Point-of-Care Diagnostic Lateral Flow Tests: Why are they successful and what can we learn?

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Microfluidics 2.0 Workshop

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PATH
A catalyst for global health

The Ideal POC Test

Affordable

Sensitive

Specific

User-friendly

Rapid and robust

Equipment-free

Deliverable to end-users

Pregnancy Test Evolution

- Berlin Papyrus – 1350 BCE
- One of the earliest written references for a urine pregnancy test.
- Barley and Wheat
- Approximately 70% sensitive

Pregnancy Test Evolution

Middle age urine tests

- Visual inspection

  clear pale lemon color leaning toward off-white, having a cloud on its surface

- Precipitation

  mixing urine and alcohol

Pregnancy Test Evolution

Early 1900's Exploitation of Human Reproduction Research

- Bioassay A-Z Test

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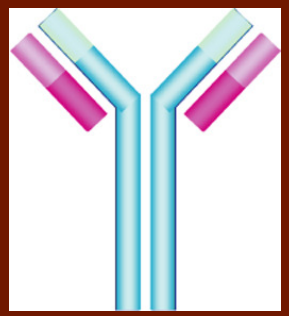
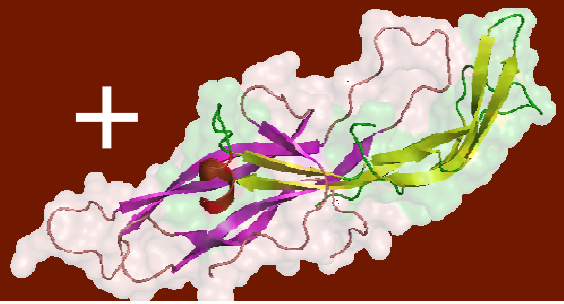
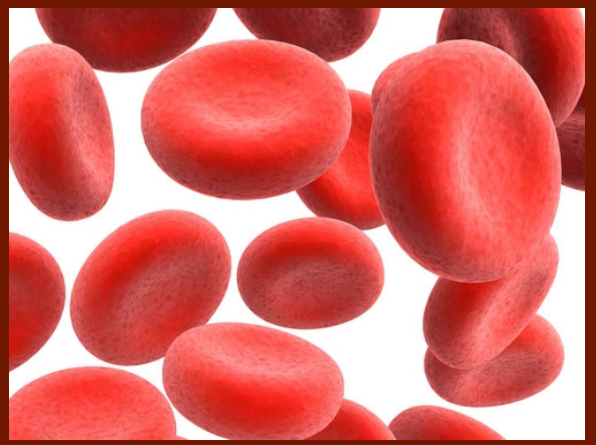
Pregnancy Test Evolution

- 1960 First Immunoassay for Pregnancy
- Hemagglutination inhibition assay
- Significantly faster and cheaper

Pregnancy Test Evolution

- 1970's

  "For your $10 you get pre-measured ingredients consisting of a vial of purified water, a test tube containing, among other things, sheep red blood cells…as well as a medicine dropper and clear plastic support for the test tube, with an angled mirror at the bottom."

  The test took two hours

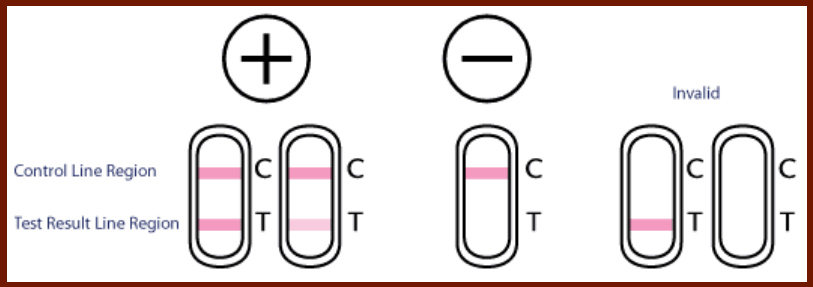
  97% Sensitive, 80% Specific

  1976 FDA approval

  1977 First marketed

Pregnancy Test Evolution

- 1980's-1990's
  - Expansion of pregnancy tests to the home market with single step testing procedures



Pregnancy Test Evolution

- 2003 Digital Pregnancy Test Introduced

Lateral Flow Test Characteristics

- Accurate
- Easy to use and interpret
- Inexpensive
- Portable
- Stable
- Accepted
- Mass producible

Downfalls

- Lack sensitivity for certain applications
- Frequently used incorrectly
- Difficult to properly develop and make
- Vulnerable to environment
- Controlled IP
- Need good materials and reagents

Developing the test is more than Research and Development

- Understand user needs
- Use a need driven development approach
- Validate tests in a meanigful way

Making the test useful

- Understanding interactions between:
  - Users
  - Device
  - Healthcare system

Examples of user design features

- Ergonomic design
- Integrated sample collection
- Graphic instructions
- Build on intuition

Defining Point-of-Care

- Doctor's office/Primary care facility
- Clinic
- Pharmacy
- Kiosk
- Home

Control Lines

- Procedural Control
- Sample Adequacy
- How do you know if you did something wrong?
- How do you trust the results?
- Is the test good?

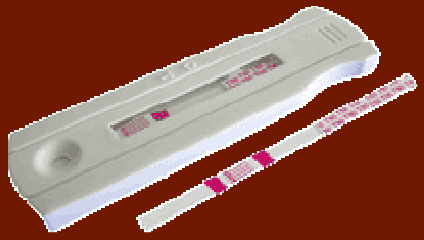
Interpretation

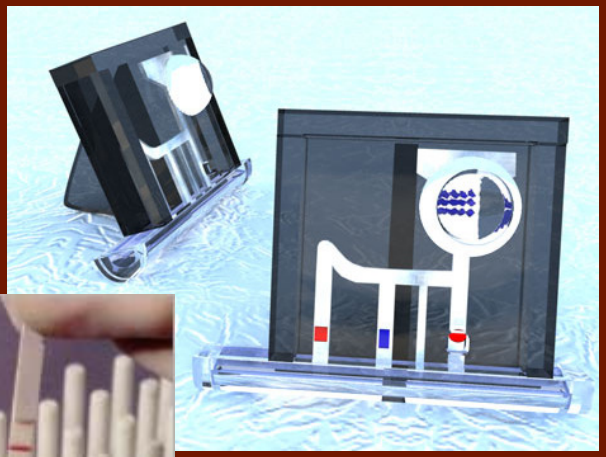
- One line = negative, right?
- What does a faint line mean
- What if there is heavy color (blood, reporter reagent) in the reading window.

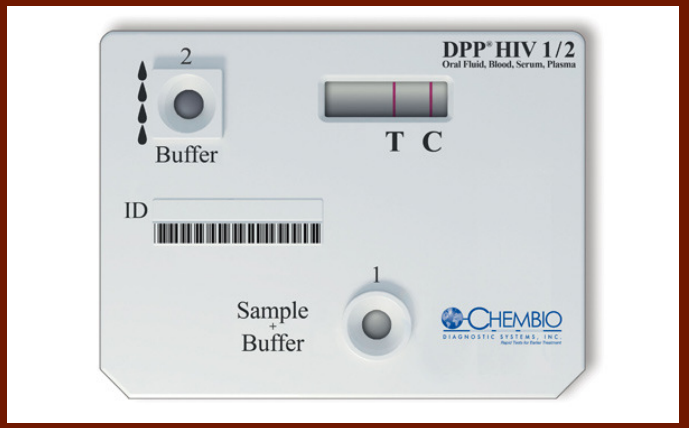
Applications

- Pregnancy
- HIV
- Malaria
- HBsAg
- Syphilis
- Chlamydia
- Gonorrhea
- Cardiac markers
- Hepatitis C
- HPV
- Mononucleosis
- Influenza
- Lymphatic filariasis
- C. difficile
- Dengue
- H. pylori
- Bladder cancer
- Drugs of abuse

Where Next?



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DPP® HIV 1/2
Oral Fluid, Blood, Serum, Plasma
Buffer
T C
ID
1
Sample
+
Buffer
CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

Research Bias

- We each bring our own experiences and biases…some are beneficial, some are hindrances
- Let the market need drive your decisions

Moving product to market

- Regulatory
- Manufacturing
- Distribution
- Realistic costs
- Understanding timelines

Conclusions

- POC lateral flow tests fill a need
- There is room for growth
- This is just the beginning

Additional Training Opportinities

- Center for Point-of-Care Diagnostics for Global Health (GHDx Center) training course. Seattle, WA
- Advanced Course on Diagnostics (ACDx). Annecy, France

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