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!!!]
Guiacol, 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

- Too High:
  - Toxicity
  - Compromised immunity
  - Higher treatment costs

- Optimal Therapeutic Range

- Too Low:
  - Lack of therapeutic response
  - Continued growth of cancer
  - Higher cost of recurrence
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/