esoteric testing (**LabCorp**/Monogram/Genzyme Genetics, Quest)
- PBM offering personalized medicine tests for customers (Medco)
- OTC/homecare consolidation (**Alere**/Hemosense/Biosite/Cholestech...)
- DTC (Navigenics, Pathway Genomics, 23&Me)
- In vivo players expanding into IVD (**Siemens**/Bayer/DPC/DB, **GE**/Abbott/Clariant, **Philips**/Raytel, **Hologic**/Third Wave/Cytec)
- Large players leverage across industry (Sony, Samsung)

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Key Risks in Commercializing Novel IVD Tests

- **Product risk** - technical challenges, complex biology, pipeline
- **Market risk**
 - Branding and positioning
 - Product design and pricing strategy
 - Adoption and penetration
- **Clinical risk** - clinical validation and outcomes improvement
- **Regulatory risk** - FDA revising LDT and 510(k) rules
 - **Operational risk** - scale the business beyond early adopters
 - **Reimbursement levels** from governmental payors and private insurers

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IVD Start-Up Investment Trends

- **Unmet medical needs:** driven by aging, obesity, public health and healthcare cost reduction pressure: cancers, neurological disorders, diabetes, cardiovascular diseases, infectious diseases
- **Test utility:** from Dx to predictive, preventive, personalized and participatory
- **Reduce technical risk:** off-the-shelf solution or open system with innovative contents
- **Business model:** CLIA services with LDTs vs. FDA approved IVD kits/platforms
- **Clinical adoption:** emphasis on decision impact & not take away decision power from MDs
- **Pricing:** Health economics data to sustain value-based pricing
- **Reimbursement:** favor CPT code stacking than misc. code

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Attractiveness Check List

Broad funding sources from non-dilutive grants, angels, foundations, universities, corporate VCs, to VCs and they are more willing to syndicate

- Revenues: \$B market with \$300M rev. potential
- Innovative business model
- Speed to market: 2-3 yrs to market; favor LDT over FDA
- IP protection: less essential for candidate gene approach
- Efficient use of capitals to get to market and build a pipeline
- Exit options: 3-10X

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West Coast Advantages

- “Because that’s where the money is.”
- Unparalleled entrepreneurial environment
 - Premier academic and research institutions
 - Broad pool of seasoned executives and serial entrepreneurs to act as mentors and advisors
- Favorable start-up environment:
 - Knowledgeable angels, experienced VCs
 - International managerial and scientific talent pool
 - Infrastructure to support growth phase of commercialization
 - Focal point for industry collaborations and partnerships



Willie
Sutton

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