

Opportunities and Risks of Direct-to-Consumer Testing

James H. Nichols, Ph.D., DABCC, FACB

Vanderbilt University School of Medicine

Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

James H. Nichols, Ph.D., DABCC, FACB

Medical Director, Clinical Chemistry
and Point-of-Care Testing
Professor of Pathology, Microbiology and Immunology
Vanderbilt University School of Medicine

james.h.nichols@vumc.org

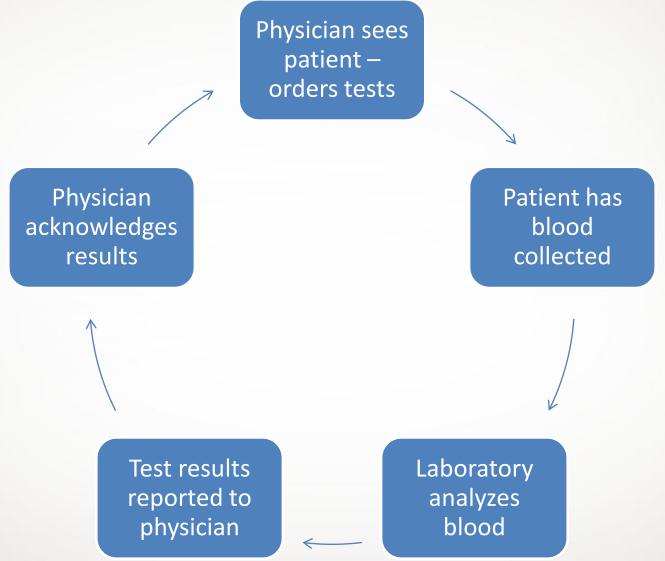


Objectives

- Identify new healthcare trends
- Describe the benefits and limitations of home testing
- Discuss the role of POCT in evolving healthcare



Current Health Care Model





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





POCT Settings

- Helicopter/airline
- Ambulance
- Cruise ship
- Military field hospitals
- Disaster relief
- Expeditions
- Space shuttle















POCT Settings



- Hospital wards
 - Clinics
 - Schools
 - Athletics
 - Events











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 (2nd 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





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What is "Home Testing" or "Direct-to-Consumer" 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 ????









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









Pinit

Read Later



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

MEDICAL CENTER

- Interpretation
- Out-of-pocket expense insurance does not reimburse cost of home testing
- Home testing should <u>not</u> 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 $(7-10^{th} \, \text{grade})$ and Q & A $(11-14^{th} \, \text{grade})$, 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)



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Newer Designs and Advertising







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girl? boy?

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ACOH!

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gender prediction test

*use as early as 10 weeks

IntelliGender's Gender Prediction TestTM... 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.

conception: week 2



week 4

boy or girl? 10 weeks





*Note: IntelliGender may not predict your baby's gender with 100% accuracy. Please <u>click here</u> for our FAO on accuracy:

https://www.indiegogo.com/projects/vitastiq-2-high-tech-vitamin-check-fitness-gadgets#/

Imported From IE

Vitastiq will help you find out whether your vitamin and mineral levels are too low, too high or just right. You can measure the levels of essential nutrients and monitor your body balance.

CHECKS THE STATUS OF 26 MOST IMPORTANT VITAMINS AND MINERALS

Chromium Vitamin C Vitamin A Magnesium Glucosamine Vitamin B1 Vitamin B12 Vitamin B2 Manganese Vitamin B3 Zinc Selenium Omega 3-6 Vitamin B6 Vitamin B5 Vitamin E Vitamin D Folic acid Calcium

Potassium Sodium lodine Iron Coenzyme Q10

Copper



An innovative device that checks your nutrient levels using a smartphone is a perfect addition to your fit lifestyle and smart dieting habits.



your vitamin and

mineral levels









GET ADVISED in improving your vitality

your nutrient status

Secure https://www.indiegogo.com/projects/vitastiq-2-high-tech-vitamin-check-fitness-gadgets#/

How Vitastiq works?

EAV Methodology

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Apps Chrome Browser

Vitastiq monitors the relationship between the present body condition and a particular nutrient. It is based on the over 60 years old method called "Electroacupuncture according to dr. Reinhard Voll". The device measures the electrical resistance of the skin at an acupuncture point in relation to the reference point (reference point is determined during calibration). One thousand years of acupuncture experience suggests that acupuncture points differ from the surrounding skin.



Pharmacists, nutritionists and other experts have been using electroacupuncture for decades to track any imbalances that might be present in the human body. So far, only impractical, large analog devices were available to them. Vitastiq has combined this well-known method with modern technology and made it accessible to everyone.

Disclaimer: App Store, iPhone, Android and iOS are the trademarks of third parties. Vitastiq Inc. is not affiliated with, sponsored, licensed or associated with any of these third parties. Vitastiq is not a medical device. It cannot prevent, treat or cure any medical problem nor can it diagnose a medical condition.

HC-212SF FitScan Breath Checker



Sensor		Display Levels	Dimensions
Semi-Conduc	or Gas Sensor	6	4.4" X 0.8" X 0.7
Power			Weight
1 AAA batter	(included)		1.1 oz.

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

Product Details

Specifications

Product Manual

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



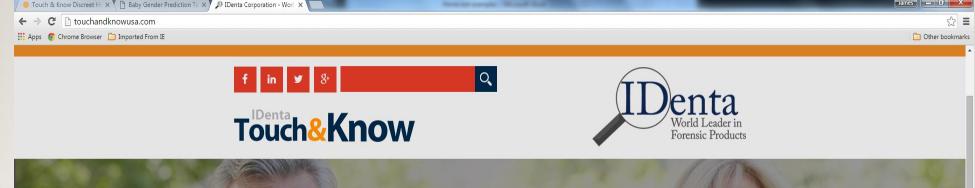
Strong odor



ntense odor



Emor Please try again









Touch&Know

DRUG TESTING KIT

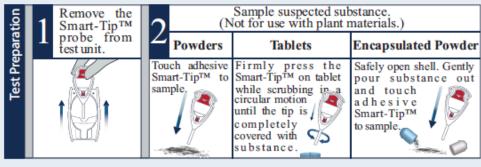
Procedure Card for IDT 9000-10 IDenta **General Screening Drugs** Substance

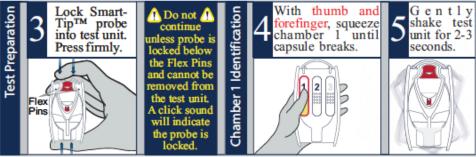
As a precaution, gloves and eye protection should be worn when handling drug substances and using test units.

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.





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.

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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.

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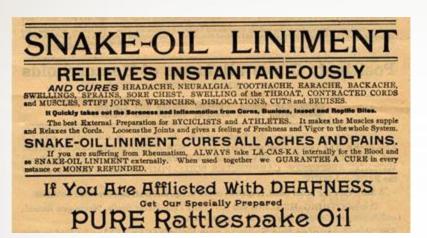


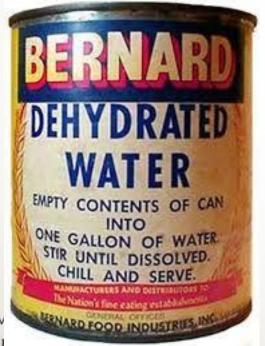


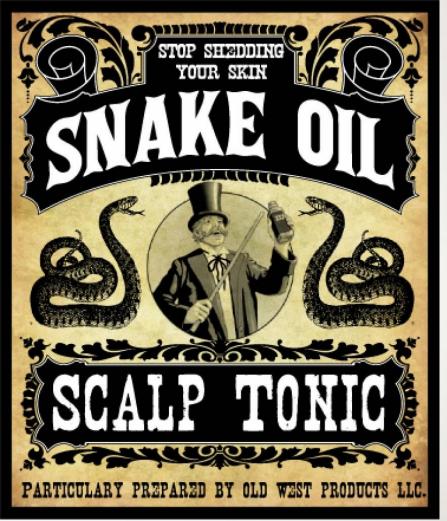




Home Testing can be Snake Oil!

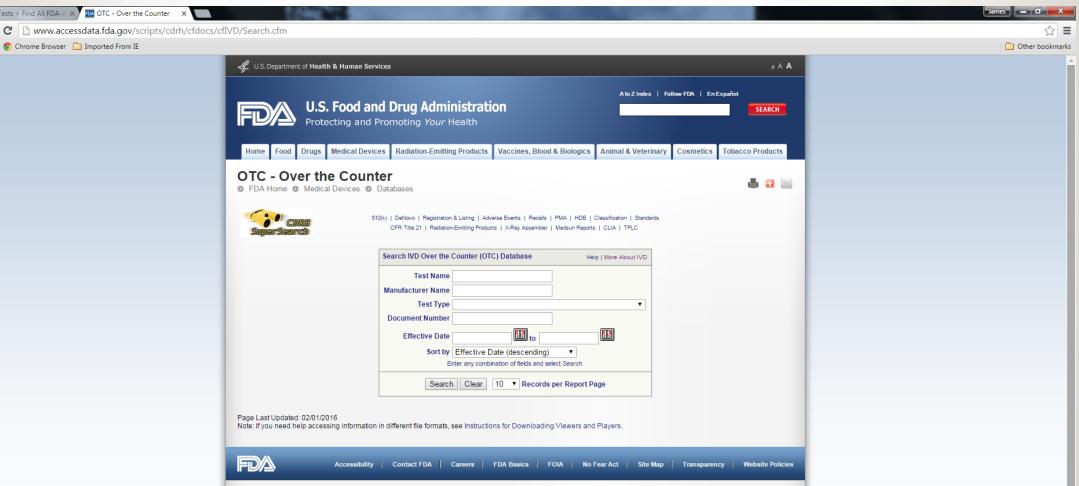






How are Consumers to Know?

- Consult a doctor!
- Search the product for FDA Approval!



Your Guide to Quackery, Health Fraud, and Intelligent Decisions

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 exclusive 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 large medical offices, very few facilities have high-complexity approval. Only a few states restrict the use of unestablished laboratory tests. Nevertheless, if you encountered ask your state laboratory department to investigate.

Blood Tests

- ALCAT testing
- · Aroonsakul 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
- · Bolan'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 Metabolics Analysis
- Glucose tolerance test for "hypoglycemia"
- · Health Equations Blood Test Evaluation
- HealthPrint
- · Hemobiographic analysis
- Individualized Optimal Nutrition (ION)
- <u>Live Blood Cell Analysis</u> (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"
- NuTron Testing
- *Nutrabalance
- OncoDiagnosticator
- · Oxymark and Oxymark Stress tests
- · Polymerase chain reaction test for protomyxzoa
- · Polymerase chain reaction (PCR) for Lyme disease
- Polymerase chain reaction: other inappropriate uses (link to Aetna Clinical Policy Bulletin)
- · 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

















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our price: \$26.99

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Additional Required Labratory Fee has Increased

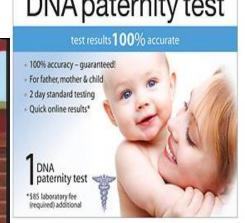
For Father, Mother & Child

- 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.







view larger image



reveal DNA Paternity Test 1ea











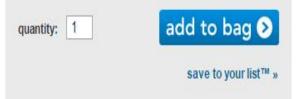
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reveal DNA Paternity Test 1 ea



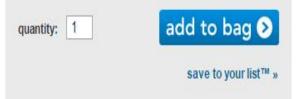
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- Laboratory/manufacturer marketing to consumer
- Pay for test out-of-pocket insurance doesn't cover
- Order tests without a physician
- Menu may be limited by state laws varies by location
- Blood collected onsite
- Sent to CLIA certified lab for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





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- » 5-Androstendiol
- » Bolasterone
- » Boldione
- » Calusterone
- » Clostebol
- » Dehydrochlormethyltestosterone
- » 5?-Dihydrotestosterone

- » 1-Androstendione
- » 4-Androstendione
- » 5-Androstendione
- » Bolandiol (Norandrostendiol)
- » Boldenone
- » Clenbuterol (anabolic agent)
- » Danazol
- » Desoxymethyltestosterone
- » Drostandiol

FEATURES & BENEFITS

- » Convenient collection kit for use in the home, school or workplace
- » Innovative specimen collector design minimizes leakage during transportation
- » Use of LC/MC/MC technology for highly accurate results
- » Comprehensive testing
- » Laboratory and 2-Day FedEx shipping included
- » Medical Review Officer (MRO) Report for a complete interpretation of
- » The option to do a confidential test (for home use) or a professional test (for school, workplace and business use). Please note: confidential



Register kit



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Learn how your body responds to 204 different foods



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Screen for 6 common sexually transmitted infections



Measure 11 key biomarkers

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Women's Health Test Metabolism Test

Measures three hormones that can affect weight and energy levels



Everlywell News and Info

Are Everlywell tests covered by FSA/HSA?

Key Points

- Everlywell can give you an itemized receipt for a kit you order (as long as the kit has been registered). You can then submit that receipt for FSA/HSA reimbursement.
- Many FSA/HSA benefits coordinators consider Everlywell tests to be qualified medical expenses (as defined by the IRS).
- Some FSA/HSA benefits coordinators, however, might deny reimbursement so consider checking with your benefits coordinator to see if your FSA/HSA covers Everlywell's tests before purchasing.
- To get an itemized receipt for your Everlywell test, simply send an email to contact@everlywell.com (include your order number in the email).

So you've got some money in an FSA/HSA account – but now what? Can you use it to get any of Everlywell's at-home lab tests or online telemedicine option?

Whether you open a Flexible Spending Account (FSA) or Health Savings Account (HSA), you're basically opening a savings account – that comes with tax benefits – to use specifically for healthcare expenses. This includes expenses that are part of your health insurance plan, like deductibles and copays, but you can also use the funds to cover qualified medical expenses.

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- No Insurance? High Deductible

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Paternity/DNA



STDs







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- Blood Tests

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ANY LAB TEST NOW® is the first direct access lab testing services company,

Genetic Direct-to-Consumer

Testing

- Ancestry and heritage
- Predisposition
 - Type 2 diabetes
 - BRCA1/BRCA2
 - Celiac disease
 - Late-onset Alzheimer's disease
 - Parkinson's Disease
 - Allergies
- Wellness deep sleep, lactose intolerance, genetic weight, diet/exercise
- Carrier Status cystic fibrosis, sickle cell anemia, hereditary hearing loss
- Traits hair loss, unibrow, sweet vs salty, skin tone, morning sickness
- Personality aptitude, wine match, neuroticism, loneliness





ancestry Health



mygenomebox⁶



Direct-to Consumer Testing

Advantages

- Patients become consumers of medical information, more educated about health
- More control and access to personal information
- Benefits of self-testing for prevention/management of chronic disease (diabetes, lipids)
- Cost more transparent high insurance deductibles vs DTC lower cost pricing

Limitations

- Overutilization easy access and affordable pricing can lead to false positives
- Patients can't interpret results or misinterpret out of context with Hx and symptoms
 - Misunderstanding of reference interval (95%) if normal, I must be healthy!
 - Worried well (needless concern) versus overestimating health (unaware and should refer to doctor)
- Quality consumers can't scientifically validate POCT devices, judge on usability
- Economics abnormal result, who pays for PT self-referral to physician follow-up?

Unintended Consequences

- False claims selling vitamin supplements, cancer treatments, miracle health cures
- Opportunity for laboratory professionals to become leaders in patient education



Recent Trends in Genetic DTC Tests

- Human genome discovery, Ancestry, gained 10 million users (2017 2019); 23 and Me gained 10 million users in 2019 alone, more than doubling previous 5 years
- Early adopters genealogy enthusiasts looking to fill family trees rushed to take tests, but concern over privacy of personal information keeping potential customers away
- As of January 2020, 3 companies (Arivale, Everlywell Inc, Vinome) have closed or suspended operation and Ancestry.com and 23 and Me have cut workforce (by more than 100 jobs or 14%); Arivale used genetics to find a disorder, while Everlywell offered food sensitivity testing and Vinome matched clients to wine based on genetics
- Genetic predisposition testing for dozens of diseases and traits have changed little. Family
 history is better predictor of disease risk than genetics for most and deciding action for
 troubling result is confusing. Customers don't know what to do with genetic results.



On-Demand Health Care

- COVID testing demands provided opportunity for public health and hospitals to open new healthcare facilities
- Mobile/Drive-Thru specimen collection tents
- Outpatient testing facilities for COVID testing
- Vanderbilt added ED extension in heated enclosed parking lot to handle patient overflow and prevent waiting room crowding (also added molecular POCT at neighboring walk-in clinic)
 - Controlled environment for POCT and reagent storage
 - Eyewash and biohazard disposal facilities
 - Ensure operator training and competency





Demand for coronavirus tests soars at Dallas County's main ...





Chicago hospitals set up testing tents, cancel non ..



Theranos in Turmoil

Continuing coverage of the blood-testing startup's rise and fall



- In AZ, Theranos successfully lobbied for law allowing labs to provide blood tests directly to patients without involvement by doctors, who are trained to question unusual results
- Gov Doug Ducey signed the law at Theranos' lab in Scottsdale in April 2015, citing Ms. Holmes' "devotion to serving and empowering patients with new and improved technology"
- Spokesman Daniel Scarpinato said AZ governor "continues to support citizens having access to their personal medical information, and other providers are currently operating under this reform"

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, and 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!)



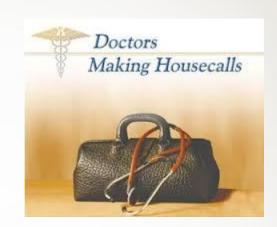
The New Wave of Healthcare (or is it?)

- Doctors making house calls
- POCT available for onsite testing!



ON THE CALL AGAIN: John A. Sterba, MD, PhD, FACEP, arrives with numerous med/surg kits at his disposal. Used with permission.







 $Q \equiv$

Patients and Visitors go to VanderbiltHealth.com



A-Z Index

Maps and Parking

People Finder

RESOURCES FOR EMPLOYEES

C2HR Self-Service

Email

Kronos

Nursing

Starbrite

Star Panel





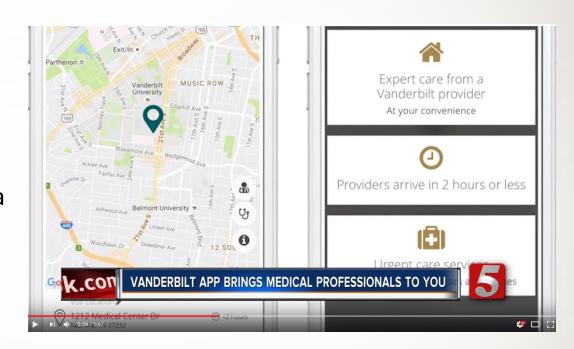
Giving

We are a nonprofit, academic medical institution relying on generous support to translate discovery into better health.

Vanderbilt Health OnCall

Rest where you are while we come to you.

- A nurse practitioner comes directly to the patient's home, office, or hotel
- After patients request an appointment, patients receive a non-emergent focused assessment, point of care lab testing and first dose medication delivery within two hours of their request







Future of POCT

- 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



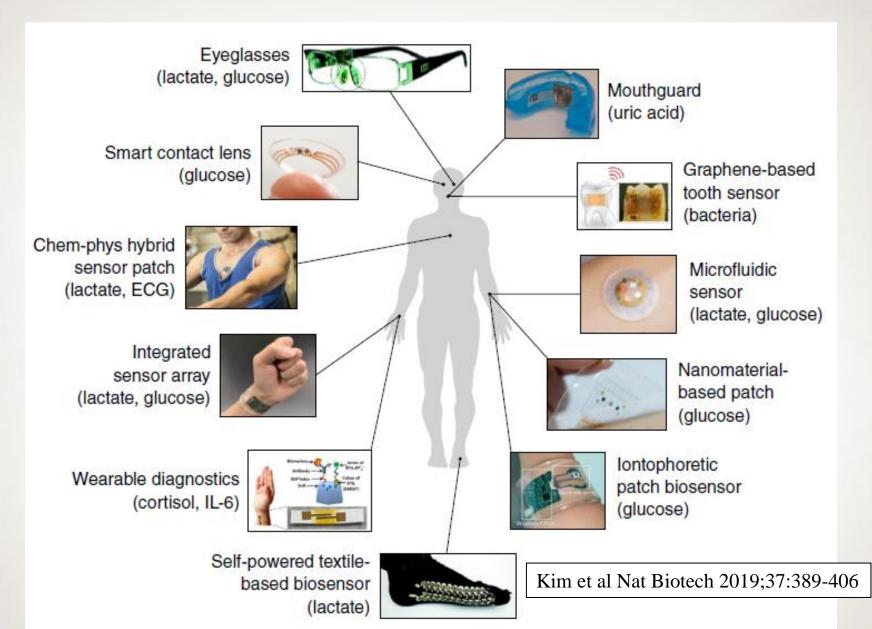














CAUTION BUYER BEWARE! Proceed At Own Risk



- · Enter the date of your last period
- . Tell it when you last had sexual intercourse
- · Check off the symptoms you're experiencing, such as nausea or fatigue
- · Indicate the types of birth control you're using, if any

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, and doctor house calls as an alternative to direct-toconsumer testing



Thank you

