Home Health and Opportunities for Point-of-Care Testing in Diverse Settings

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

- Define point-of-care testing (POCT)
- Identify ways that POCT is meeting new patient-driven requests
- Discuss the challenges of new POCT delivery models

• Disclosure: I have no vendor conflicts to disclose.



Early Healthcare

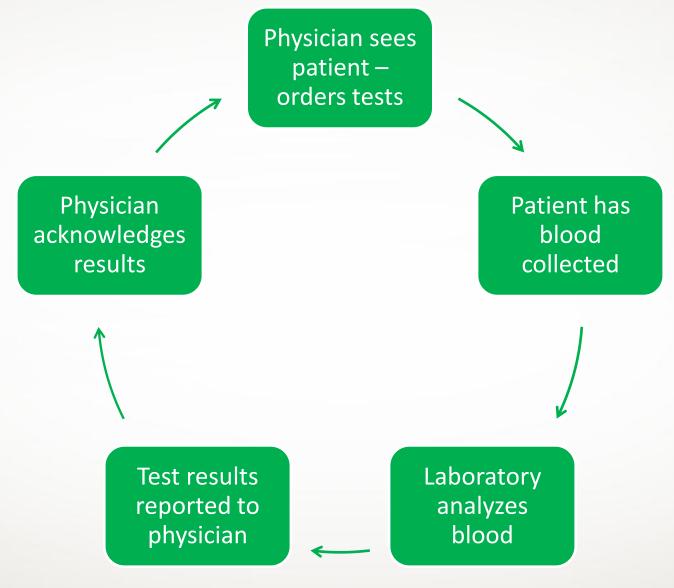
- Doctor house calls
- Physician visits patient in their home (patient-centered care)







Current Health Care Model





Point of Care Testing

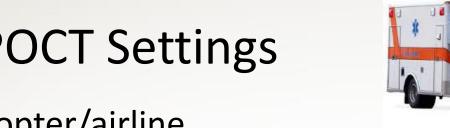
- Portable
- Native samples (unprocessed blood or urine)
- Doesn't require power or purified water
- Reliable enough for medical triage and management
- Simple can be performed by non-laboratory operators with minimal training and orientation
- Most POCT are CLIA waived tests in the US



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





Patient-Driven Point-of-Care Testing



Home Self-Testing

Antigen Self-Test Guided by a smartphone app The Intrivo On/Go COVID-19 Antigen Self

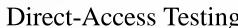
Test (also two tests per box) pairs with a

smartphone app that walks you through testing (including a timer to ensure you're collect your sample) and displays the



Direct-Access Testing











\$13.98 Amazon.com



Pregnancy Test \$71.68 Wholesale Sock



Walgreens Early Result Pregnancy Test - 2.0 Ea Walgreens.com

\$64.35



31% price drop

Mobile Collection **Testing Facilities**







Doctor On-Call Telemedicine

> Pharmacy Clinic



Urgent



Hospital



ED



Doctor's Office





**** 230

POCT Delivery Options

- Home self-testing = Patient conducts test/interprets result at home
- Self-Collection = Patient collects sample, mails to lab for testing
- Direct-Access = Facility where patient can order test and have sample collected
- Telemedicine = Remote physician consultation service
- Doctor On-Call = Clinician that makes house call or visits in home
- Hospital at-home = Inpatients discharged to home with visiting care
- Urgent Care/Pharmacy Clinics = Clinic for on-demand patient visits
- Doctor's Office = Walk-in and appointment based primary care clinics
- Emergency room/hospital = Acute care and inpatient health care



Home Tests Are Not Intuitive





INFERTILITY

Are You Fertile? Don't Rely on a Drug-Store Fertility Test to Tell You

By Bonnie Rochman | Oct. 28, 2010











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))

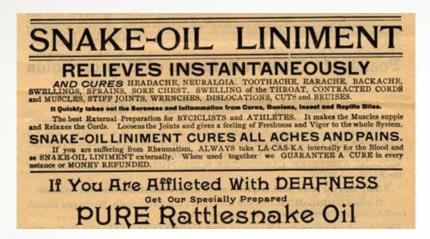


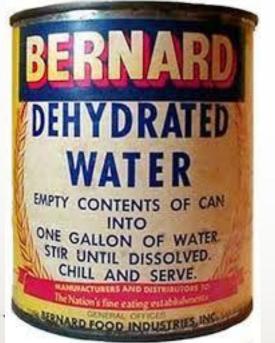


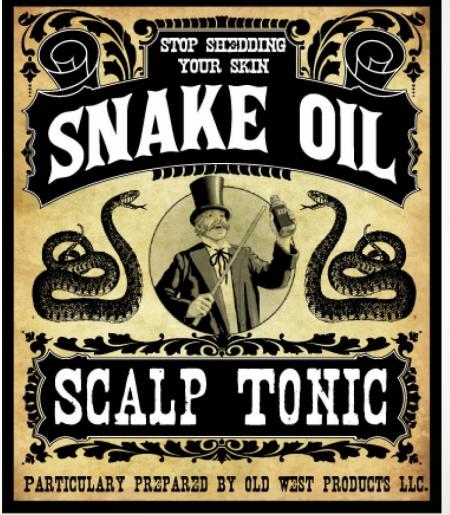




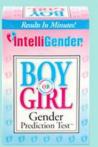
Home Testing can be Snake Oil!











{home} {aboutus} {contactus} {login} {register} {cart;;}

girl? boy?

Share the joy!

Experience the joy of discovery at home



KOR

CintelliGender

Prediction Test

{ order now

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 }





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: boy or girl? week 2 10 weeks







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

Limitations

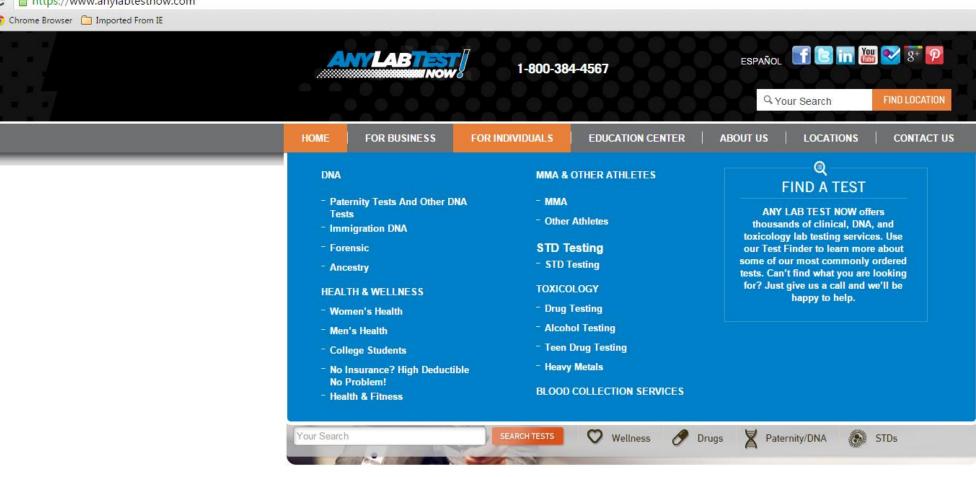
- Home tests may not be accurate!
- Performance depends on many factors:
 - Proper specimen collection,
 - Test operation,
 - Timing
 - Interpretation
- Out-of-pocket expense. Insurance does not reimburse cost of home testing.
- Home testing should <u>not</u> replace laboratory testing or regular physician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



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 or by POCT kit at home
- Sent to CLIA certified lab for analysis
- Results mailed back to patient or available online
- No physician interaction











Other

LATEST NEWS

Indiana Franchisees featured on IndyStar
 /® Congratulates

MOST POPULAR TESTS

- Allergy Tests
- Blood Tests

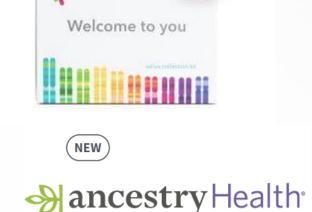
ABOUT US

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

Genetic Direct-to-Consumer Testing

X22srethe

- 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, morningness
- Personality aptitude, wine match, neuroticism, loneliness



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 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



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
 - These sites are laboratories!
 - Controlled environment for POCT and reagent storage
 - Eyewash and biohazard disposal facilities
 - Ensure operator training and competency
- COVID became first molecular POCT at Vanderbilt Clinics
 - Drafted policy requiring glove change and environment disinfection between each test!
 - Added environmental controls and increased frequency QC
 - Supply chain, unable to get COVID only test implemented COVID/Flu panel but had Flu antigen readers at clinics!





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





Chicago hospitals set up testing tents, cancel non .





Pharmacy 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)!

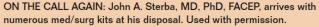




The New Wave of Healthcare (Or is it?)

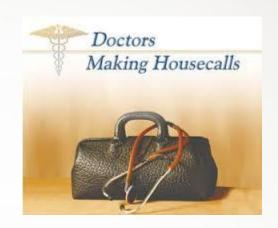
- Doctors making house calls
- POCT available for onsite testing!





VANDERBILT











Patients and Visitors go to VanderbiltHealth.com



A-Z Index

Maps and Parking

People Finder

RESOURCES FOR EMPLOYEES

C2HR Self-Service

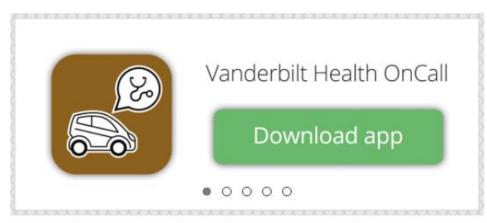
Email

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

Jennifer Mitchell, MSN, APRN-BC, Clinical Director

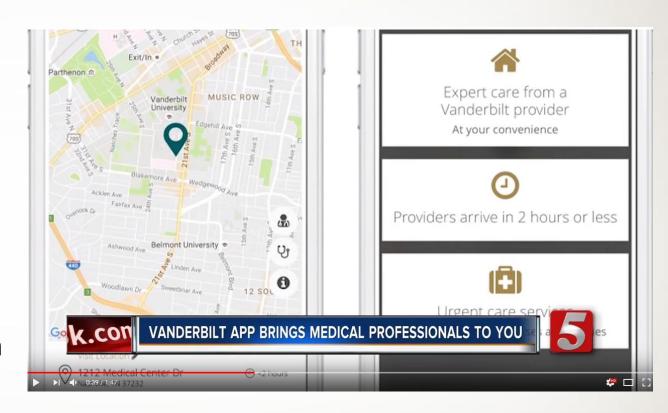




Vanderbilt Health OnCall

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.







How is a visit requested?

Visit <u>www.vanderbilthealthoncall.com</u> or download the app

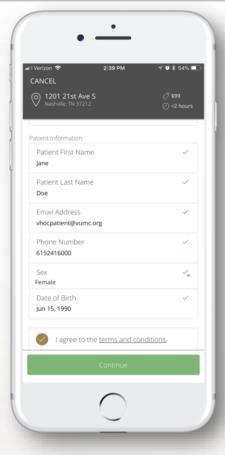


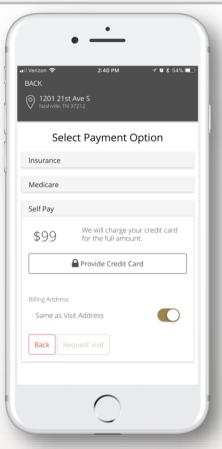


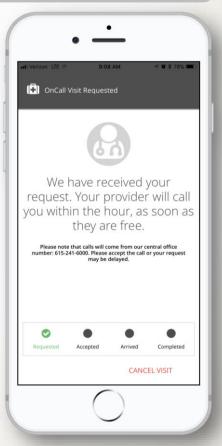














Point of Care Tests

- Strep A antigen test
- Influenza A & B antigen
- Urine pregnancy Test
- Dipstick urinalysis (visually read but want to make a reader portable)







Patient feedback through Social Media

"After a week of attempting to get over a sinus infection on my own, I finally decided I needed to take a trip to the doctor, but it was Saturday and I'd already missed my PCP's walk-in hours!

I looked online for a nearby urgent care and Vanderbilt OnCall came up. I requested a visit. I received a call from Kris letting me know that she'd be at my apartment in 40 minutes.

Vanderbilt OnCall is an amazing new service. Young people (like myself) who put off going to the doctor for lack of time...this will change your life!!"

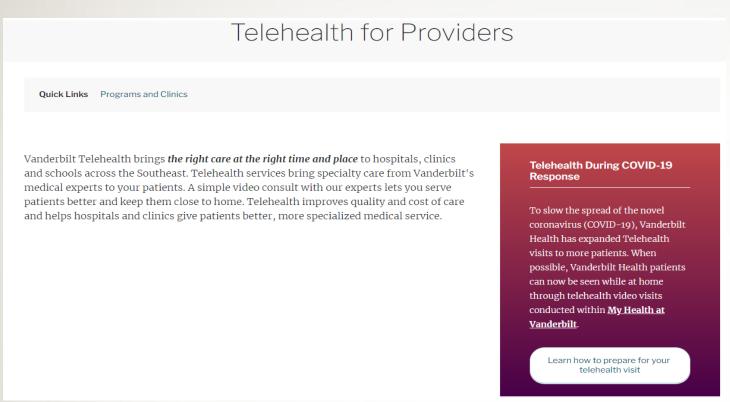
- J Moore







Telemedicine and Remote Health Care



Why Choose Vanderbilt Telehealth



Brings our expertise to you

Vanderbilt Telehealth is a convenient and cost-saving way to expand your medical services. Telehealth brings our specialty care to your hospital, clinic or school. A simple video consult with our experts from any location lets you serve patients better and keep them close to home.



Meets patient needs

Telehealth helps you serve patients better by connecting them to a Vanderbilt medical expert without needing to travel from your local hospital, clinic or school. A recent survey of patients by Vanderbilt University Medical Center shows over 90% interest in using more telehealth services.



Convenient and easy to use

Vanderbilt Telehealth is affordable and simple to set up. The only technical requirement is a networked device such as a laptop, tablet or phone.



Easy implementation and support

Once you are ready to begin using Vanderbilt Telehealth, we provide full implementation services. Our free support includes testing, observation and training. We will continue working with your team after your service begins.



Customized service

Vanderbilt Telehealth works with providers to develop a custom service model for their unique needs.



Secure communication

All video conferencing is secure and HIPAA compliant. Any medical records or other information can be exchanged through a secure platform.

With COVID more patients prefer telehealth visits, but this increases reliance of clinicians on the patient's home testing devices – with unverified performance and no routine QC. Clinics with only flu antigen testing – request patient to use home COVID test, if negative, come in for flu testing.



Hospital at Home

- Inpatients treated at home
- Challenges POCT management
- Many patients have diabetes
 - Allow use of patient's glucose meter?
 - Performance not verified, no routine QC
 - Variable devices and test strips on market
 - Manual recording of results, potential for entry errors
 - Some on continuous glucose monitors
 - How to input data in electronic medical record?
 - How to document accuracy/reliability of results?
 - Visiting clinicians use hospital glucose meters?
 - Performance verified, meters regularly QC'd
 - Data transmitted to EMR when connected to wireless



Quick Links Programs and Clinics

Many patients would rather be at home than in the hospital when they're sick. Our program provides the same high level of care you get in the hospital to the comfort of your home. You may be offered this service based on your condition, insurance plan and geography after you have been assessed in the hospital or emergency department.

Why Choose Hospital at Home Care at Vanderbilt



Highly skilled caregivers

Our dedicated team is specially trained to deliver home care services to meet all of your unique needs. We deliver the quality and level of care you expect from Vanderbilt. That team may include doctors, nurse practitioners, nurses, phlebotomist, physical and occupational therapy, social work or mobile radiology.



Patient-centered care

Our team, which includes nurses and nurse practitioners with your doctor's oversight, provides sensitive and compassionate care focused on you. Caregivers work closely with your doctor to provide you with personalized care tailored to your specific needs, abilities and preferences. Our team provides transportation, food, nutrition, medical equipment, medication and access to telehealth and remote imaging. Together, we will find the right care options for you.



Advanced technologies and treatments

Our team utilizes the latest technologies and research-based treatments to provide you with the most advanced care available.



Convenient care

In addition to in home visits by your nurse and provider, you will have, your nurse will give you a tablet with a simple button that allows you to connect to the care team via telehealth 24 hours a day, seven days a week. We'll also give you a phone number to call if you have any questions or problems. We can take your calls 24 hours a day, every day.

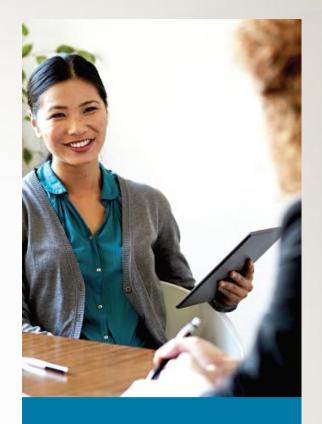


Corporate Health Services

- Corporate Health Services encompasses Executive Health, Corporate Health and Wellness and Workman's Compensation to corporate clients and their employees
- COVID pandemic led to new opportunities for testing
- Concierge medicine
 - Football, Hockey, Soccer and other sports team player testing
 - Attendees to events who have not been vaccinated or require COVID testing for entry to show, event, or concert

Challenges

- The only COVID "antigen" test offered in health enterprise
- Concern over making a COVID antigen reader that is intended to remain plugged in on a lab counter, portable - quality concerns with moving readers



Vanderbilt Corporate Health and Wellness

Vanderbilt Corporate Health and Wellness offers comprehensive and customized health screenings, immunization services and wellness education to improve the health of employees in Nashville and throughout Tennessee and the region.



Shade Tree Clinic



- Free health clinic run by students at Vanderbilt University School of Medicine
- Primary care home for underserved individuals in Davidson County providing comprehensive care for chronic illnesses, social services and health education.
- Interdisciplinary teams of medical, nursing, pharmacy and law students, supervised by professionals in their fields.
- Cost-free medical, social and pharmaceutical support to over 4,000 patients; uninsured, underserved, and patients experiencing housing insecurity.
- Laboratory services consists of 10 medical/nursing students who collect lab specimens during clinic hours and perform POCT (glucose, pregnancy, HbA1c, urinalysis)
- Other services include Community outreach (vaccines, Narcan kits, emergency food boxes),
 Nursing, Dermatology, Neurology, Ophthalmology, Orthopaedics, Physical therapy, Psychiatry,
 Rheumatology, Acute care, Patient Assistance and Spanish Services.

Summary

- POCT can provide rapid on-site laboratory testing near the patient
- Patient directed self-care is on the rise with home test kits and directaccess marketing
- POCT is expanding to a variety of settings
 - Pharmacies, minute clinics, home collection kits, direct-to-consumer testing and doctor house calls!
- The COVID pandemic has opened new opportunities for POCT as well as challenges to managing the quality and reliability of testing in order to meet changing patient-driven needs

