The Evolving Role of POCT in Healthcare Around the Globe

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Objectives

• Identify new healthcare trends
• Describe the benefits and limitations of home testing
• Discuss the role of POCT in evolving healthcare
Point of Care Testing

• Portable
• Native samples (unprocessed blood or urine)
• Doesn’t require power or purified water
• Reliable enough for medical triage and management
• Can be performed by non-laboratory operators with minimal training and orientation
History of POCT

• First POCT – prior to 11th century, urine or “water tasters” detect sugar in urine of diabetics
POCT Settings

- Helicopter/airline
- Ambulance
- Cruise Ship
- Military field hospitals
- Disaster relief
- Expeditions
- Space shuttle
POCT Settings

- Hospital wards
- Clinics
- Schools
- Athletics
- Events
- Remote settings
Early Healthcare

- Doctor house calls
- Physician visits patient in their home
Current Health Care Model

1. Physician sees patient – orders tests
2. Patient has blood collected
3. Laboratory analyzes blood
4. Test results reported to physician
5. Physician acknowledges results
Empowering Patient Self-Health

- Recent US regulatory changes allow patients the right to access personal health information under HIPAA – the Health Insurance Portability and Accountability Act
- 2/3/2014: CLIA ‘88 amendment allows labs to give a patient or their representative access to completed test reports. (2\textsuperscript{nd} option to get information other than their doctor)
- Final Rule issued jointly by CMS, CDC, and Office of Civil Rights (OCR) (agency that enforces HIPAA).
- “Information like lab results empowers patients to track health progress, make decisions with healthcare professionals and adhere to treatment plans” Kathleen Sebelius, Department Health and Human Services Secretary
Watch the video below to learn about all of the features My Health at Vanderbilt has to offer.

Click here for more information about My Health at Vanderbilt.
What is “Home Testing”? 

• Laboratory diagnostics and tests marketed for use in a person’s home. 
• Available for sale, over-the-counter or directly to the consumer 
• Marketed over the internet and available without a prescription in pharmacies, grocery stores and other retailers 
• The U.S. Food and Drug Administration and European CE oversee the product claims for home tests
Benefits

• Obtain without a prescription, over-the-counter
• Provides diagnostic testing in privacy of home
• Rapid point-of-care diagnostics
• Screen for illness when no symptoms, without waiting for an expensive clinic appointment – hepatitis, occult blood, HIV
• Seek early treatment, avoid complications
Home Tests

• Infectious Disease – HIV, hepatitis C, UTI
• Chronic Conditions – Cholesterol, HDL, triglycerides, glucose, HgbA1c, (PT/INR)
• General Screening – Pulse oximeters, blood pressure, body composition, colon disease
• Addiction management – urine and saliva drugs of abuse, nicotine, breath alcohol, steroids, hair confirmation
• Fertility – pregnancy, ovulation, sperm counts, menopause, paternity tests
• Other countries - ????
Family Matters
By Bonnie Rochman

INFERTILITY
Are You Fertile? Don’t Rely on a Drug-Store Fertility Test to Tell You
By Bonnie Rochman @brochman | Oct. 28, 2010 | 1 Comment

We women are accustomed to peeing on chemically-treated sticks to learn what our bodies are up to. Pregnancy tests administered in the confines of the master bathroom are more accurate than ever, but new research indicates that home fertility tests can’t be relied upon. A quarter of women were labeled infertile by the tests, according to a study conducted by researchers at the University of North Carolina at Chapel Hill, although in actuality they had no more trouble getting pregnant than other study participants. (More on Time.com: 5 Pregnancy Taboos Explained (or Debunked))

Home fertility tests are gaining in popularity as women increasingly delay baby-making. Some haven’t found the right guy; others are sailing ahead in their careers. When they decide the time is right for baby, more than a few are turning to home fertility tests to assess their chances. Inaccurate assessments of infertility could lead otherwise healthy women to seek unnecessary fertility interventions.
Limitations

• Home tests may not be accurate!
• Performance depends on many factors:
  – Proper specimen collection,
  – Test operation,
  – Timing
  – Interpretation
• Out-of-pocket expense. Insurance does not reimburse cost of home testing.
• Home testing should not replace laboratory testing or regular physician visits!
• Tests are best evaluated in conjunction with symptoms, history, and physical exam
Home Tests Are Not Intuitive

• 638 laywomen using 11 hCG tests, falsely interpreted 230/478 coded positive urines as negative due to difficulty understanding explanatory leaflets and reading results. (Clin Chem 1993;39:53-9)

• 16 pregnancy test instructions found reading levels for how to use (7 – 10th grade) and Q & A (11 – 14th grade), with graphics and paper size too small for user friendliness (J Womens Health 2009;18:363-8)

• Digitally read results offer significant benefits over non-digital pregnancy tests (CMRO 2008;24:1645-9)

• Lack of consensus analytical sensitivity of tests, methods for expressing performance, variable reactivity to hCG forms, and discrepancies between technician and volunteer interpretation. Consumers lack appreciation of strengths and limitations of tests and rely on marketing claims (CCLM 2015;53:339-41)
Newer Designs and Advertising

Is she?
Or isn’t she?
Gender Prediction Test

gpt home
how it works
sample results
sonogram results
chinese gender chart
gender myths
order now

Testimonials
in the news
faq’s

Independent Studies

Store Locator
become a retailer

girl? boy?
Share the joy!
Experience the joy of discovery at home

gender prediction test

Use as early as 10 weeks
IntelliGender’s Gender Prediction Test... a fun pre-birth experience for moms who can’t wait to know! You may use our gender prediction test weeks before your sonogram.

A simple baby gender prediction test you can take at home

IntelliGender’s Gender Prediction Test is an affordable, simple-to-use urine test that provides immediate gender results in the privacy and comfort of the home. In minutes, the IntelliGender Gender Prediction Test indicates your gender result based upon an easy to read color match. Green indicates boy and orange indicates girl!

When can I use it?

As early as 10 weeks into your pregnancy (8 weeks post-conception)! Most women find out the sex of their baby at their 20-week sonogram as long as Baby chooses to cooperate. IntelliGender bridges the curiosity gap between conception and sonogram.

*Note: IntelliGender may not predict your baby’s gender with 100% accuracy. Please click here for our FAQ on accuracy:
HC-212SF FitScan Breath Checker

Features and Specifications:

- Detects and measures the level of bad breath odor in just 9 seconds
- Shows breath odor in one of six levels
- Convenient to use, shows results clearly on an LCD
- Small enough to fit discreetly into pocket or purse

New from FitScan is Breath Checker, an innovative palm-size monitor that detects and measures the presence of annoying or embarrassing breath odors. Simply turn it on, breathe into the sensor, and a reading appears on the digital display. Measures odor in seconds. Results displayed in six levels. Measures the amount of volatile sulfur compounds (VSCs) given off by bacteria. Easy to read and operate. Convenient and discrete to use.

**LCD Symbols - Breath Odour Level**

- No odor
- Slight odor
- Moderate odor
- Heavy odor
- Strong odor
- Intense odor
- Error Please try again
TEST THE DRUG, not your relationship...

DISCREET HOME DRUG TEST KIT
NO URINE OR HAIR SAMPLES NEEDED
IMPOSSIBLE TO CHEAT
A NEW TOOL TO STOP DRUG ABUSE
Procedure Card for IDT 9000-10
IDenta General Screening Drugs
Substance

As a precaution, gloves and eye protection should be worn when handling drug substances and using test units.
Do not puncture any part of unit. Do not remove probe once locked into unit.
In the unlikely event of a spill, rinse affected area thoroughly with water.
Keep out of reach of children.

1. Remove the Smart-Tip™ probe from test unit.
2. Sample suspected substance.
   (Not for use with plant materials.)
   
   **Powders**
   - Touch adhesive Smart-Tip™ to sample.

   **Tablets**
   - Firmly press the Smart-Tip™ on tablet while scrubbing in a circular motion until the tip is completely covered with substance.

   **Encapsulated Powder**
   - Safely open shell. Gently pour substance out and touch adhesive Smart-Tip™ to sample.

3. Lock Smart-Tip™ probe into test unit. Press firmly.

4. With thumb and forefinger, squeeze chamber 1 until capsule breaks.

5. Gently shake test unit for 2-3 seconds.

**Chamber 1 Results**

- The appearance of a red-violet color indicates the presence of Brown Heroin, if the substance is a brown powder.

- The appearance of a green or blue-green color indicates the presence of Crack, if the substance is a powder.

- If either color develops, proceed to Disposal.
  If no color develops, proceed to Step 6.
Do you suffer from the nightmare of suspicion and doubt caused by the infidelity of a cheating spouse? Now you can find out what’s really going on the quick and easy way with a semen detection infidelity test from CheckMate. As seen on the Today Show, Howard Stern, Dr. Phil, Maury Povich, The View, Fox News, CNN, Playboy, FHM, Maxim, Reuters, Newsweek, Popular Science, and many more.

CheckMate is the revolutionary home use forensic test for semen detection that instantly detects traces of dried semen that can be found in underwear after sex. Sold around the world since 1999 CheckMate detects even the smallest trace amounts of semen and can give you the instant information you need to deal with an impossible situation.

Each Infidelity CheckMate semen detection test kit can test 5 to 10 items for the presence of semen and you also get a second test kit free with every order. CheckMate works on any type or color of material without damaging or staining the item in any way and it gives instant yes or no results from the comfort and privacy of your own home.
Home Testing can be Snake Oil!
How are Consumers to Know?

• Consult a doctor!
• Search the product for FDA Approval!
Dubious Diagnostic Tests

Stephen Barrett, M.D.

Most of the tests listed below have little or no diagnostic value. A few are legitimate for some purposes but are used improperly for others. Those marked with an asterisk (*) are done primarily or exclusively in quack-testing laboratories, not in conventional ones. To find conventional practitioners who do these tests, you should seek advice elsewhere. Practitioners who do live cell analysis, biological terrain assessment, dental sensitivity testing, and cytotoxic testing in their offices are required to have CLIA laboratories, blood banks, hospitals, and most medical offices. Only a few facilities have high-complexity approval. Nevertheless, if you encounter a quack laboratory, please ask your state laboratory department to investigate.

Blood Tests

- ALCAT testing
- Aroonsak Provocative Test
- Biological Terrain Assessment (BTA)
- BioNutritional Analysis (BNA): Quackery for Pets
- Blood pH Self Test
- BodyBio Blood Chemistry Report and Fatty Acid Analysis Report
- Bovin’s Clot Retraction Test
- Carroll Food Test
- Circulating IgE and IgG Food-Immune Complexes
- Clifford Reactivity Materials Testing (CMRT) for selecting dental filling materials
- Cytotoxic testing, also called Metabolic Intolerance Test
- ELISA ACT
- Functional Intracellular Analysis (FIA), formerly called Essential Metabolites Analysis
- Glucose tolerance test for "hypoglycemia"
- Health Equations Blood Test Evaluation
- HealthPrint
- Hemoglobin analysis
- Individualized Optimal Nutrition (ION)
- Live Blood Cell Analysis (LBA), also called Live-cell Analysis, Nutritional Blood Analysis, and Hemaview
- Lymphocyte sensitivity tests
- Live and Dried Blood Analysis
- Mediator Release Test (MRT)
- Mercury testing for "amalgam toxicity"
- NiTron Testing
- *Nutribalance
- OncoDiagnostico
- Oxymark and Oxymark Stress tests
- Polymerase chain reaction test for protozoa
- Polymerase chain reaction (PCR) for Lyme disease
- Polymerase chain reaction: other inappropriate use
- Silicone Antibody Tests used to diagnose disease
Home Testing vs Home Collection

• Home tests are self-performed in the home
• Home collection kits have the consumer collect and mail a sample to a laboratory for analysis.
• Advantage: reliability of test result, performed in a CLIA certified laboratory in the US, confidential test code and phone # for results.
• Disadvantage: longer turn-around time
reveal DNA Paternity Test 1 ea

write a review

our price: $26.99

in stock

special offers

Click & Save: buy 2 save 20% on 2 select Reveal and TruChek home tests

quantity: 1

add to bag

save to your list™

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Please Note: Product received may temporarily differ from image shown due to packaging update.

Additional Required Laboratory Fee has Increased

For Father, Mother & Child

- 100% Accuracy
- 2 Day Standard Testing
- Quick Online Results

Reveal DNA Paternity Test Collection Kit includes three buccal (cheek) swabs each for the alleged father, the child, and the biological mother (her testing is optional). Two swabs are to be used with each testing; the third swab is an extra. Additional persons may also be tested for an additional fee.
INTRODUCING STEROIDCONFIRM™
the first on site steroid abuse test for parents and sports trainers

SteroidConfirm™, the accurate and affordable diagnostic anabolic steroids test for convenient use in the home, workplace or school, utilizes the most sophisticated, sensitive and technology available.

SteroidConfirm™ enables sports trainers, employers and parents to test individuals who they suspect may be abusing steroids. Simply take a urine sample at home, in the workplace or at school, and mail to our laboratory using the pre-paid FedEx Clinical Pak. You have the option to perform either a confidential or professional test.

Using Liquid Chromatograph Tandem Mass Spectrometry (LC/MS/MS), the most sensitive and sophisticated technology available for the steroid testing community, SteroidConfirm™ can accurately quantify substances well below the cut-off levels.

STERIODCONFIRM™ TESTS FOR
commonly abused anabolic agents including:

- 1-Androstenediol
- 4-Androstenediol
- 5-Androstenediol
- Bolasterone
- Boldione
- Calusterone
- Clostebol
- Dehydroxytestosterone
- 17α-Dihydrotestosterone
Direct-to-Consumer Testing

• Laboratory/manufacturer marketing to consumer
• Pay for test out-of-pocket – insurance doesn’t cover
• Order tests without a physician
• Menu may be limited by state laws – varies by location
• Blood collected onsite
• Sent to CLIA certified lab for analysis
• Results mailed back to patient or available online
• No physician interaction
DNA
- Paternity Tests And Other DNA Tests
- Immigration DNA
- Forensic
- Ancestry

HEALTH & WELLNESS
- Women's Health
- Men's Health
- College Students
- No Insurance? High Deductible No Problem!
- Health & Fitness

MMA & OTHER ATHLETES
- MMA
- Other Athletes

STD Testing
- STD Testing

TOXICOLOGY
- Drug Testing
- Alcohol Testing
- Teen Drug Testing
- Heavy Metals

BLOOD COLLECTION SERVICES

FIND A TEST
ANY LAB TEST NOW offers thousands of clinical, DNA, and toxicology lab testing services. Use our Test Finder to learn more about some of our most commonly ordered tests. Can’t find what you are looking for? Just give us a call and we’ll be happy to help.
Challenges with Clinical Correlation

• Multiple reasons for why a test result may be positive or negative, need for clinical correlation

• Home menopause kits – measure FSH, but FSH levels poorly correlated with symptoms. Stress, not eating regularly, drinking alcohol can cause missed periods and elevate FSH. Should also look to progesterone and estrogen levels (low in menopause)

• Home sperm counts – fertility and post-vasectomy – detect sperm protein or color label DNA and trigger positive around 20 million/mL. But fertility also related to sperm motility, vitality (# alive) and morphology not measured by home tests!
Pharmacist Testing

- Nurse practitioner/physician/pharmacist sees patient in pharmacy (Minute clinic or all-day clinic)
- Clinician orders and performs POCT – trained staff and reliable test results
- Patient provided with interpretation of test results
- Benefits of treatment on-site (children with rapid strep, able to get antibiotic from pharmacy, parents back to work next day)!
The New Wave of Healthcare (Or is it?)

• Doctors making house calls
• POCT available for onsite testing!
Future of Home Tests

- Smartphone attachments
  - Glucose apps analyze and phone results to physician
- Uchek for urinalysis
- Pregnancy tests that call/bluetooth phone for interpretation assistance/timing
- Breathalyzer ETOH
Cell Phone Medical Devices

Cellscope Microscope

Microskia $10 microscope for developing countries

NETRA – Near eye tool for refractive assessment - for eyeglass prescriptions

Nanosensor tattoo for sodium and pO2

December 2010: Dr David Albert and the iPhoneECG case
Pregnancy Test

No need to urinate, ladies. Just stick your thumbs on the screen and this app lets you know if you've got a bun in the oven. You can even get an ultrasound by rubbing your phone against your belly to see if you've got a girl, a boy, triplets, or an alien. Disclaimer: Results not accurate. ($0.99; iPhone, iPod touch, iPad)

To conduct pregnancy test with your phone, for blackberry users just dial **18p# send and place it on the woman’s belly and wait for a few seconds, you will definitely see the screen of your phone with the following displaying boldly:

- B+0.1 Which means one week pregnant
- B+0.2 Which means two weeks pregnant
- B+ CL3 Which means three weeks pregnant
- B+1 Which means one month pregnant
- B+2 Which means 2 months pregnant
Summary

• POCT is expanding to a variety of settings
• New healthcare trends allow the consumer to take charge of their health in privacy of their home
• Not all tests perform as advertised!
• Consumers should seek professional advice when in doubt!
• Many factors can affect a test result – preanalytic, analytic, postanalytic
• Options exist for consumers to have test conducted in a CLIA lab – pharmacies, minute clinics, home collection kits, direct-to-consumer testing and doctor house calls!