Evolution or Revolution?

The Present and Future of Lateral Flow

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$10 Cellphones Bring Health Care to Developing World

How Mobile Phones Are Saving Lives in the Developing World
Sensing Technologies, Portable Dx and MDx
Regulation is having trouble keeping up
New Business Models Are Threatening
Lots of effort and cash going into Revolution
The Elective Set includes:
1. Pertussis (Whooping Cough)
2. Hypertension
3. Mononucleosis
4. Allergens (airborne)
5. Hypothyroidism/hyperthyroidism
6. Food-borne illness
7. Shingles
8. Melanoma
9. Strep throat
10. Cholesterol Screen
11. HIV Screen
12. Osteoporosis

The Core Set includes:
1. Anemia
2. Urinary tract infection, lower
3. Diabetes, type 2
4. Atrial fibrillation
5. Stroke
6. Sleep apnea, obstructive
7. Tuberculosis
8. Chronic obstructive pulmonary disease (COPD)
9. Pneumonia
10. Otitis ("ear infection")
11. Leukocytosis
12. Hepatitis A
13. Absence of conditions

The Vital Signs Set includes:
1. Blood pressure
2. Electrocardiography (heart rate/variability)
3. Body temperature
4. Respiratory rate
5. Oxygen Saturation
X-Prize Finalists
It’s the sensor!

But something is missing.........
The Lateral Flow Test Strip is the most broadly applicable, mature, manufacturable immunosensor available today

But the threat level is high
Strengths

- Functional, proven technology
- Strong growth in traditional markets
- New applications continue to appear - new market segments continue to open up
- Supply chain established
- Existing dominant market share in rapid sample to answer testing
- Strong manufacturing capability
- Market acceptance
- Regulatory acceptance
- Absence of coherent platform competition

Predicted Percent of Market by Application
Total Market 2015*: USD $4.2 billion, predicted ongoing CAGR 7-9% average

*Source: Stratcom, Montreal
Weaknesses

- History
- Poor market perception
- Not "sexy"
- Rarely designed for use
- Performance issues: Variability, sensitivity, quantification, speed
- Cost for some applications
- Multiplexing
- Fragmented approach to reading technology implementation - no industry standards
- Not easily amenable to electrochemical detection methods - integration to electronics based readers difficult
Opportunities

- Demand for new applications in medical diagnostics - biomarker based
- Strong opportunity for growth in non medical market segments
- Consumer demand
- Emerging infectious disease applications
- Point of care molecular applications
- Cross-over technology opportunities
- Entrance of new players
Threats

- Emergence of new immunoDx technology
- Emergence of POC molecular Dx
- Entrance of new players, with branding and manufacturing capabilities from other industries
- New business models
- Regulatory changes
- Crowded I.P. space
Changing Perceptions

Accuracy

Decentralization

Point of Care/Field Use

Lateral Flow

PCR

ELISA

Microscopy

Adapted from LaBarre, P. Instrument free diagnostics for low resource environments
What do we think about when we think Lateral Flow?

Simple!

- Sample addition
- Conjugate solubilization
- Capillary flow; antibody binding
- Membrane clearing; optical reading
## What we think we know

### Positive Aspects of the Technology

- **Easy to use. Minimal operator dependent steps and interpretation**
- **Can handle multiple sample types and run in a single step using small volumes**
- **Can have adequate performance for many applications; sensitivity, specificity, reproducibility**
- **Good manufacturability and Scalability**
- **Minimal market and user education required**
- **Market and regulatory acceptance good**
- **Relatively low cost and short timelines for development and approval – quick and cost effective to get to market**
What we think we know: Room for Improvement

- Performance issues; Reproducibility and sensitivity
- Poor user experience – products often not designed with user in mind
- Perception
- Cost for some applications
- Multiplexing is difficult in standard formats
- Quantification is difficult in standard formats
But lateral flow is unusual for such an established technology 30 years old, and it’s still not fully mature.