

**10 October 2012**

# **Point of Care Testing**

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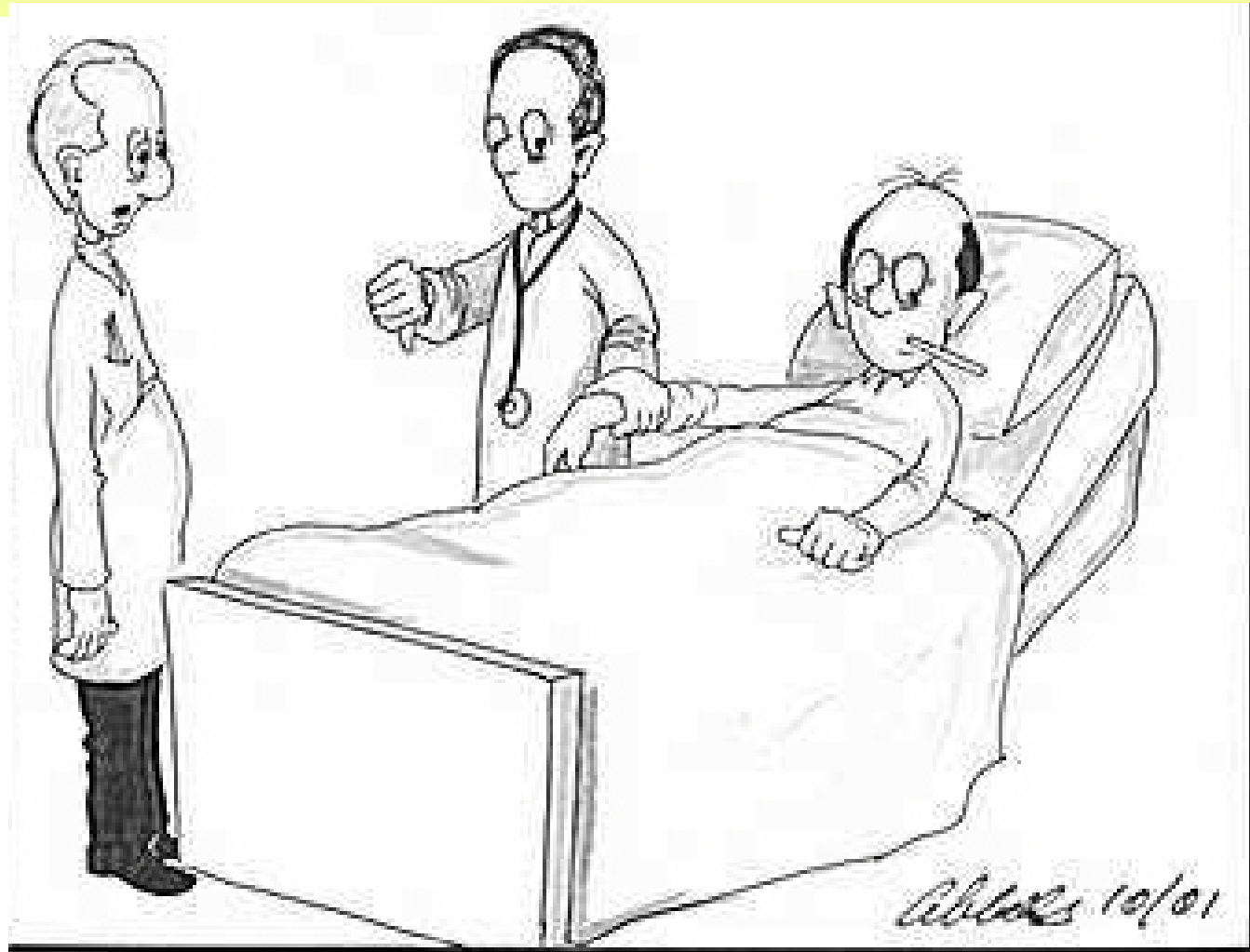
Chemistry

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What do these have in common?



# And this? (thermometer)



"Do you still have my rectal thermometer?"

And this?



# And this?



# And this?



**And even this?**



& this, THE Most Popular!





**THESE ARE ALL  
POINT-OF-CARE (POC)  
ASSAY KITS**

***Now Just What is “Point-of-Care”?***

***Answer: Home, bed-side, office***

## **WHY PERFORM “POINT-OF-CARE”?**

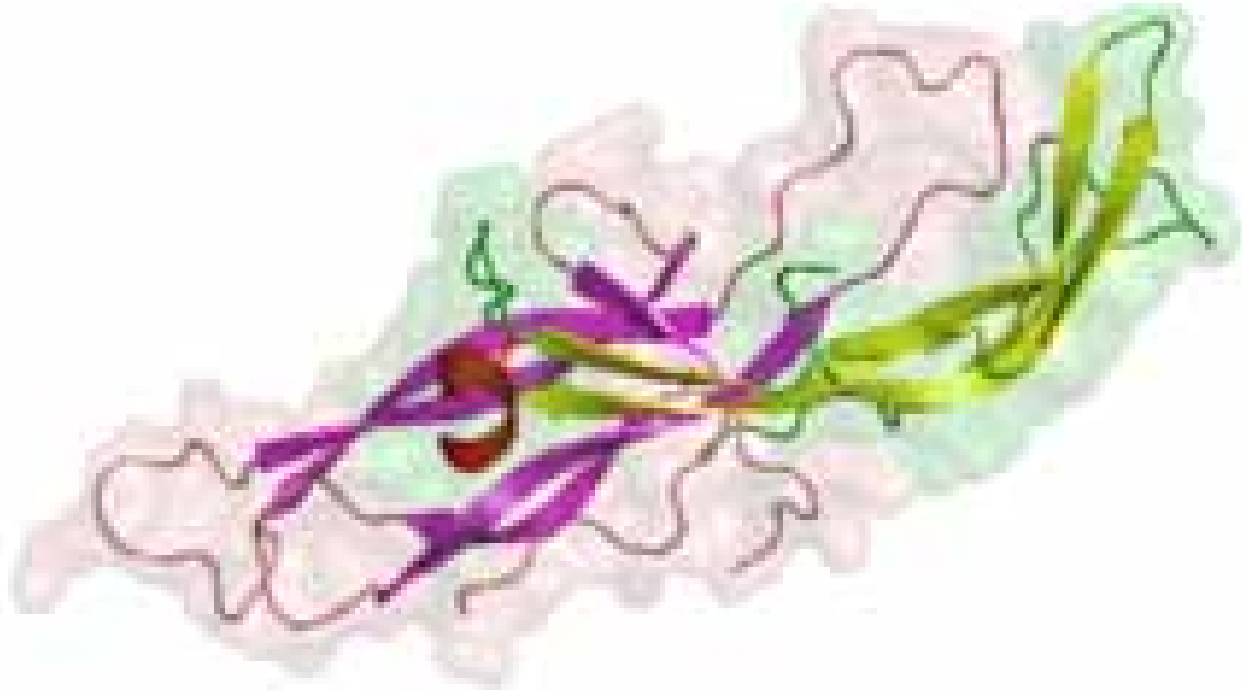
- **\$7.50 vs. \$55.20 [careful here!]**
- **1 minute response vs. 24 hour response**
- **Therapy (response) can be instantly coupled to the measurement**
- **Patient sees consequences of action**
- **Patient can receive results confidentially**

**WHAT'S THE ROLE OF FDA IN POC DIAGNOSTICS?**

# How Does FDA View Pt-of-Care?

- **Will test results be used to alter patient therapy? If so...FDA approval needed**
  - Blood glucose?**
  - Blood pressure?**
  - Pregnancy? Ovulation?**
- **Will assay be sold overseas? If *in total* FDA approval needed, if *in part*, not.**

# Ya Gotta Have a Specific “Bio-Marker” or POC Won’t Work



**Beta-HCG, 244 amino acids, 36,700 D, made by embryo**

# Other Bio-markers

**Elevated glucose in urine or blood**

**High Blood Pressure or Body Temperature**

**Cardiac (or liver) enzymes ex-organ**

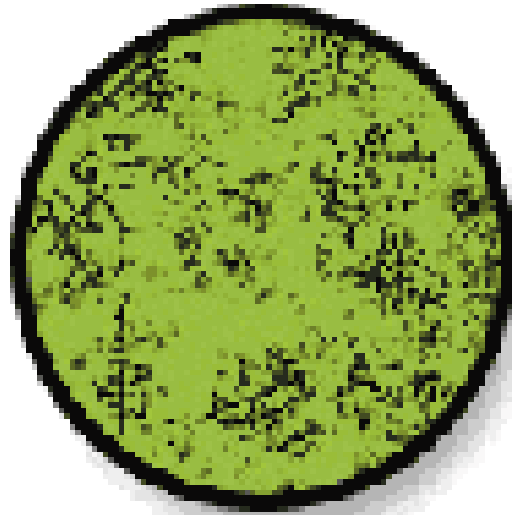
**Luteinizing Hormone**

**And many, many others!** (some observational)

# “Ferning” & Fertility



**1. INFERTILE**



**2. POSSIBLE**

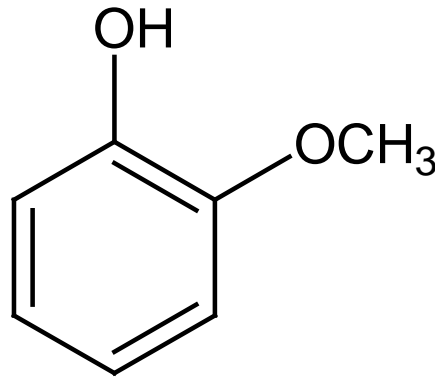


**3. FERTILE**

**“High Content Screening”**

**[This is an insult to Chemists!!!]**

# Guaiacol, Fertility, Blood, and Steve Klasko, LU B.A. '74



# What Clinical Conditions do we Test for by POC?

- **Glucose** (ca 65%)
- **Pregnancy/ovulation/sperm count** (ca 12%)  
*FertilMARQ “yes” v “no” at 20M swimmers/mL*
- **Cardiological assays** (ca 10%)
- **Coagulation**
- **Infectious Diseases**
- a) HIV
- b) hepatitis
- c) bladder infections
- **Electrolytes, Blood Gases**
- **Alcohol Intoxication**
- **Heart Attack**
- **Rupture of Liver Cells**
- **Impaired Metabolism of Multi-Drug Prescriptions (Saladax)**



# How do We Get Specificity?

- **A Specific Chromatographic Migration**
- **Enzymatic Recognition**
- **Immuno-Recognition**
- **Electrochemical Reduction**

# Electrochem Specificity

## Pharmaceutical Examples

**DRUG + e<sup>-</sup> → [DRUG]<sup>-</sup> (at precise potential)**

**Misonidazole -0.64 v**

**Clotrimazole -0.19 v**

**Streptozotocin -1.34 v**

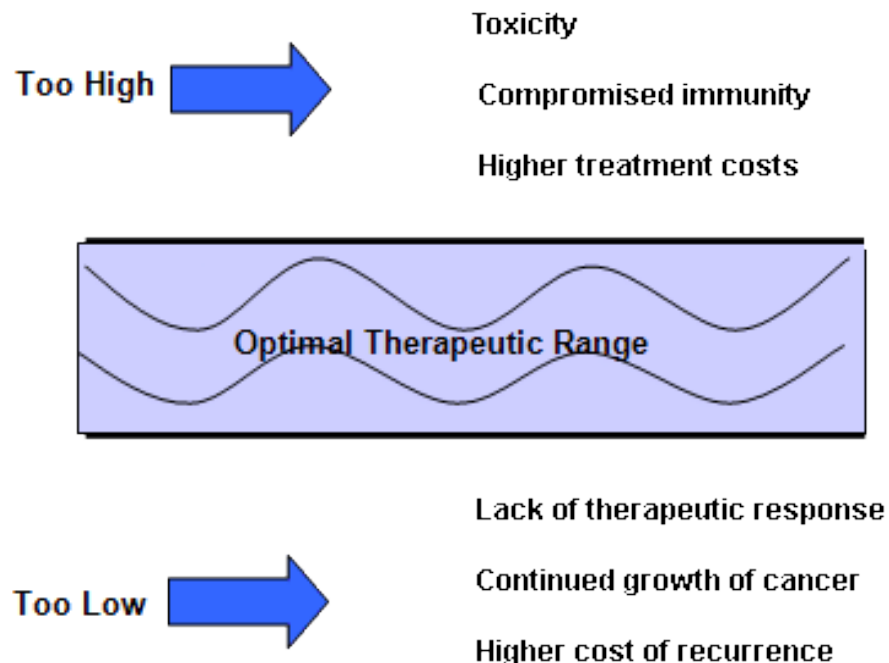
**Ritonavir -1.91 v**

**Precise potential for reduction identifies the drug, total current flow measures the amount**

# What are the Justifications?

## Most are obvious...a few not so.

Monitoring anticancer drug metabolism at home or at lab



# Challenges in Configuring the Assay

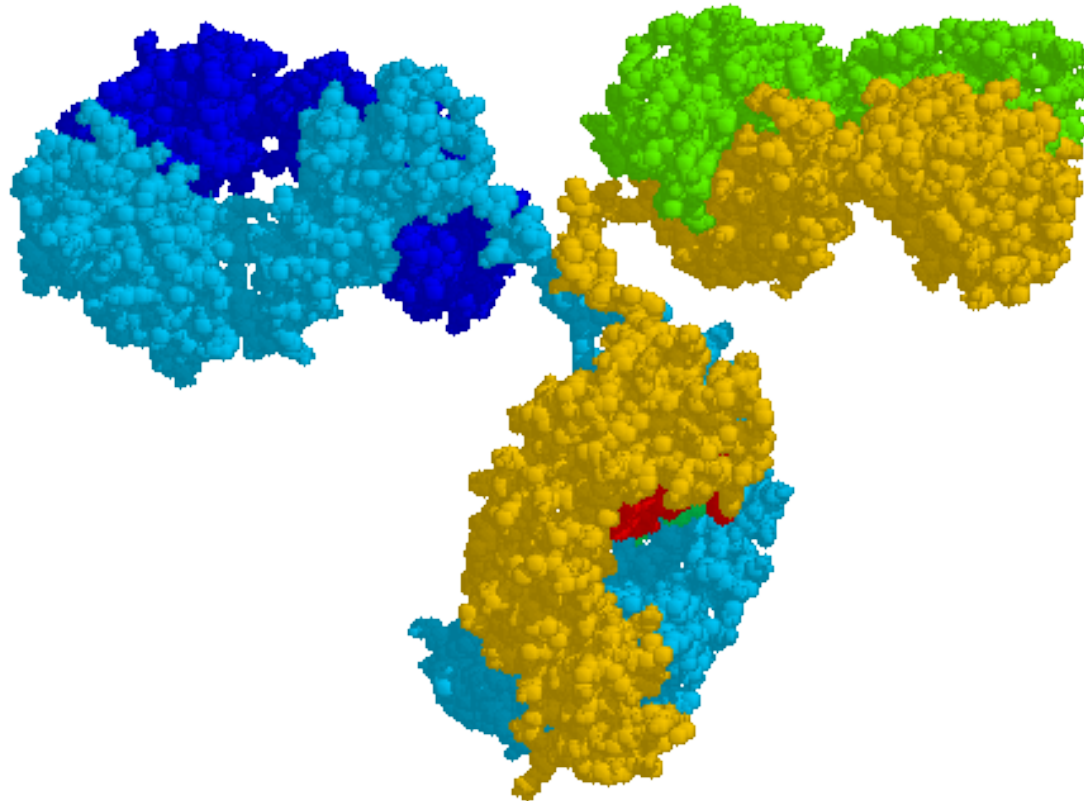
- **What should we sample?**
- **“Yes” vs. “No” (cut-off assay) or precise measurement assay**
- **Simplicity of Use** (the ‘blue line’ rushes past)
- **Checks-and-balances** (air, water, sun, decomp of reagents, stabilizing reagents)
- **Handling confirmation of serious finding**

# Handling Reagents

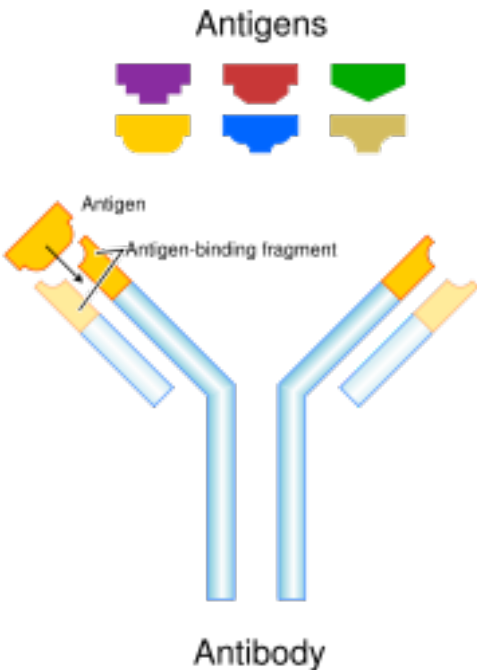


# CONSTRUCTING AN ASSAY with MAb

heavy chains = yellow & light blue, light chains green & dark blue. carbohydrate = red



# CONSTRUCTING AN ASSAY



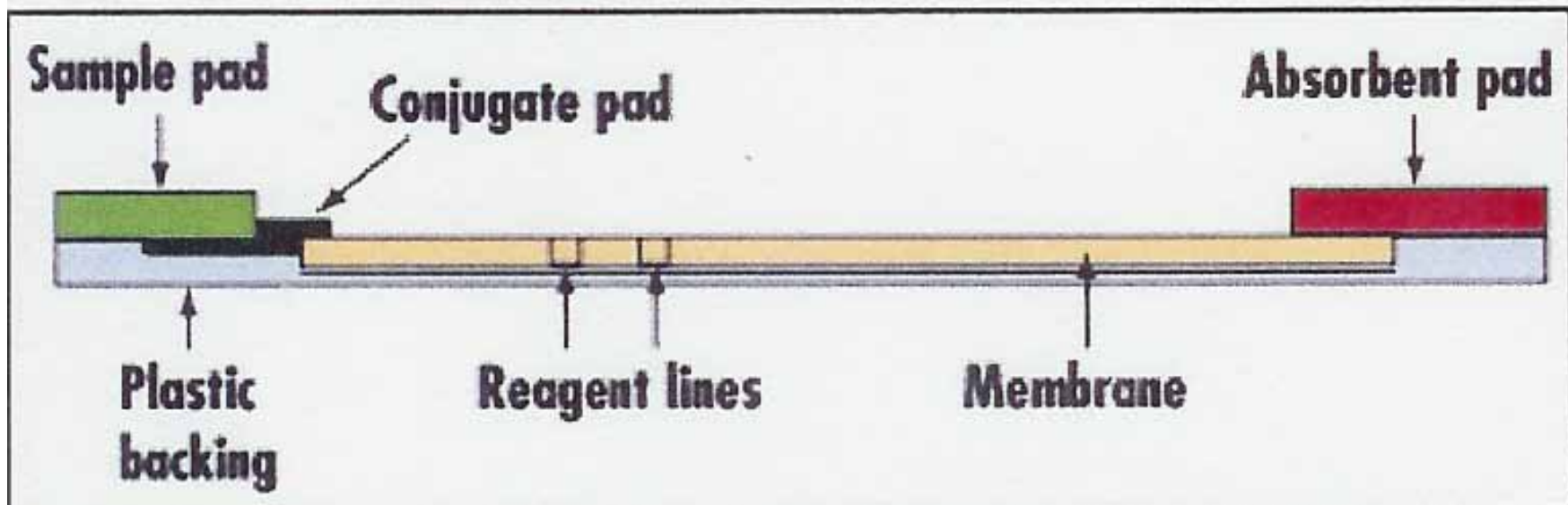
**MAb[tag] + analyte =**

**MAb[tag]--analyte *then***

**Anti-MAb to MAb[tag]--analyte  
grabs & holds this combo in  
a narrow target zone**

**Visual “tag” not bound covalently can be released by the binding event**

# Assembling the Assay





# What Can Go Wrong?

- **Untrained assayer**
- **Test is inherently less accurate**
- **Community medicine misses a community trend**
- **Insurance seldom covers “point-of-care”**

# A FEW FAMOUS FAILURES

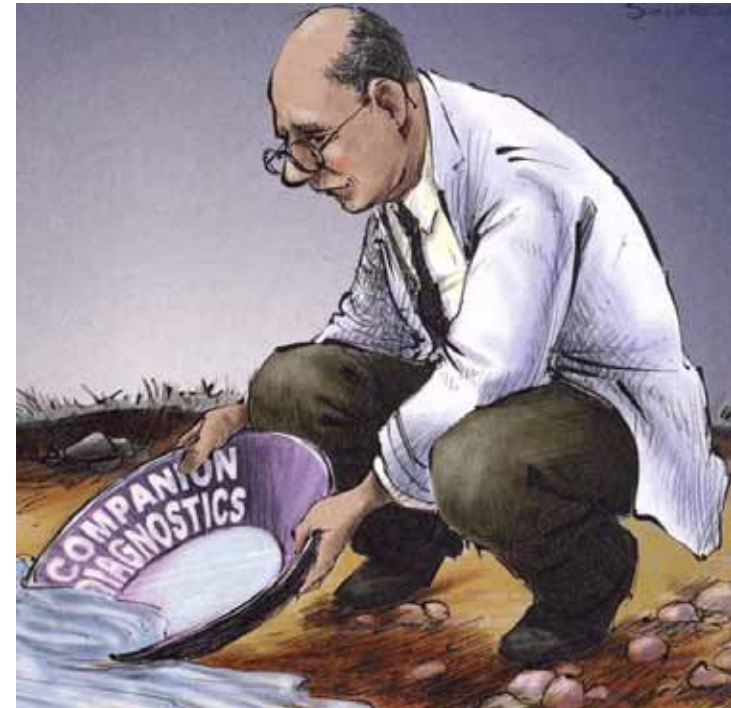
- Toilet paper fecal blood test
- Fecal sampling spoon and rubbing paper
- Ejaculate on bulls eye and microwave
- Heated patch for sweat sampling
- Home-use “ferning” assay with scope

# Let's Look at it as a Business

- Time to market for a diagnostic = 3.5 yr
- Time to market for a drug = 9.2 yr
  
- ROI per year for diagnostic ca 8.5%
- ROI per year for a drug ca 18%
  
- Legal protection for a diagnostic ca \$65K / year/ product
- Legal protection for a drug > \$150K/yr/product
- *Companion Products: an Exciting \$\$\$*

# What's a Companion Product?

- Track efficacy
    - 5-FU test for Lung cancer
  - Eliminate non-responders
    - HER-2 for Herceptin
    - AChE for Aricept
- PERSONALIZED MEDS**



# WHAT'S THE FUTURE?

- **A bright future for R&D and investment where chemistry, biology, & medicine meet**
- **Possible cost savings to the patient (For now, a few tests do appear to cost more per test)**
- **Major increase in medical effectiveness**
- **Confidentiality and increased patient responsibility for personal health**

**“Better things for better living  
through CHEMISTRY”!**



<http://www.craigmedical.com/>