Sense and Simplicity in In Vitro Diagnostics

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Diagnostics

• In Vitro Diagnostics is Changing Healthcare
  • Philips in In Vitro Diagnostics: Sense and Simplicity
  • Programs in Innovation & Emerging Businesses
  • Build and Partner Approach
Next generation diagnostics: a range of tests

**Genes (DNA, RNA)**
- Genome (DNA)
- Transcriptome (RNA)

**Proteins, Metabolites**
- Proteome
- Metabolome Physiome

**Cell, tissue, …**
- Live Cell/Tissue/System/Organism

**Molecular Diagnostics (MDx)**
- Genetic predisposition
- Pathogen detection
- DNA modifications (SNP)

**Protein Testing (IA)**
- Immune system
- Oncology, Cardiac diseases
- Metabolic disorders

**Cell and Tissue Testing**
- Digital pathology
- Full blood cell counting
- Cell analysis
Next-generation tests will affect the full Care Cycle

- Early and rapid diagnosis
  Identifying the molecular basis of disease

- Screening for early detection of people at risk

- Patient stratification for treatment selection (companion diagnostics)

- Therapy monitoring

- Management of chronic disease

- Monitoring for relapse

- Predisposition Testing, Influencing Lifestyle
Changing Healthcare: Infectious Diseases

**ER**
Screening for pathogens (MRSA)

**ICU**
Pathogen identification
Monitoring immune system response

**Physician Office**
Determine cause of common infections
Select appropriate treatment

**Home**
Common cold or Influenza?
Changing Healthcare: Cardiovascular Diseases

**ER**
Cardiac markers for heart attack
Differential stroke diagnosis

**ICU**
Select drug therapy based on genetic profile
Monitor therapy response

**Physician Office**
Early detection of vulnerable plaque
Genetic risk assessment for stroke or heart attack

**Home**
Monitor disease progression for heart failure patients
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Decentralized rapid diagnostic testing

Benefits
- Short time to result -> rapid therapy decisions
- Compact & simple to use -> 24/7 availability
- Personalized therapy selection -> reduced cost, improved outcomes
External perspective

“Physician office, clinic and hospital near patient testing are among the fastest growing segments as tests that were done in the central lab are now available as near patient tests.”

“The time is ripe for more user friendly digital OTC devices that leave nothing to interpretation. On the horizon are OTC test devices that say yes or no or provide a numeric read out instead of a series of lines or dots. The public is ready.”

Sources: Kalorama IVD 2006 5th ed., FIND/SVP home market survey, 2004
Decentralized rapid diagnostic testing

Embedding in enterprise wide healthcare informatics, added value from decision support systems
Addressing the most attractive segments of the $32B In Vitro Diagnostics market

100% = $32.2B

- Other: 12%
- Microbiology: 5%
- Hematology: 5%
- Immunoassay: 18%
- Clinical Chemistry: 16%
- POC – Diabetes self-testing: 20%
- POC Consumer (excl. diabetes): 28%
- POC – Professional: 13%
- Flow Cytometry: 2%
- MDx: 7%

Projected CAGR ‘05-’10

- Other: 6%
- Microbiology: 5%
- Hematology: 1%
- Immunoassay: 7%
- Clinical Chemistry: 2%
- POC – Diabetes self-testing: 9%
- POC Consumer (excl. diabetes): 5%
- POC – Professional: 7%
- Flow Cytometry: 16%
- MDx: 15%

Source: Kalorama 04/06, SDG analysis, analyst reports; Other includes radioimmunoassay, coagulation, histology/cytology, blood screening

“Traditional” (central and reference lab) IVD: 44% of the market, growing at 4%

Potential for decentralized RDT: 24% of the total IVD market, growing at 10% in aggregate
Philips is a world leader in near-patient settings

**Patient Monitoring – 37% global market share**

- Cardiac/Critical Care
- Obstetrics/ Neonatal Intensive Care
- Anesthesia Care
- Emergency and Sub Acute Care

**Consumer Healthcare Solutions**

- Philips Lifeline, Health watch: Independent living
- PTS: Post-discharge telemonitoring
- Motiva: Care of chronically ill
Decentralized rapid diagnostic testing
Excellent fit with Philips’ broader healthcare strategy and attractive business opportunity

- Combining patient monitoring with bio-chemical and vital sign monitoring in acute care settings (pre-hospital and hospital)
- Take advantage of access to GP/Obstetrician for Women’s Health applications

- Data integration and decision support for networked near-patient DNA and protein testing

- Rapid alerts and diagnostic tests for chronic disease management with Connected Care Solutions

- Significant strengths in platform and miniaturization technologies for DNA, protein, and cell based tests in research/incubation
Success factors

- **Platform.** Ownership and control of a clinical platform with a roadmap for moving from the lab towards the patient and potentially the home.
- **Menu.** Access to the rapidly developing content leading to new assays and tests.
- **Channel.** Ability to sell and support products into the market.
- **Regulatory & reimbursement.** Clear understanding of the new FDA guidelines and policies for reimbursement.
- **Clinical IT.** Translation of raw data into clinically relevant recommendations linking together broad data sets.

Note: platform means instrument, disposable, core IP, and assay development including key reagents.
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High Tech Campus Eindhoven
Adding life sciences to physics and engineering

- Chemical Synthesis Labs
- Molecular and Cell Biology Labs
- Bacteriology Labs
- Molecular Imaging Labs
- Radiochemistry Labs
- Microsystems Fab
DNA Amplification and Detection Platform

- Based on flow-through array
- For pathogen detection e.g. bacteria
Miniaturized Protein (or DNA) detection platform

- Reader based on DVD optics
- Disposable cartridge with on-board reagents
- 1 step assay

Fluorescence (AU) vs Time (s)

10 nM CRP

Philips Research
Technology platform for ultimate miniaturization

Lab-on-glass

- Low-cost integration of electronics on glass/plastic
- Integration of detection, thermal cycling, fluidics
- For protein, DNA/RNA and cell analysis
New Business Creation: Drugs-of-abuse testing

- Venture in the healthcare incubator
  - Partnership with Cozart

- Based on Philips’ magnetic biosensor technology

- Drugs of Abuse testing
  - 100-500 M$ market in 2013

- Healthcare opportunities
  - Hospital/ambulance testing
  - Therapeutic drug monitoring

Current performance:
Detection of Morphine in saliva assay in less than 5 minutes
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### Success factors – why we need to partner

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**We have:**
- Significant expertise and IP in platform instrumentation
- Clinical IT
- State of the art research facilities
- Programs on next generation IVD
- Channels to decentralized settings

**We need a partner for:**
- IVD regulatory and reimbursement competencies
- Deep know-how on sample preparation, bio content, and assay development
- Complementary channel access

**Active discussions with best-in-class candidate partners are ongoing**

Our business strengths and technical achievements make us an attractive partner.
Philips in In Vitro Diagnostics: 
Sense and Simplicity

• **Easy to operate solutions for decentralized rapid diagnostic testing**
  – Throughout the care cycle

• **Create shareholder value through focus on most attractive segments, and prudent use of our capital**
  – High value MDx and proteomic tests
  – Added value through connectivity and clinical IT

• **Leverage our expertise with best in class partners**
  – Build new competencies and create ventures
  – Partner with complementary players