

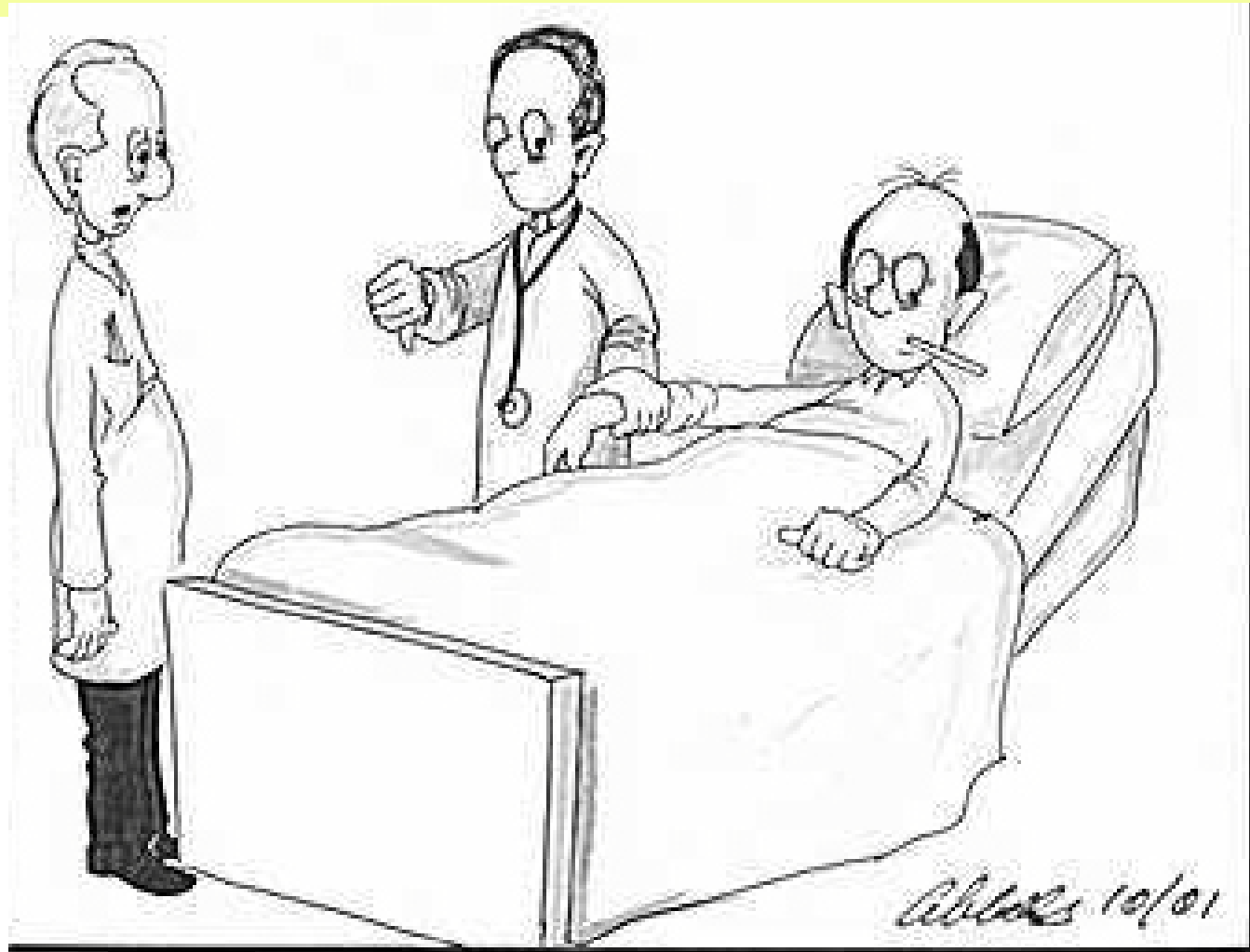
Point of Care Testing

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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”?

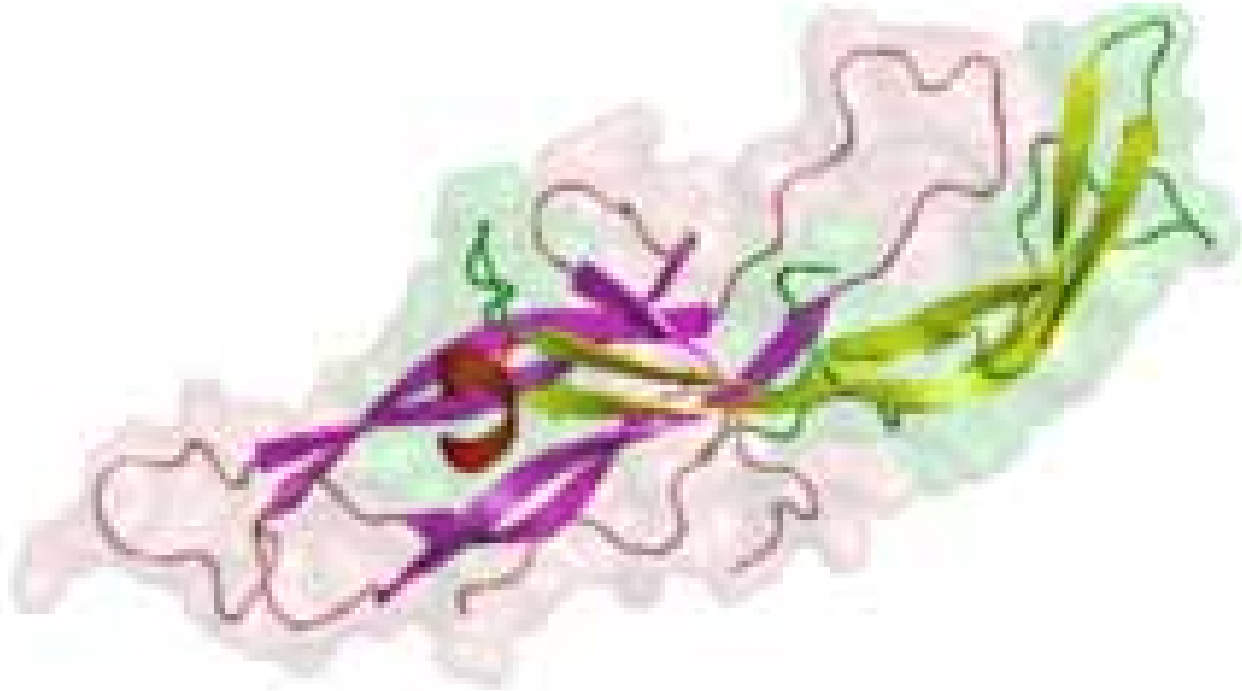
- **\$7.50 vs. \$55.20 [careful here!]**
- **1 minute response vs. 24 hour response**
- **Therapy (response) can be instantly coupled to the measurement**
- **Patient sees consequences of action**
- **Patient can receive results confidentially**

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

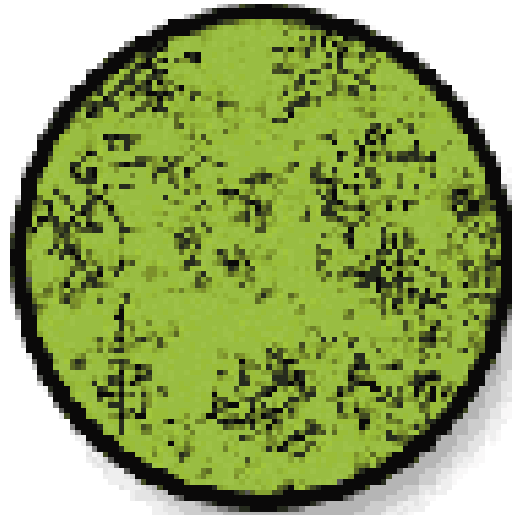
Luteinizing Hormone

And many, many others! (some observational)

“Ferning” & Fertility



1. INFERTILE



2. POSSIBLE

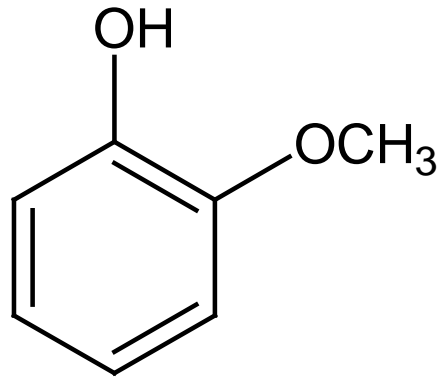


3. FERTILE

“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⁻ → [DRUG]⁻ (at precise potential)

Misonidazole -0.64 v

Clotrimazole -0.19 v

Streptozotocin -1.34 v

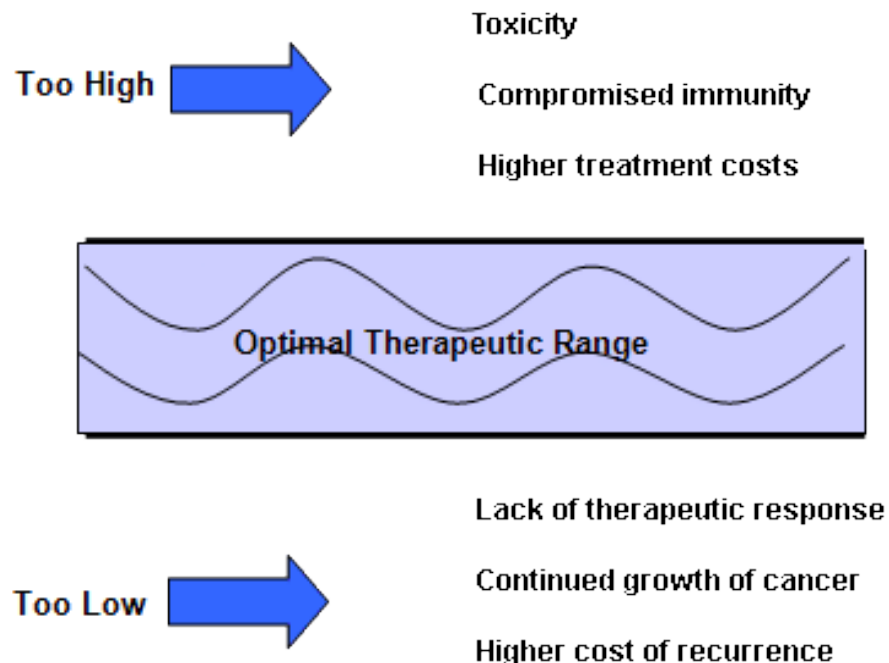
Ritonavir -1.91 v

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

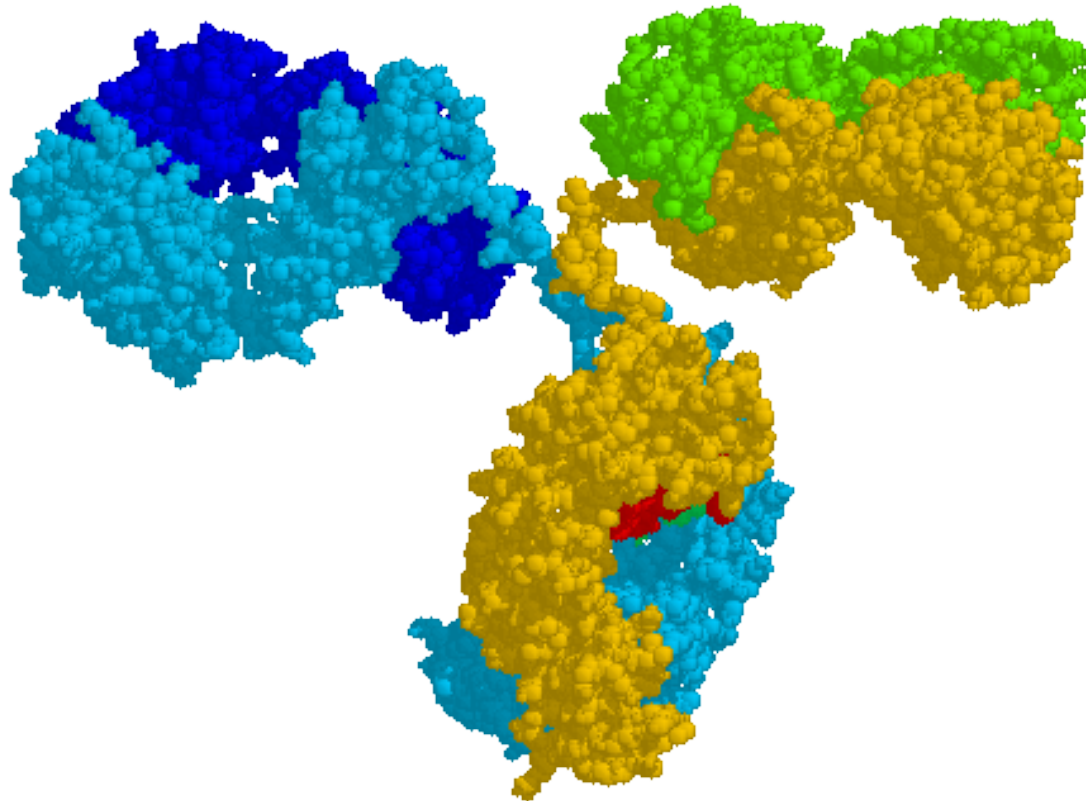
- **What should we sample?**
- **“Yes” vs. “No” (cut-off assay) or precise measurement assay**
- **Simplicity of Use** (the ‘blue line’ rushes past)
- **Checks-and-balances** (air, water, sun, decomp of reagents, stabilizing reagents)
- **Handling confirmation of serious finding**

Handling Reagents

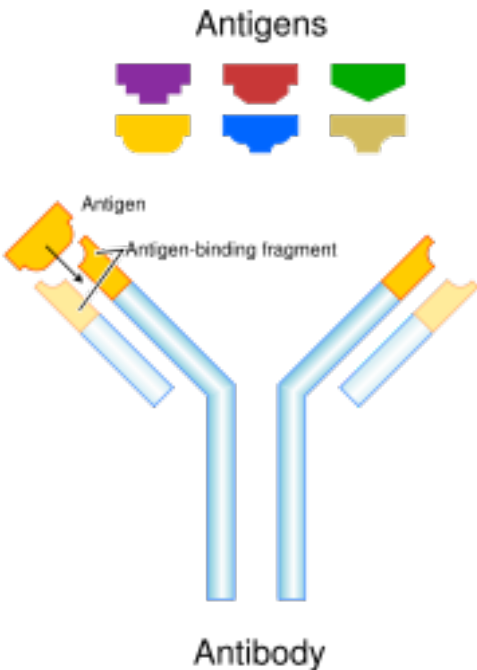


CONSTRUCTING AN ASSAY with MAb

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



CONSTRUCTING AN ASSAY



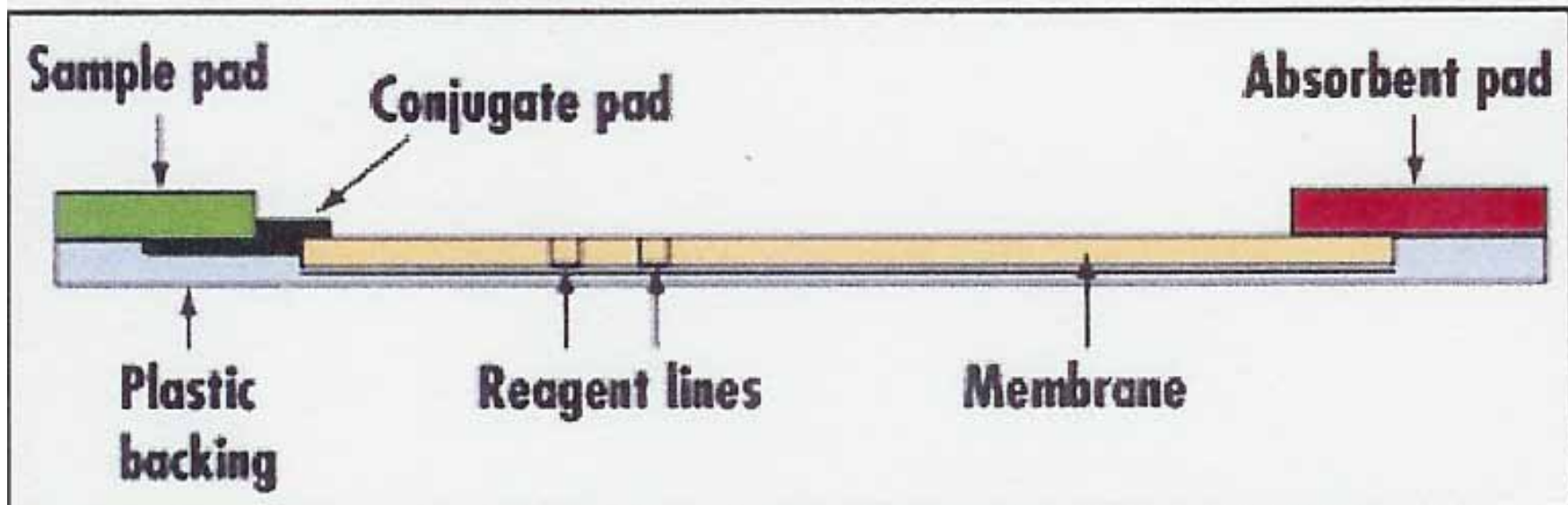
MAb[tag] + analyte =

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

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**

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

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



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