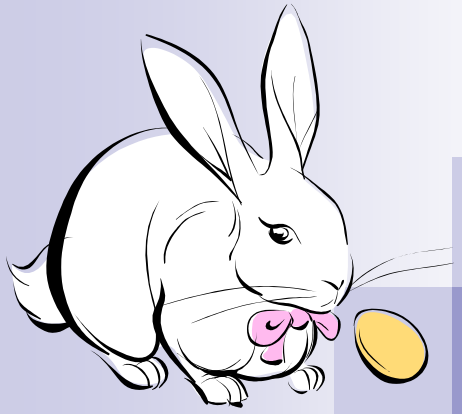


“The Rabbit Died!!”

Professor H. R. Piehler

42-644 / 42-744 Medical Devices

May 8, 2003

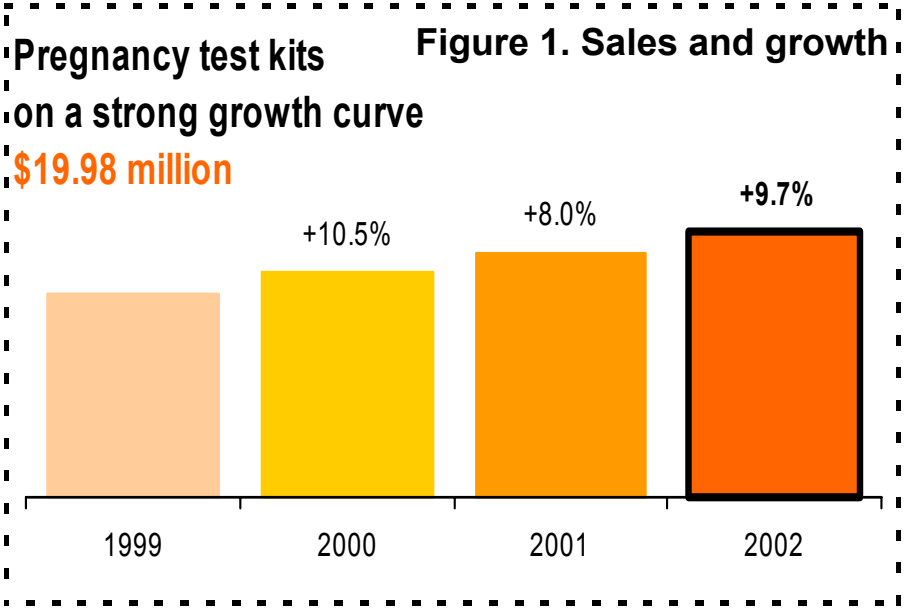
Paul Ko
Marvi Matos
James Tseng

Background

- “The Rabbit Died” (1920s)
  - Rabbits injected with pregnant woman’s urine
  - Rabbits died of ovarian hyperplasia (proliferation of ovarian tissues)
- Present home pregnancy test
  - hCG-directed monoclonal antibodies
- Types of pregnancy tests – hCG hormone detection
  - Urine – After 14 days of ovulation
  - Blood – After 10 days of ovulation

Brands and Companies

- Pregnancy test kits offer convenience and confidentiality
  - $19.98 million in sales during 2002
  - $15 average price tag
  - Two-test packages are common
- Different brands have different sensitivities
  - Clearblue Easy, 25 mIU
  - Eckerd One Step, 50 mIU
  - Wal-Mart Equate, 100 mIU
- Clearblue Easy is selected
  - One of the most sensitive
  - Best seller



Meaning of Results & Conditions of Testing

- Types of incorrect pregnancy test readings:
  - False positive: Not actually pregnant, but the reading shows otherwise due to higher than usual amount of hCG in urine
  - False negative: Pregnancy not detected due to lower amount of hCG than needed for detection

- Factors that could affect test reading
  - Environmental: temperature, pH
  - Chemical: interferences from chemical compounds/substances

Goals of the Project

- To understand . . .

  . . . the principles and detection methods behind the recognition of hCG hormone by the pregnancy medical device

- To test . . .

  . . . the accuracy of pregnancy medical device, specifically the ClearBlue Easy, under various conditions

Sensor Recognition System

Figure 2. Pregnancy window.

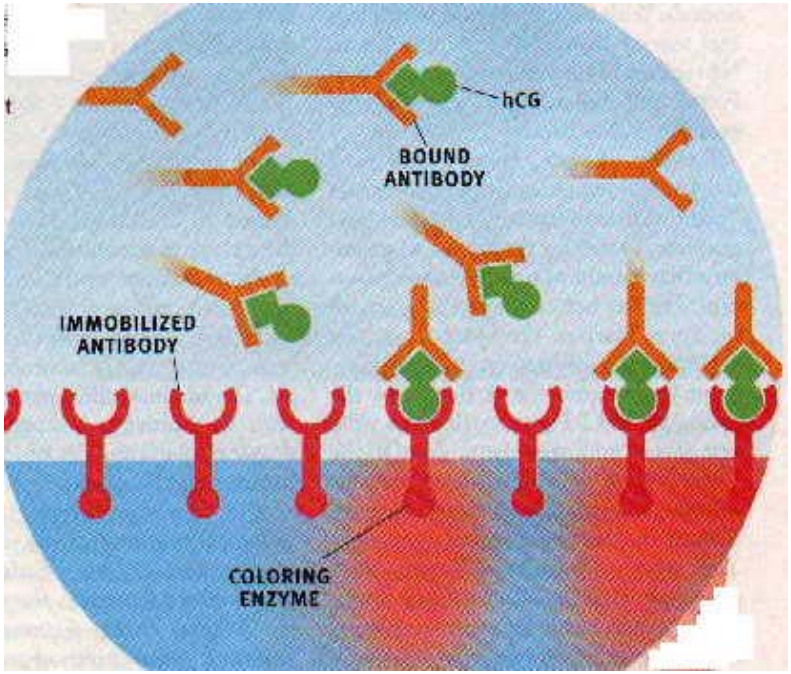
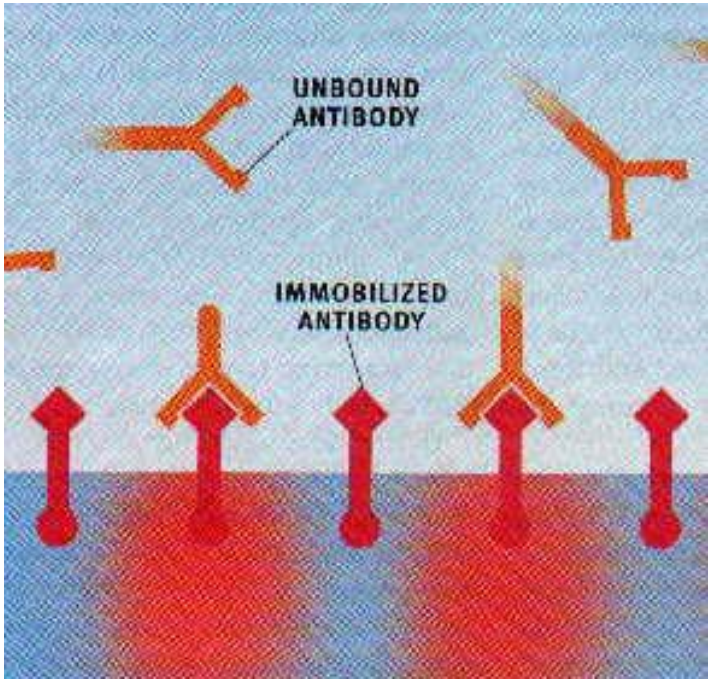
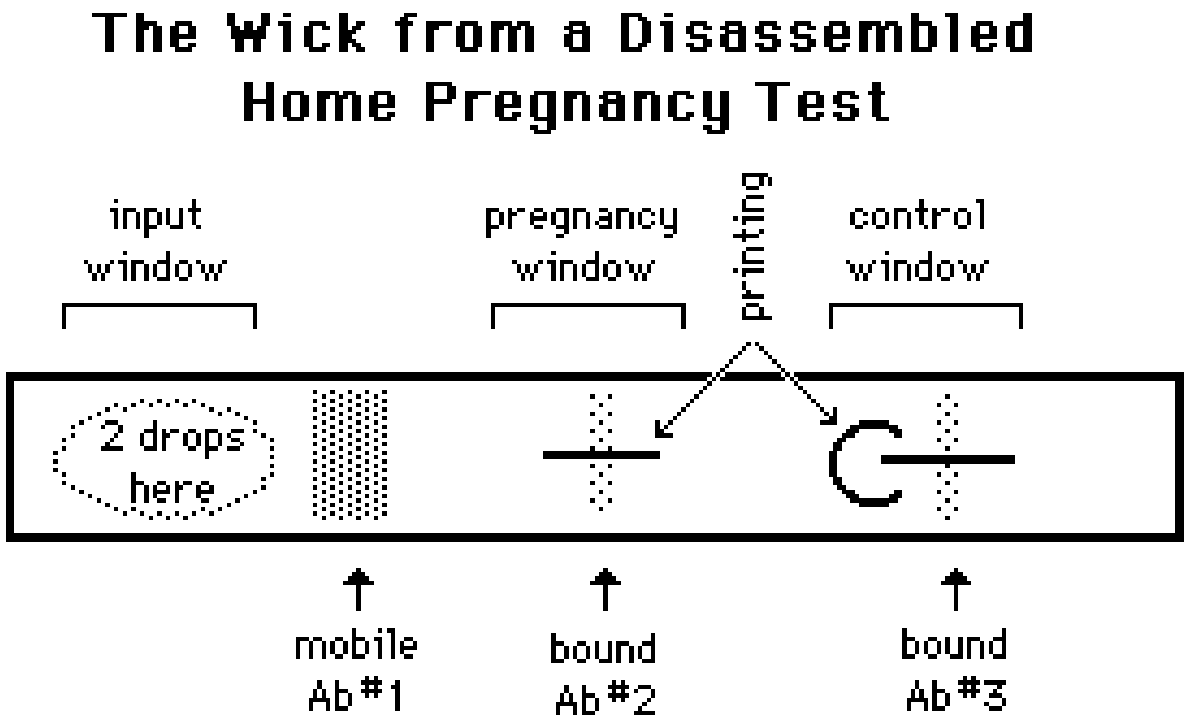


Figure 3. Control window.



Sensor Recognition System (cont'd)

Figure 4. Layout of a HPT.



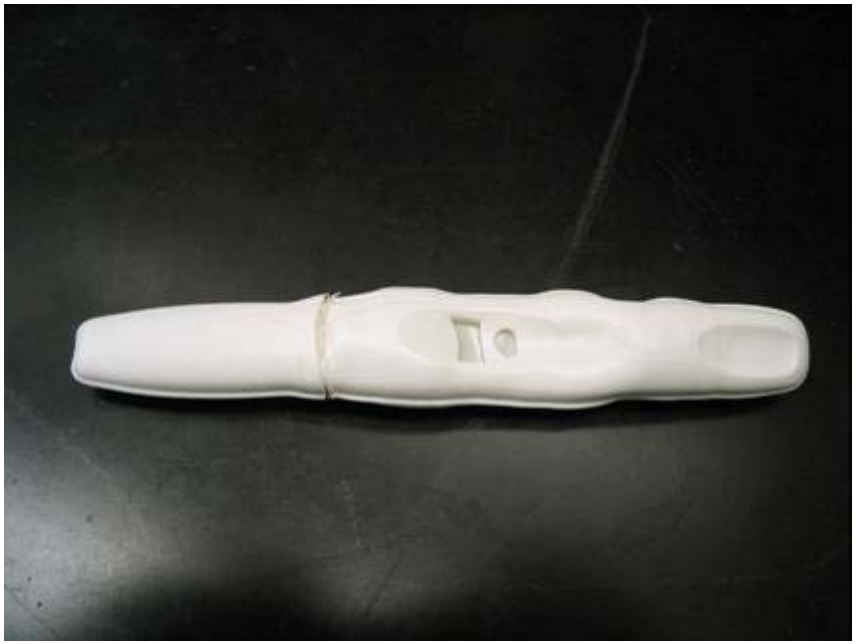
Experimental Section

- Materials
  - Deionized Water
  - Human chorionic gonadotropin (hCG)
  - ClearBlue Easy home pregnancy tests
  - Acetic acid, sodium acetate, monobasic sodium phosphate and dibasic sodium phosphate
  - Caffeine and Vitamin C
- Tests Performed
  - Low and high temperature
  - Low and high pH
  - Vitamin C and Caffeine
  - Controls
- All manufacturer's guidelines were followed

Results

Group	Type	Parameter	Working
Control	Hormone only	--	--
Chemical	Ascorbic acid (Vitamin C)	2.25 mg/mL	Yes
	Caffeine	0.038 mg/mL	Yes
Buffer	Low pH	pH = 5.0	Yes
	High pH	pH = 8.0	Yes
Environmental	Low temperature	15°F (-9°C)	Yes
	High temperature	120°F (49°C)	No

Results



Discussion

- Chemical compounds
  - No effect encountered with caffeine and vitamin C
- Buffer conditions
  - No effect found with extreme low and high pH when compared with normal samples
- Temperature conditions
  - No effect for cold storage
  - Shrinkage and recognition problem when stored in an oven.

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Questions