Point-of-Care Testing: Delivering Laboratory Quality Across the Continuum of Care

James H. Nichols, PhD, DABCC, FADLM
Professor of Pathology, Microbiology and Immunology
Medical Director, Clinical Chemistry and POCT
Vanderbilt University Medical Center, Nashville, TN
james.h.nichols@vumc.org

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Objectives

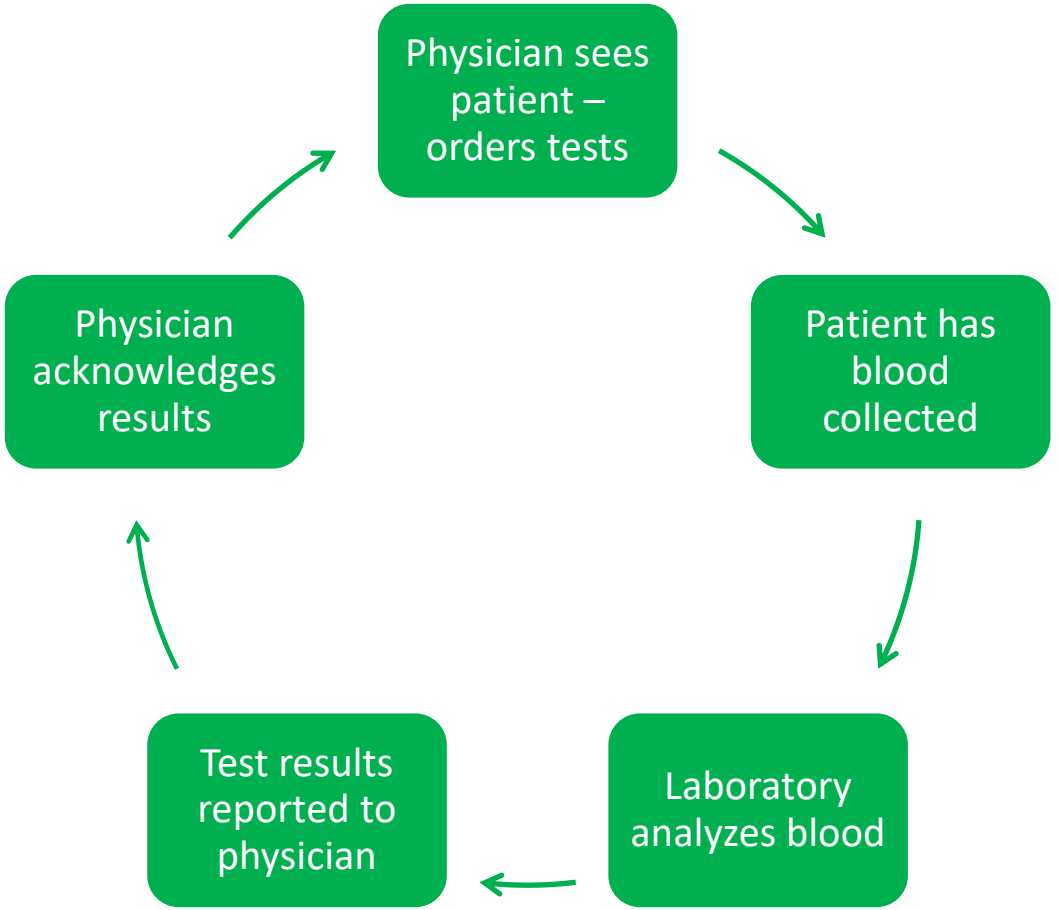
- Describe how point-of-care testing (POCT) is meeting patient needs in new ways
- Assess common mistakes operators make when performing POCT
- Identify the challenges of implementing POCT in different settings
- Define the elements of a quality management system for POCT

There is no conflict of interest

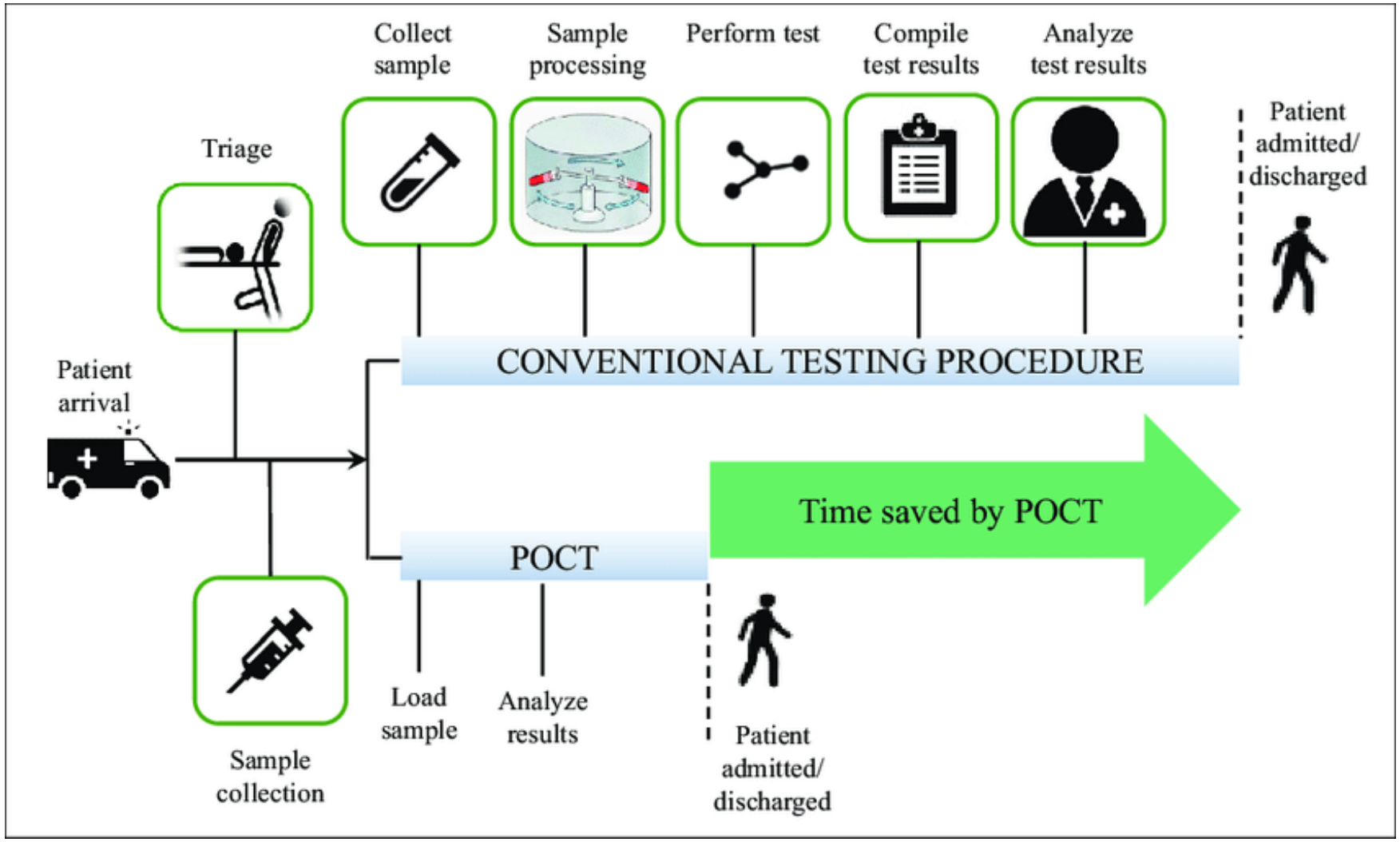
Early Healthcare

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

Current Health Care Model



POCT is a Disruptive Technology



Point-of-Care Testing

- Portable diagnostic testing
- 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

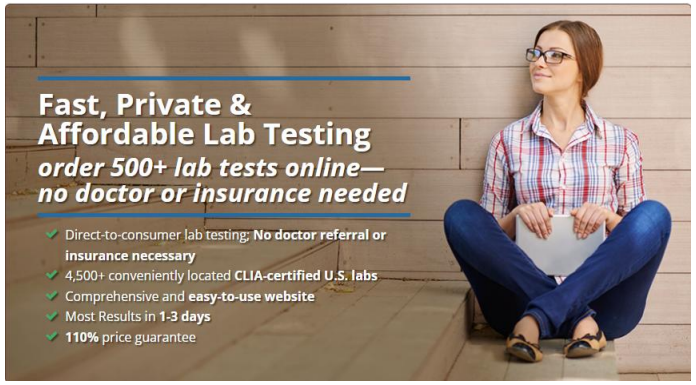
- Helicopter/airline
- Ambulance
- Cruise Ship
- Military field hospitals
- Disaster relief
- Expeditions
- Space shuttle

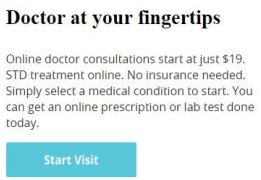
POCT Settings

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

Patient Driven Point-of-Care Testing

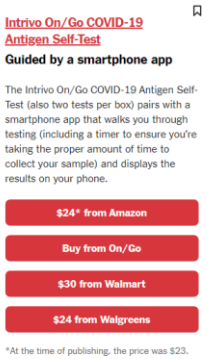
Home Self-Testing



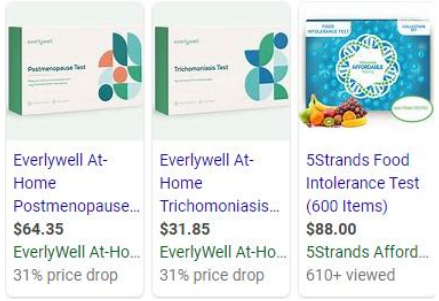


Doctor On-Call
Telemedicine

Hospital



Direct-Access Testing



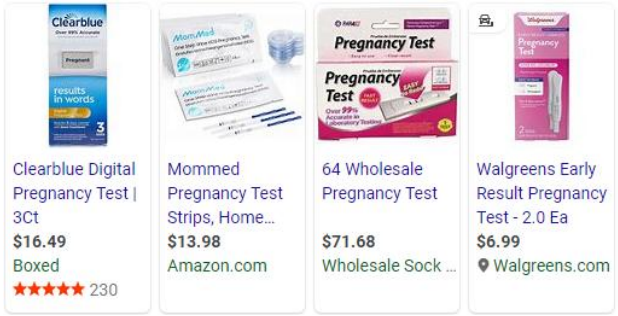
Online Ordering
Self-Collection

Pharmacy
Clinic

minute clinic

ED

Mobile Collection
Testing Facilities



Urgent
Care

Doctor's
Office

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 Self-Testing is Not Intuitive

TIME

Family Matters
By Bonnie Rochman

INFERTILITY

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

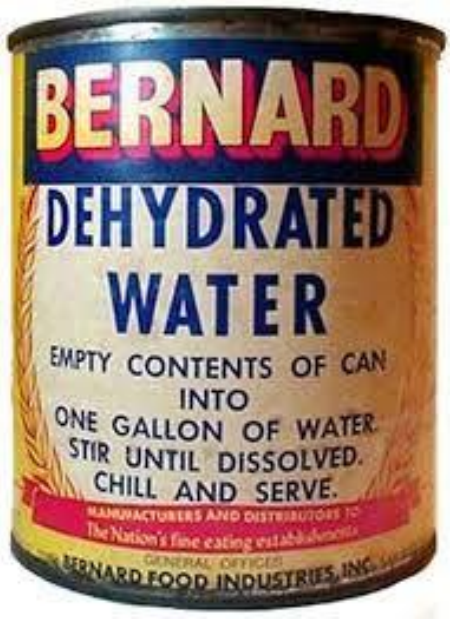
By Bonnie Rochman | Oct. 28, 2010

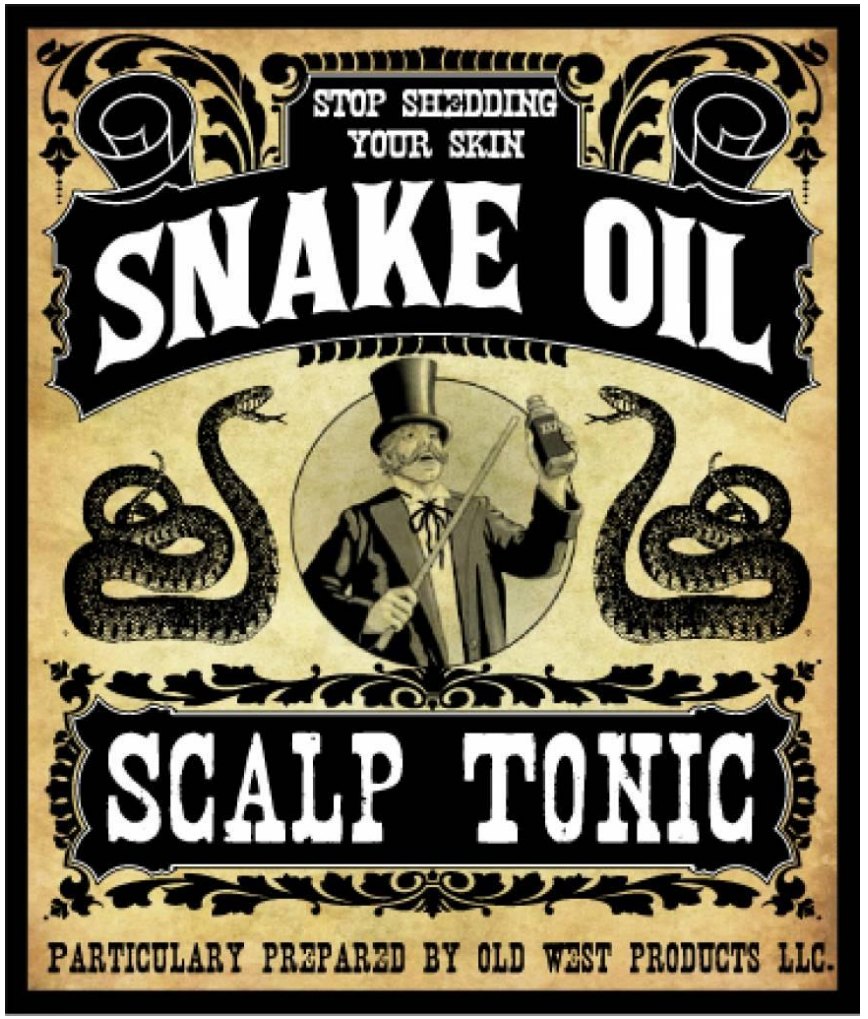
Share Like 0 Tweet Share Save Read Later

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))


BUYER
BEWARE

Home Testing Can Be Snake Oil!

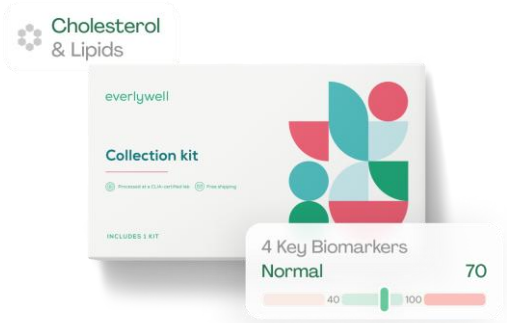


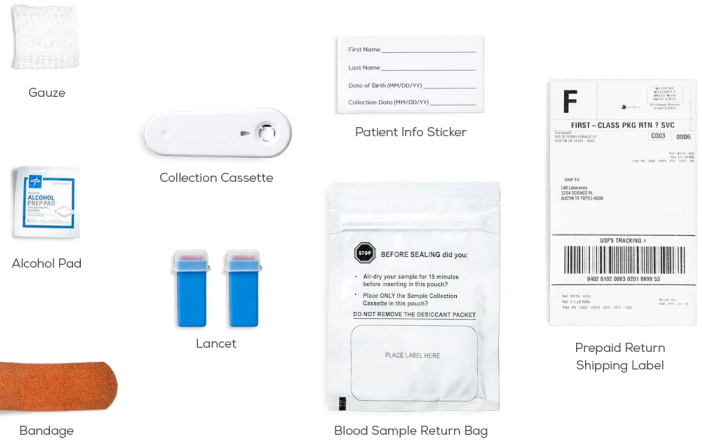


Limitations of Home Self-Tests

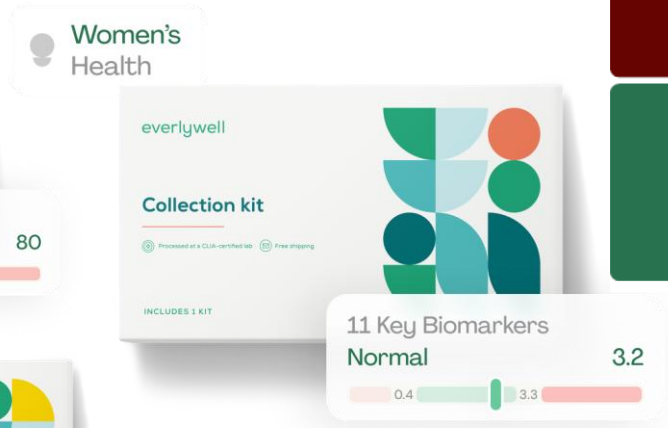
- Home tests may not be accurate!
- Performance depends on many factors:
  - Proper specimen collection,
  - Test operation,
  - Timing,
  - Interpretation
- Out-of-pocket expense. Insurance does not reimburse cost of home testing.
- Home testing should ***not*** replace laboratory testing or regular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

Home Collection Kits



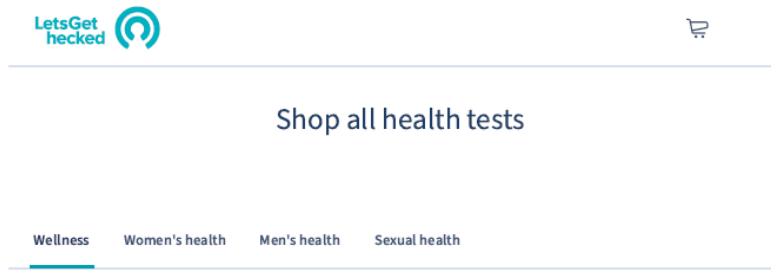


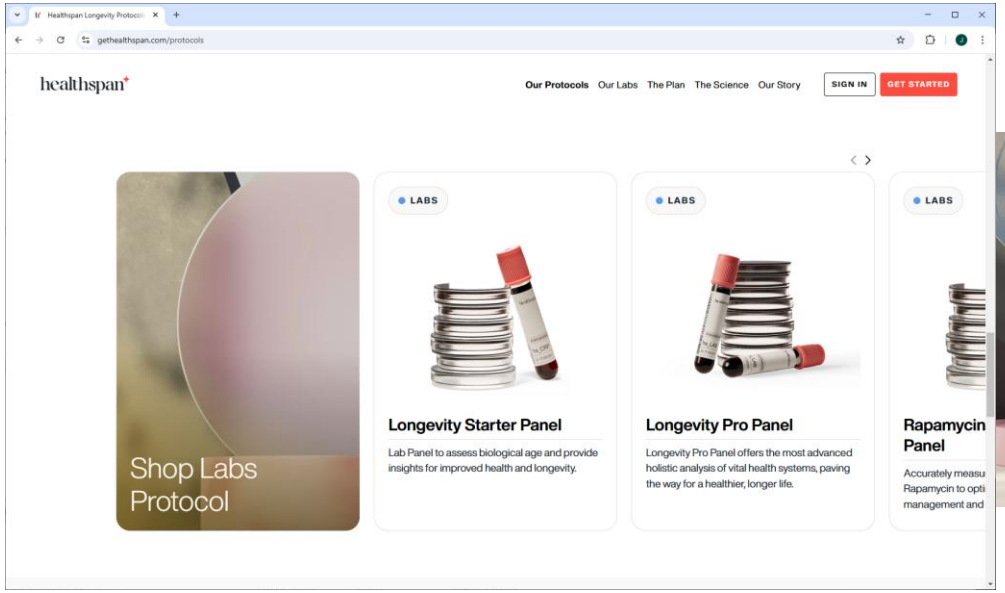
Cortisol, DHEA, Estradiol, Free Testosterone



Estradiol, Progesterone, LH, FSH, DHEAS, Cortisol, TSH, fT3, fT4, fTesto, TPOAB

IgG Ab to 204 Foods

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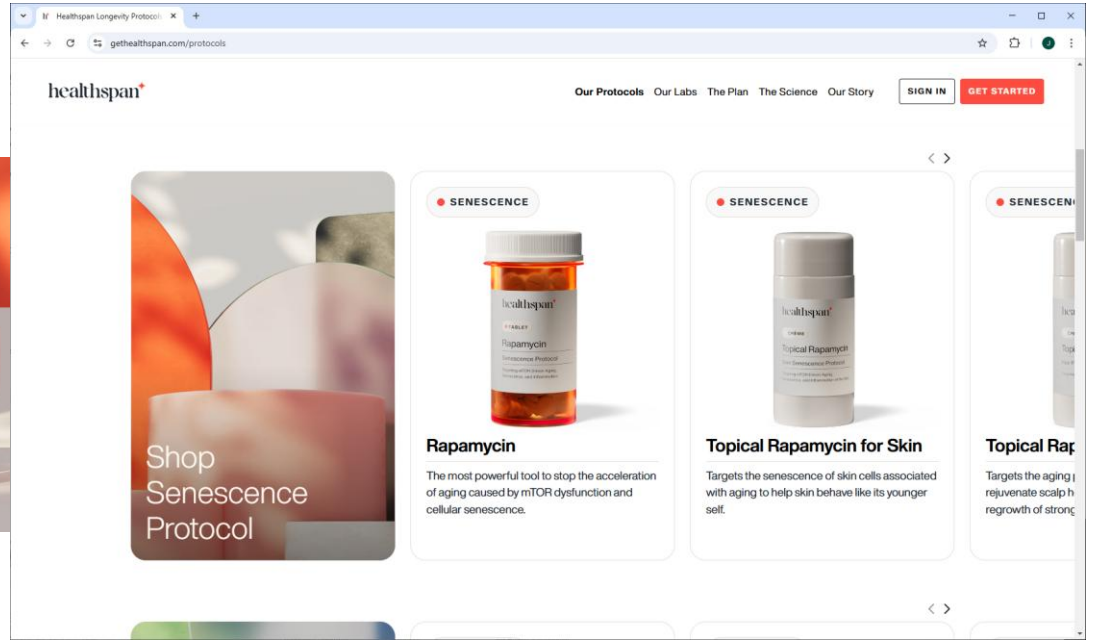
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Rapamycin
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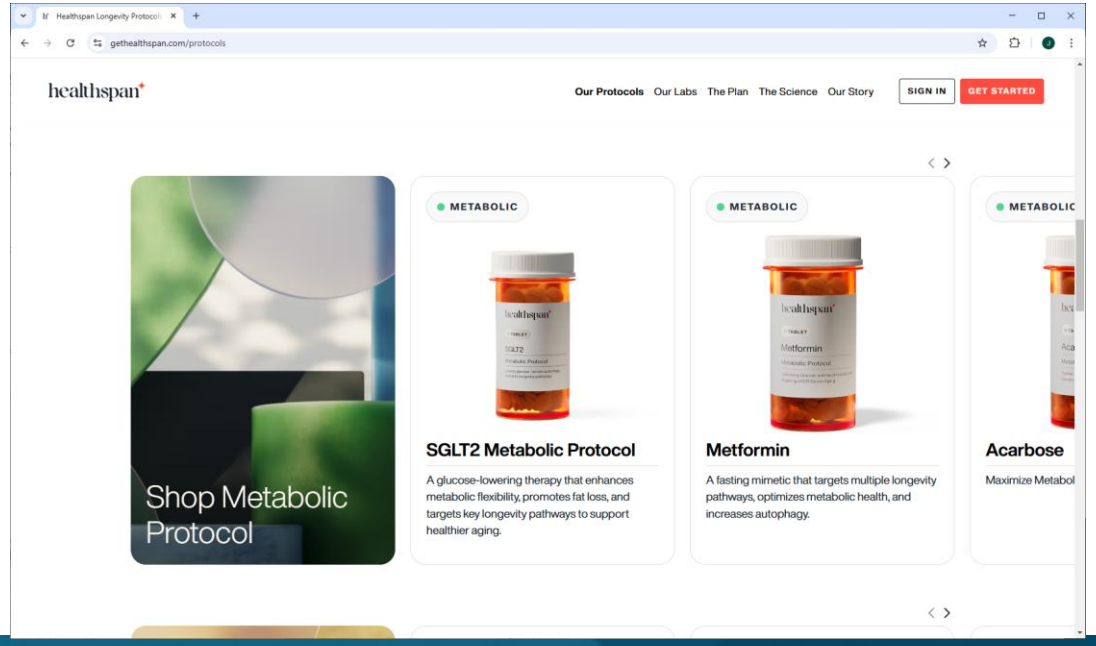
Targets the senescence of skin cells associated with aging to help skin behave like its younger self.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METABOLIC
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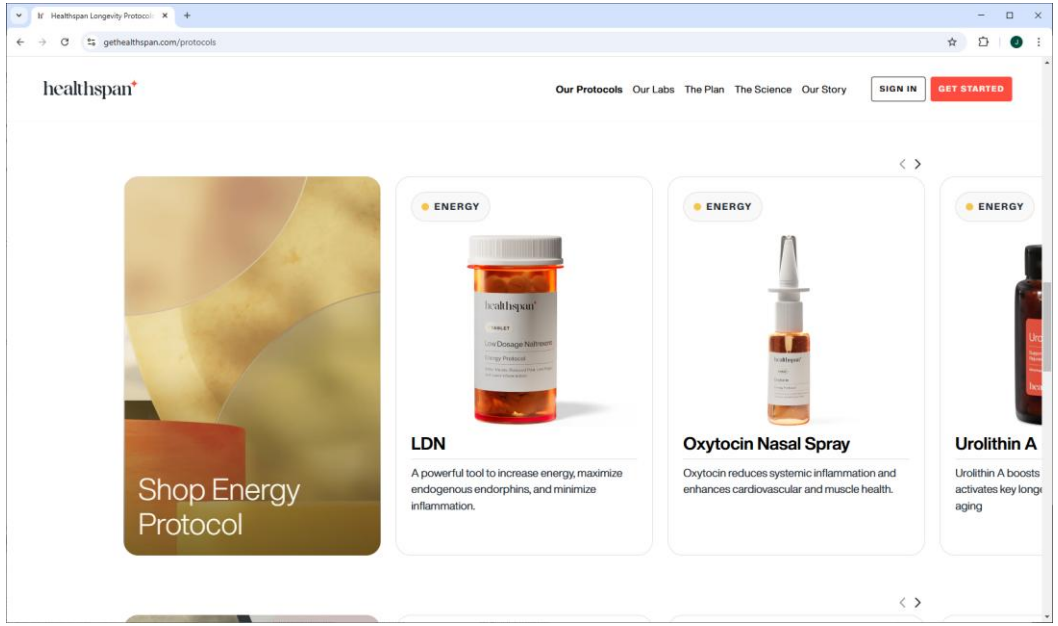
METABOLIC
Acarbose
Maximize Metabol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Oxytocin reduces systemic inflammation and enhances cardiovascular and muscle health.
ENERGY
Urolithin A
Urolithin A boosts
activates key longe
aging

Quality Laboratory Tests

- How does a patient ensure reliable, quality test results?

- Visit a professional healthcare facility with CLIA certified lab where clinical staff can properly collect specimens, perform testing and interpret test results in light of patient's symptoms, past medical history, and medications.

Patient Case

- Clinical complaint about glucose meter result discrepancy from ambulance service.
- Patient being transferred to another hospital had critically low glucose (40 mg/dL). Staff administered glucose bolus followed by another fingerstick glucose (49 mg/dL). Gave a second bolus of glucose and upon arrival at outside hospital, patient's lab glucose was 450 mg/dL.
- Critically ill patient with complex medical history, congestive heart failure, decreasing kidney and liver function, hypotensive on pressors to support circulation.

FDA Blood Glucose Monitoring System Guidance

- Concerns have been raised regarding performance of glucose meters in some populations
- Patients in healthcare settings more acutely ill, medically fragile and present with physiologic/pathologic factors that could interfere with glucose measurements
- Errors in BGMS accuracy can lead to incorrect insulin dosing, increased episodes hypoglycemia, and further risk to health
- For professional use, identify those critically ill sub-populations where BGMS may function differently.
- All inpatients, by virtue of their hospitalization, may be considered “critically ill”. So, critically ill patients are not just those patients in the ICU
  - Consider the OR, ED, Trauma, Sepsis, and others
- CMS and FDA indicate that the definition of what constitutes “critically ill” must be defined by each institution.

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

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Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 11, 2016.

The draft of this document was issued on January 7, 2014.

For questions regarding this document, contact Leslie Landree at leslie.landree@fda.hhs.gov, or at 301-796-6147.

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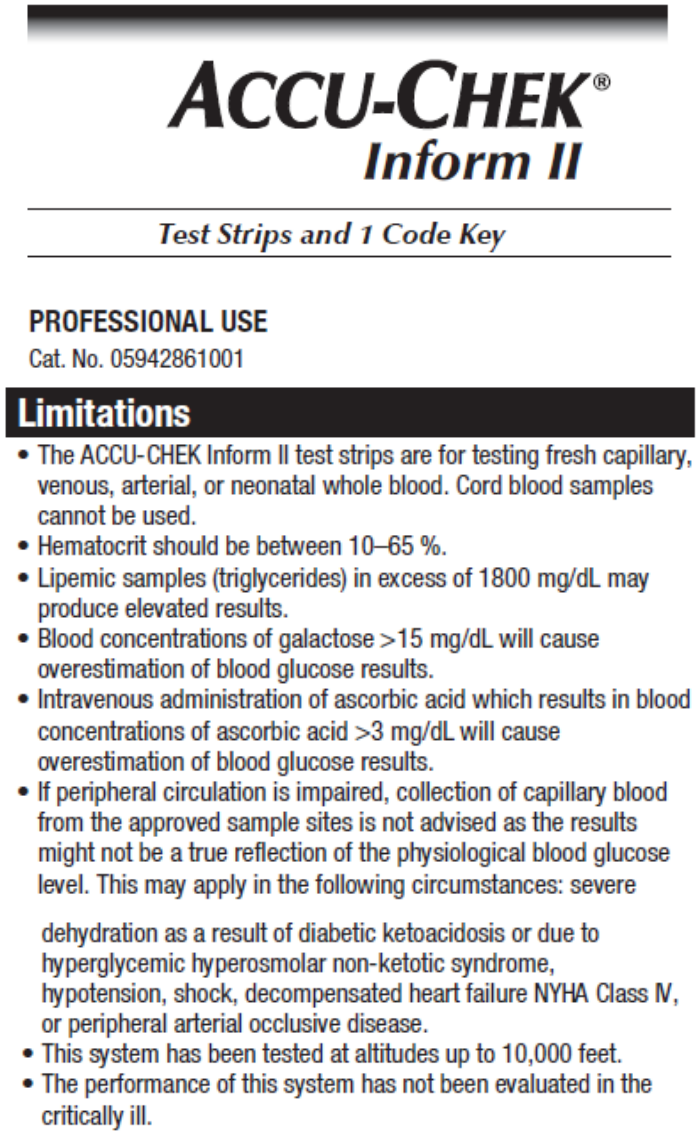

ACCU-CHEK®
Inform II

Test Strips and 1 Code Key

PROFESSIONAL USE

Cat. No. 05942861001

Limitations

- The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.
- The performance of this system has not been evaluated in the critically ill.

This limitation is new as of December 2012 for all glucose meters!

- Our policies and procedures reflect these limitations
- Staff trained to recognize these conditions
- Prevents off-label use of glucose meters which would revert test from CLIA waived to CLIA high-complexity

POCT is a Complex System

- **Laboratory**
  - One site
  - Limited instrumentation to perform bulk of testing
  - Limited staff, focused on same equipment daily
  - Staff trained in laboratory skills

- **POCT**
  - Dozens of sites, hundreds of devices and thousands of operators
  - Testing operators are clinically focused on patient not on equipment
  - Staff do not have laboratory training background
  - Testing delegated to lowest level staff (Patient Care Partners, MAs)

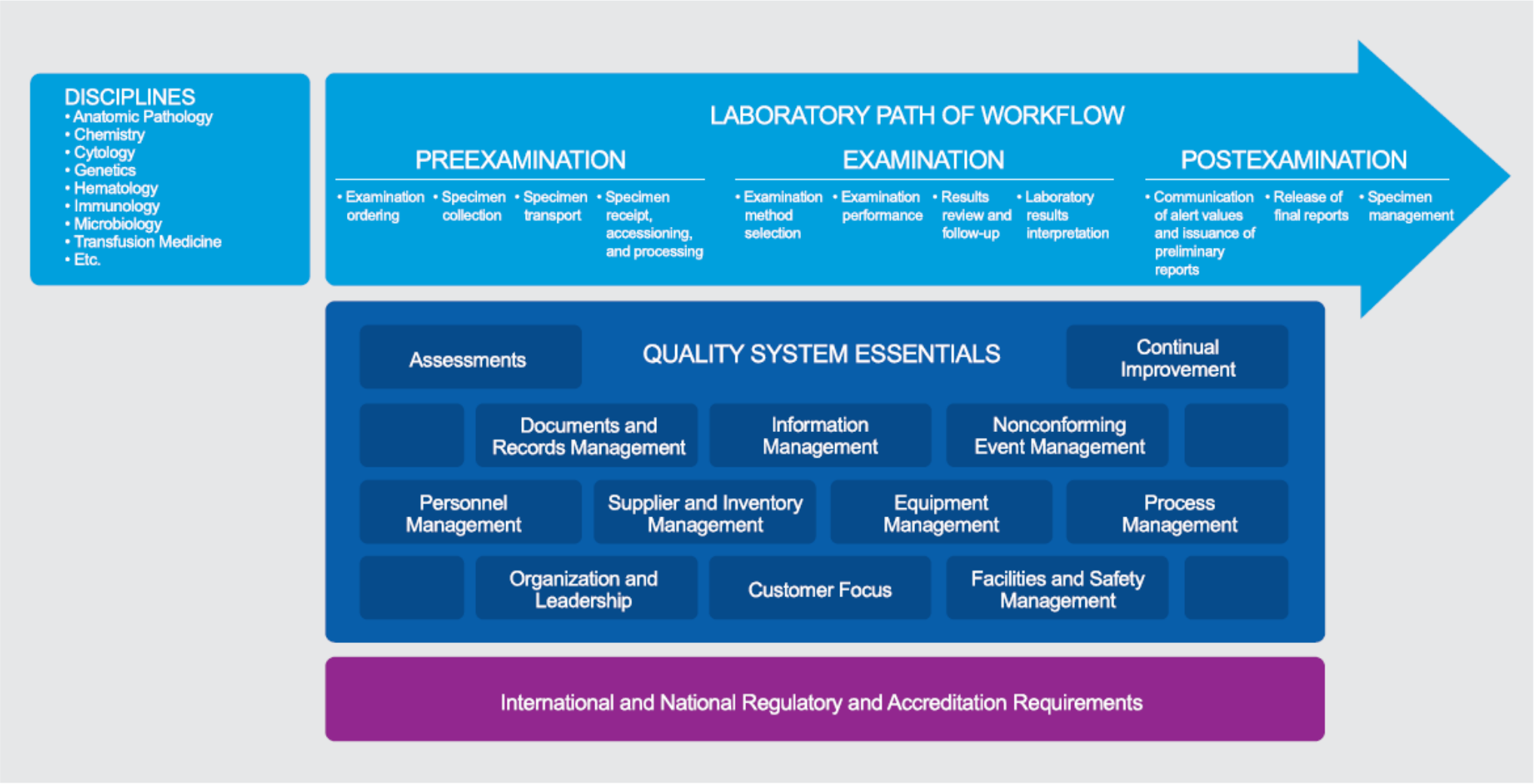

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

A QMS Defines Good Laboratory Practice

- Staff education and training
- Method validation, policies and procedures
- Reagent management and environment
- Quality control
- Documentation of results
- Proficiency testing
- Problem resolution and improvement
- Periodic inspection

Personnel

- Medical director: MD or PhD with board certification
- Clinical consultant: can be filled by medical director
- General/Technical supervisor: manage staff, resources and ensure policies are followed
- Testing personnel: minimum education requirement depends on test complexity
  - Waived – PCT/aids with High school and on the job training
  - Non-waived – 2/4 year college degree with science major

A Top 10 Inspection Deficiency

- CFR493.1403 Laboratory Director- Moderate (D6000) CONDITION – the laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart. (18.2% of all labs with deficiency)
- CFR493.1441 Personnel High Complexity (D6076) CONDITION – The laboratory must have a director who meets the qualification requirements of §493.1443 and provides overall management and direction in accordance with §493.1445. (9.56% of all labs with deficiency.
- CAP COM.01200 Activity Menu – the laboratory's current CAP Activity Menu accurately reflects the testing performed.

Non-Pathologist CLIA Medical Directors

(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least 1 year directing or supervising nonwaived laboratory testing; and

(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or

(3)

(i)

(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(B) Hold an earned doctoral degree; and

(*1*) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(*2*) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

42 CFR 493.1405(b)(3)(ii) (enhanced display)

Clinical Laboratory Improvement Amendments (CLIA)

- How to Apply for a CLIA Certificate, Including International Laboratories
- CLIA Accreditation and Testing
- CLIA Brochures
- CLIA Regulations and Federal Register Documents

CE Courses for Laboratory Directors

Continuing education (CE) credits for Laboratory Director qualifications should cover the laboratory director responsibilities defined at § 493.1407 and § 493.1445.

Please see the related links below for example courses. CMS does not sanction or endorse any specific course.

Related Links

CLIA – CME Course for Physician Lab Directors of Moderate Complexity Laboratories (University of Iowa)

CLIA Personnel Interpretive Guidance Revision

- CMS notes that the breadth and depth of science courses in a nursing curriculum is considerably less than those required for a B.S. in biology or chemistry.
- Nurses' education also lacks training in fundamental areas of laboratory science such as preanalytic, analytic and postanalytic phases of testing, calibration, quality control, and proficiency testing.
- Individuals with a nursing degree may still qualify as moderate complexity testing personnel, which covers most point-of-care testing, but cannot serve as Lab Directors, or Technical Consultants in those settings.

CAP Personnel Guidance Document

Use of Nursing for Annual Moderate-Complexity Competencies

Effective 12/28/2024

Technical Consultant Qualifications (GEN.53625)

Qualifying Degree	Training and experience	Education
Bachelor's degree, other 42CFR493.1405(b)(5)(i)(B)	Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the individual is responsible	At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either: • 48 semester hours of medical laboratory science or medical laboratory technology courses; **OR** • 48 semester hours of science courses that include: ○ 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; ○ 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and ○ 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination
Associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science	Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the individual is responsible	
Have qualified and served as a technical consultant **prior to December 28, 2024** in a CLIA-certified laboratory, and have worked continuously in the same role since then		CMS Survey and Certification memo 16–18–CLIA, issued in 2016, permitted a nursing degree to be considered equivalent to a bachelor's degree in a biological science. Under the CLIA final rule effective December 28, 2024, this interpretation was removed and nursing degrees will only qualify when specifically listed in the regulation.
Blood Gas Testing Only (unmodified moderate complexity testing)		
Qualify with a bachelor's degree or higher, as listed in the rows above		
Bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution	Have at least 2 years of laboratory training or experience, or both, in blood gas analysis	

A Top 10 Inspection Deficiency

- CAP GEN.55500 Competency Assessment Elements – Nonwaived Testing. The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

The **six required elements** of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens) or external proficiency testing specimens
6. Evaluation of problem-solving skills

- CFR493.1235 Personnel Competency Assessment (D5209) Standard – As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. (18.96% of all labs with deficiency)

Maintaining Competency with Infrequent Testing

- Clinic wants POCT glucose and 50 staff trained, but only rarely performs test (<5 x a year)

Multiple studies have concluded a single training event is not sufficient, and that ongoing competency, training, and support from the laboratory are needed to maintain improved test performance (12–17). The College of American Pathologists Q-Probes Study on bedside glucose monitoring found that institutions with a policy for scheduled performance reviews of operator or repeat/ongoing training had performed better than their counterparts (12, 13). We therefore recommend that POCT programs maintain on-going training and support for the clinical staff in conjunction with consistent monitoring of test performance.

Multiple studies document improved performance and quality of POCT when laboratories participate in PT/EQA programs, incorporate the PT results into a total quality improvement program, and act on the trends to identify and correct their mistakes. We recommend that all laboratories performing POCT participate in a PT/EQA program for each test that they perform.

While no studies have examined the number of tests performed by an operator as a factor for successful POCT PT performance, there are publications that indicate laboratories performing more than 10 tests a week, or greater than 100 tests per month, perform better on PT surveys and have fewer failures. We recommend that sites performing at least 10 tests a week or greater than 100 tests per month enroll in PT/EQA programs to monitor their performance and those performing POCT less frequently reconsider the clinical need for POCT at that location.

SPECIAL REPORT

AACC Guidance Document on Management of Point-of-Care Testing

James H. Nichols,[a,*] David Alter,[b] Yu Chen,[c] T. Scott Isbell,[d] Ellis Jacobs,[e] Norman Moore,[f] and Zahra Shajani-Yi[a]

INTRODUCTION

The American Association for Clinical Chemistry (AACC) Academy (formerly known as the National Academy of Clinical Biochemistry, NACB) formed a committee of experts on point-of-care testing (POCT) to revise the Laboratory Medicine Practice Guidelines (LMPG) Evidence-Based Practice for Point-of-Care Testing published in 2006 (*1*, *2*). The committee noted several areas of the previous guideline where there have been few additional publications over the past decade, such as transcutaneous bilirubin, intraoperative parathyroid hormone, and pH testing; however, most areas in the previous guidelines have several recent publications including cardiac markers, coagulation, critical care, diabetes, drugs and ethanol, infectious disease, renal function, and reproductive testing. Many of these areas have guidelines that are under revision by other organizations. Tackling all areas needing revision would greatly delay publication of the revised guidelines; hence the committee members felt that the highest priority for revision should address the "management of POCT."

POCT is a now proven approach that can provide faster turnaround (TAT) of laboratory test results. As manufacturers continue to introduce new POCT technologies, POCT is increasing in popularity, breadth of testing, and in the diversity of available clinical applications. POCT is currently routine in all hospitals and has become the standard for patient care in a variety of other health care settings. Therefore, this guideline revision will not focus on the various ways that POCT is utilized to support healthcare, nor focus on proving the value of POCT. Instead this guideline will focus on how clinicians can get the most efficacy and highest quality results from implementing best practices for POCT. A quality assurance program is vital to managing errors and the reliability of POCT results, and the intent of this guideline revision is not to debate the value or need for a quality management program. Instead, this revision will provide an update on the latest peer literature since publication of the previous guideline and focus on several key aspects of POCT process and patient outcomes such as:

- What is the value of an interdisciplinary committee to oversee POCT?

[a]Vanderbilt University School of Medicine, Nashville, TN; [b]Emory University School of Medicine, Atlanta, GA; [c]Dr. Everett Chalmers Regional Hospital Horizon Health Network, Fredericton, NB, Canada; [d]Saint Louis University School of Medicine, St. Louis, MO; [e]EJ Clinical Consulting, Teaneck, NJ; [f]Abbott Diagnostics, Scarborough, ME.
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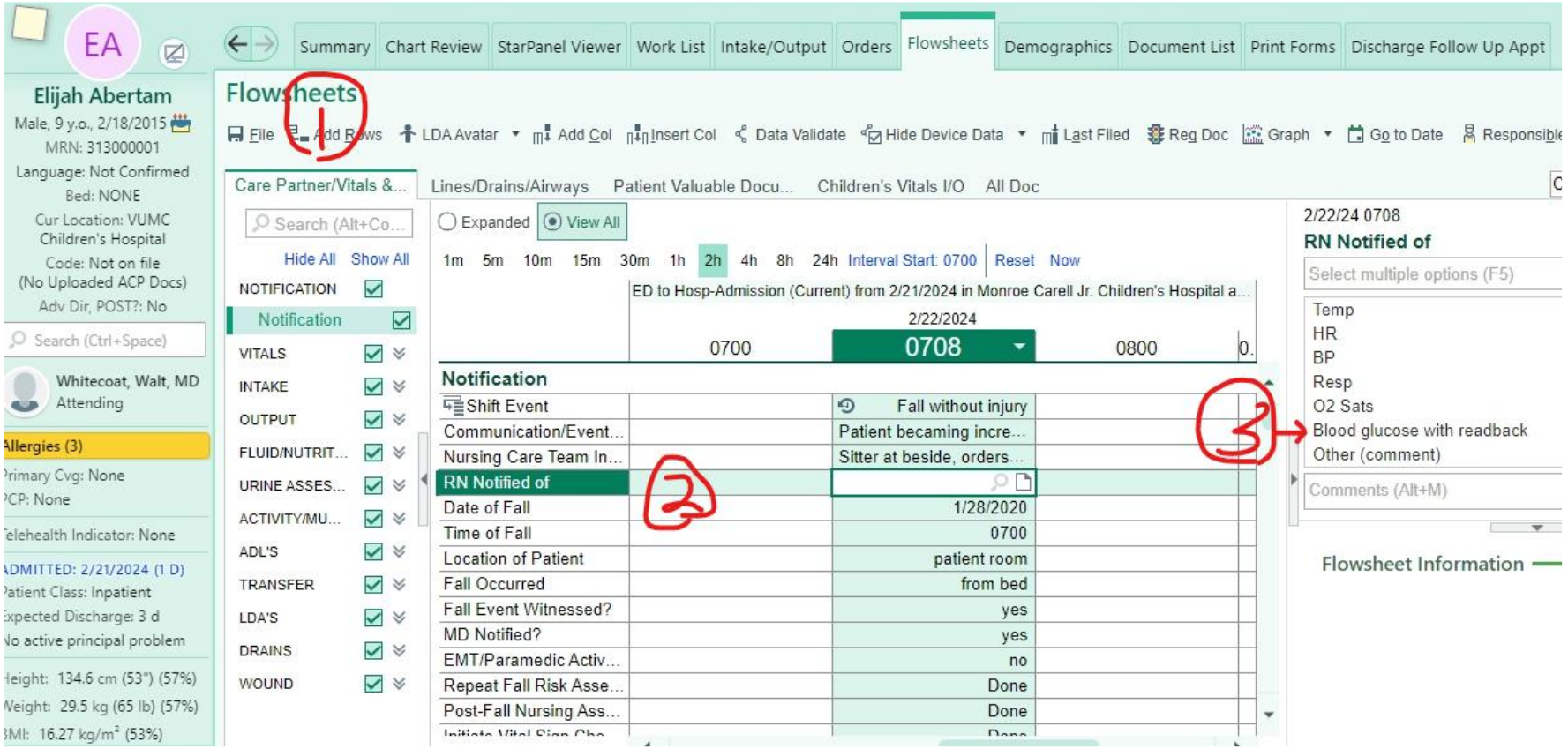
Care Partners and POCT

- Care Partners – high school diploma, no medical background and on the job training
- Historically conduct urine pregnancy and urine dipsticks in clinics
- Want to add Care Partners as operators for inpatient glucose meters
- Concerns:
  - Capillary fingersticks should not be conducted on patients with poor-peripheral circulation (severe dehydration (DKA), hypotension, shock, heart failure and peripheral vascular disease). But, Care Partners can't make medical/physical assessments of patients
  - Medications and conditions can interfere with glucose meters (hematocrit <10% or >65%, triglycerides >1800 mg/dL, galactose >15 mg/dL, IV ascorbic acid, IV N-acetylcysteine)
  - If poorly perfused, a venous or arterial sample can be obtained and analyzed on the glucose meter, but Care Partners do not perform phlebotomy

Care Partners and POCT

- Nurse is responsible for completing a physical assessment of patient to ensure patent circulation and no medication or condition that could interfere before delegating task of glucose testing to Care Partners.
- Possible signs and symptoms of impaired circulation could include:
  - Pigmentation, mottling, texture changes to skin, including peripheral cyanosis
  - Temperature changes in fingertips, specifically cold skin
  - Delayed capillary refill time (>3 seconds)
  - Diminished or absence of a pulse
  - Bilateral or unilateral edema
  - Sensation of touch decreased or lost, ie diabetic neuropathy
  - Pain, aching or throbbing
  - Clubbing of nail beds

Reference: Rhoads, J. & Peterson, S.W. (2014). *Advanced Health Assessment and Diagnostic Reasoning (2nd ed.).* Jones and Bartlett. pp. 238-69.



- **Care Partner Assessment:**
  - RNs delegate blood glucose POCT to CPs.
  - CPs must report blood glucose values to the RN.
  - CPs must report and document that they notified the RN of critical POCT blood glucose values (<40 and >500).
  - The option of 'Blood Glucose with Readback' will be added to the 'RN Notified of' flowsheet row.

Case Falsely Decreased Glucose Results

- Complaint from an ICU of sporadic falsely decreased glucose results
- Immediate repeat test on same meter, gave significantly higher “clinically sensible” values
- Inspection of unit found nurses taking procedural shortcuts to save time
- Bottles of test strips dumped on counter in spare utility room
- Some strips not making it into trash, falling back on counter and being “REUSED”

Risk of Error From Open Reagents

- Manufacturer expiration date imprinted on side of reagents/controls. Once opened, reagents and controls prematurely expire (30, 60 or 90 days) after opening.
- Glucose test strips exposed to air for as little as 2 hours have been shown to cause -26% bias.[1]
- Strips left on counters pose risk of reuse, leading to falsely low results.
- Some meters catch reuse and “error” preventing a result. Other meters do not![2]

1. Keffer P, Kampa IS. *Diabetes* 1998; 47; abs 0170.
2. Silverman BC, Humbertson SK, Stem JE, Nichols JH. Operational errors cause inaccurate glucose results. *Diabetes Care* 2000;23:429-30.

A Top 10 Inspection Deficiency

- CFR 493.1252(b) Analytic Systems (D5413) Standard – The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented. (17.5% of all labs cited with deficiency)
- CFR 493.1291 (c) Analytic Systems (D5417) Standard – Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. (12.9% of all labs cited with deficiency)
- CAP COM.30750 Temperature Checks – The laboratory monitors and records temperatures using a calibrated thermometer as defined in written procedure

Reagent Errors: Expired Reagents

- **Centers for Disease Control**
- "Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired."[1]

- **U.S. Food and Drug Administration**
- "Check the expiration date on the test strips. As a test strip ages, its chemical coating breaks down. If the strip is used after this time, it may give inaccurate results."[2]

1. Ready? Set? Test! Centers for Disease Control booklet https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf
2. Useful Tips to Increase Accuracy and Reduce Errors in Test Results from Glucose Meters, U.S. Food and Drug Administration http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109519.htm

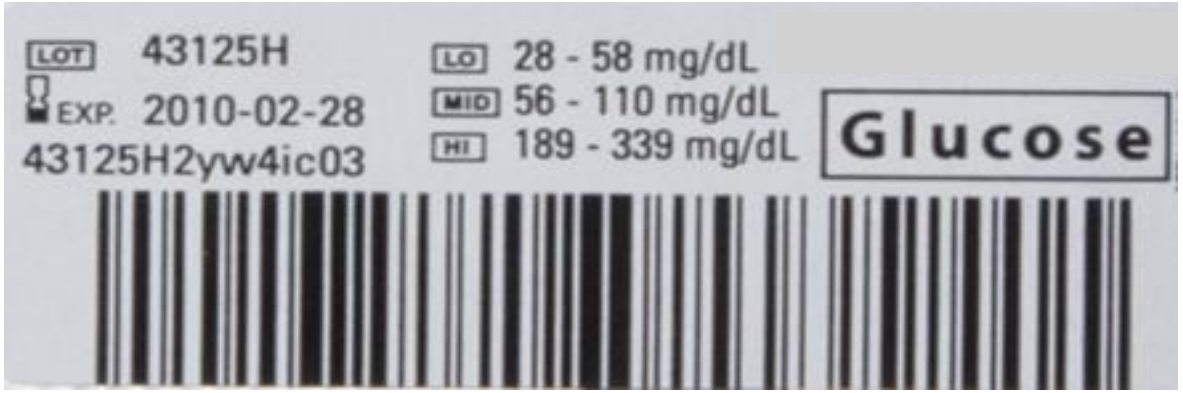
Strip Wastage When Outdated

- Operator must check manufacturer's open expiration date prior to testing.
- Vials/strips and controls must be manually dated when opened by operator (prematurely expires once opened)
- Undated, opened vials must be discarded. (? expiration)

1. Undated vials between September, 2010 and May, 2011, Willis-Knighton Medical Center, Shreveport, Louisiana

Reagent Errors: Expired Reagents

- Single-packaged test strips/reagents
- Newer serialized vials/strips and controls barcoded for lot number and expiration date (good to stamped expiration date) can recognize individual vials on first open use (30, 60 or 90 day open expiration)
- Automatic lockout for expired test strips and controls
- Some devices can also recognize exposure to humidity (few hours), wet or reused strips as additional control measure



POCT Temperature Error Complaints

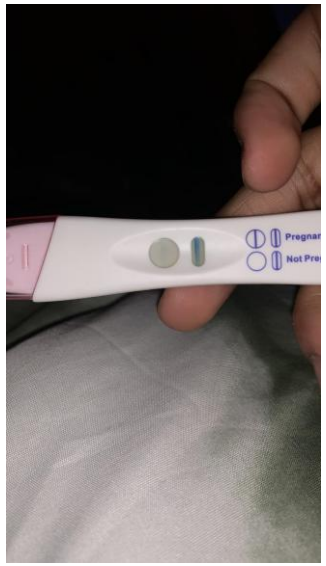
- Events management team complain that our current meter “temperature errors” in the field during concerts, festivals, and marathons outdoors in summer.
- Glucose test strips contain enzymes that can be denatured by temperature and humidity exposure.
- The staff need a glucose result.
- Another helicopter service stated their meter does not error outdoors. Team wants to change meters. Just need a number!

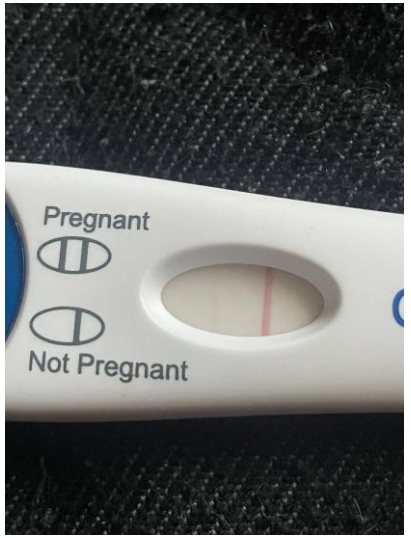
- Nashville highest temp 43C (109F in 2012), but typically has >7 days above 35C (95F)
- Current meter:
  - Use test strips 16–35C (61–95F)
  - Store test strips 2–30C (36–86F)
- Requested meter:
  - Use test strips 15–40C (59–104F)
  - Store test strips 1–30C (34–86F)
- Both meters temp error when testing outside “Use specifications”, at 42C.
- Current meter showed acceptable performance (+/- 6 mg/dL or 8%) for strips exposed up to 40C for 3 days while requested meter strip performance was outside TEa limits when incubated at 37C and 40C.

Seema Bhandari and James Nichols abstract submitted to ACPLS and ADLM 2025 meetings.

Urine hCG POCT – Importance of Timing

- Time the read of the test correctly – use a timer
- Any visible line at test zone is positive
- Overtiming can lead to ghost lines or evaporation lines
- Could be interpreted as early pregnancy
- Repeat test in 24 to 48 hrs
- Could also be “hook effect”
- Follow-up by different test

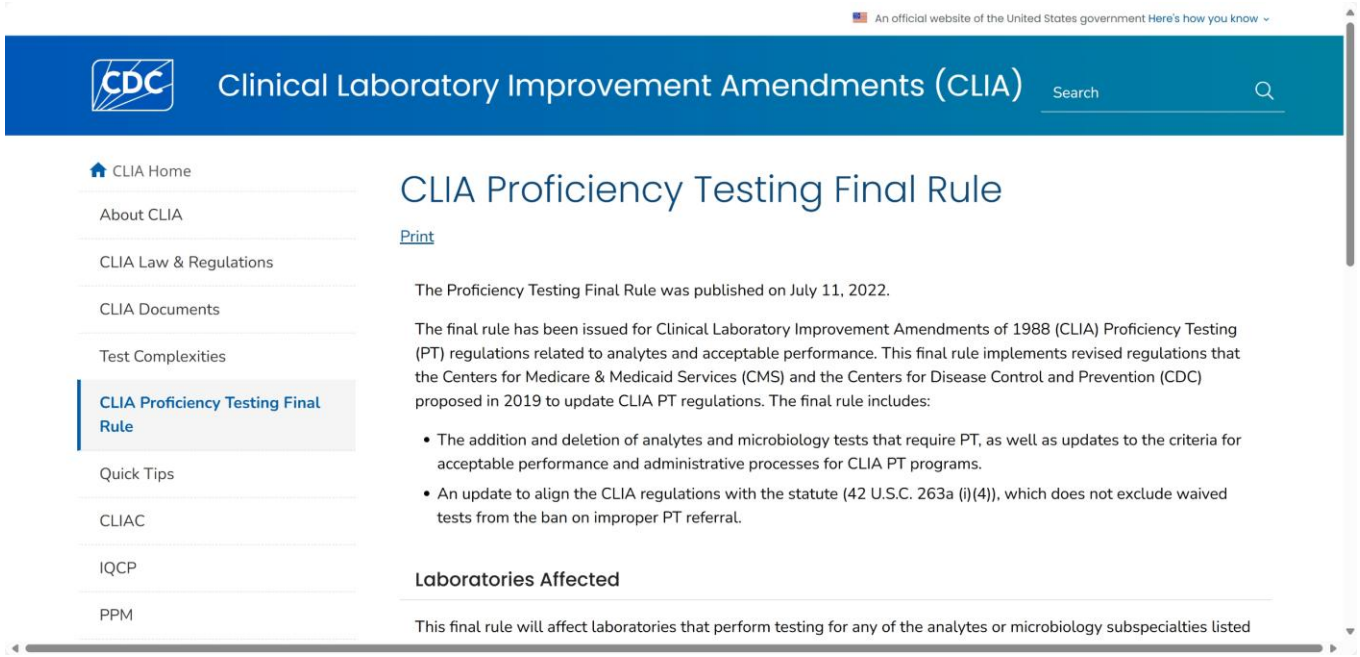




A Top 10 Inspection Deficiency

- CAP COM.01700 PT and Alternative Performance Assessment Result Evaluation – there is ongoing evaluation of proficiency testing (PT) and alternative performance assessment results by the laboratory director or designee with appropriate corrective action taken for each unacceptable result.
- CFR 493.803 – Proficiency Testing (D2016) CONDITION – Each laboratory performing nonwaived testing must successfully participate in a PT program approved by CMS as described in subpart I of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA (22.85% of all labs cited with deficiency)
- CFR 493.801 – Proficiency Testing (D2000) CONDITION – Each laboratory must enroll in a PT program that meets the criteria in subpart I and is approved by HHS. The laboratory must enroll for each specialty and subspecialty and must test the samples in the same manner as patient's specimens. (6.71% of all labs cited with deficiency)

New CLIA PT Allowable Error Limits (7/11/24)

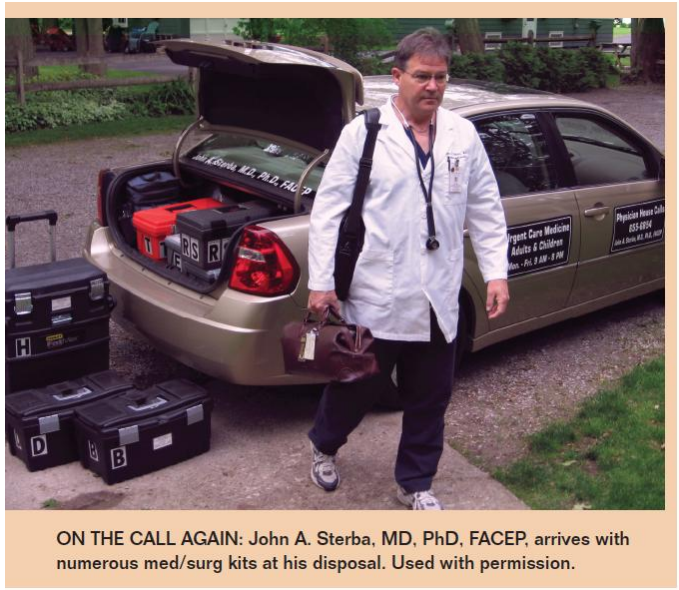


New CLIA criteria for acceptable PT performance

Analyte	Old Limits	New Limits
ALT	+/- 20%	+/-15% or +/- 6U/L
Albumin	+/- 10%	+/- 8%
ALK Phos	+/- 30%	+/- 20%
Amylase	+/- 30%	+/- 20%
AST	+/- 20%	+/-15% or +/- 6U/L
Total Bili	+/-0.4 mg/dL or +/- 20%	+/-0.4 mg/dL or +/- 20%
Blood Gas pO2	+/- 3SD	+/-15% or +/-15 mm Hg

The New Wave of Healthcare (Or Is It?)

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

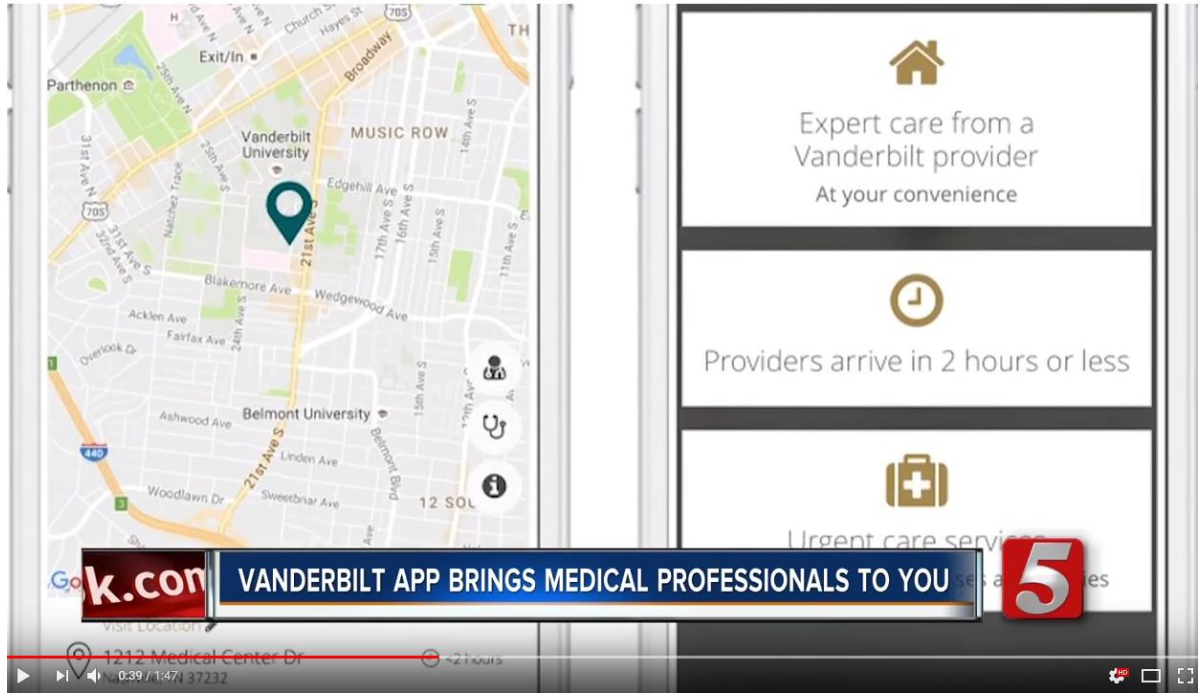


ON THE CALL AGAIN: John A. Sterba, MD, PhD, FACEP, arrives with numerous med/surg kits at his disposal. Used with permission.

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 (Strep, Influenza, COVID, Urine dipsticks and hCG) and first dose medication delivery within two hours of their request.



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

Visiting Nurses and Mobile Doctor Concerns

- Antigen strip readers, POCT instruments and molecular devices intended manufacturer “use-case” - bench with continuous power.
- Concern for moving devices – repeated plug/unplug, vibration effects on device alignment, temperature exposure in vehicles.
- We have noted more frequent device failures and replacements.
- Our policy requires more frequent QC – after every move and power on.

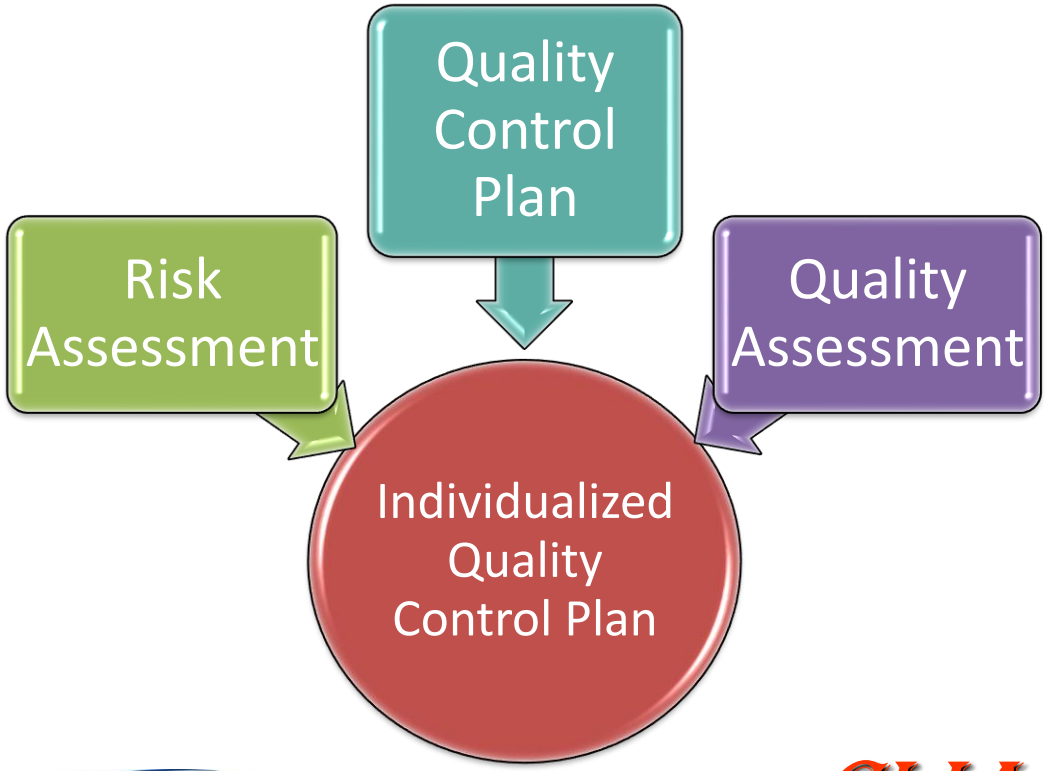
On-Demand Health Care

- 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

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

Chicago hospitals set up testing tents, cancel non ...

Risk Management



CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA

GEN.NEW Risk Management Phase 0

The quality management system (QMS) uses a prospective risk management process that includes identification, control, and monitoring of risks throughout the laboratory. Potential sources of errors and non-conforming events are incorporated into the risk management process.

Note: Risk assessment includes a process to identify sources of potential failures and errors in the laboratory's systems related to patient testing. The process should evaluate the frequency and severity of potential failures and errors. Strategies for process modification to mitigate significant risks should be developed. Monitoring should continue until data demonstrates acceptable reduction of risk. Proficiency testing (PT), quality control (QC) reviews, event occurrence management, recognizing patterns in data, and feedback from laboratorians/clients/patients are key ways to identify potential sources of error and non-conformances that could be included in the risk management process. The risk management process should be proactive, it should focus on "what could go wrong." A laboratory culture of transparency, process orientation rather than personal blame, open communication, and strong leadership support is essential to a successful risk management process. Risk identification and mitigation should be incorporated into policies and procedures. Assessment of risk should be documented in development of new laboratory processes and test methods.

Evidence of compliance

Records of risk evaluation and risk mitigation **AND**
Records of investigation of complaints, and non-conformities includes assessment of future negative impact on process outcome and identification of mitigating actions **AND**
Description of risk identification, evaluation, mitigation and monitoring described in the Quality Plan

REFERENCES

ISO 15189:2022 Medical laboratories, Requirements for Quality and Competence. International Organization for Standardization. 2022.
ISO 22367:2020 Medical laboratories, Application of risk management to medical laboratories. International Organization for Standardization. 2020.
ISO 23824:2024 Medical laboratories, Guidance on application of ISO 15189 in anatomic pathology. International Organization for Standardization. 2024.
College of American Pathologists. Accreditation Resources - Quality Management. www.cap.org, e-LAB Solutions Suite (login required). Accessed 1/2/2025.

*****REVISED** 10/24/2022***

POC.08675 Quality Monitoring Statistics Phase I

The laboratory monitors for the presence of false positive results (eg, due to nucleic acid contamination) for all molecular microbiology tests.

NOTE: Examples include: review of summary statistics (eg, monitoring percentage of positive results relative to current local and regional rates and increased positive Strep results above historical rate within a run or over multiple runs), performance of wipe (environmental) testing, and review and investigation of physician inquiries. Based on monitoring data, the laboratory may implement additional mitigation strategies to minimize the risk of contamination, such as process controls.

Evidence of Compliance:

✓ Records of data review, wipe testing, statistical data evaluation and corrective action if indicated

REFERENCES
1) Borst A, Box AT, Fluit AC. False-positive results and contamination in nucleic acid amplification assays: suggestions for a prevent and destroy strategy. *Eur J Clin Microbiol Infect Dis.* 2004; 23(4):289-99.
2) Cone RW, Hobson AC, Huang ML, Fairfax MR. Polymerase chain reaction decontamination: the wipe test. *Lancet.*1990; 336:686–687.
3) McCormack JM, Sherman ML, Maurer DH. Quality control for DNA contamination in laboratories using PCR- based class II HLA typing methods. *Hum Immunol.* 1997;54:82–88.
4) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments;* 1st ed. CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, 2011.

Take Home Points

- POCT is moving diagnostic testing out of the laboratory and into the community to meet a continuum of patient care needs.
- A variety of challenges must be considered including environmental exposure, staff competency, and method limitations.
- A risk assessment can identify potential sources of errors and the best control processes to minimize risk.
- A robust quality management system is the optimal way to ensure quality POCT results in any setting.

James H. Nichols, PhD, DABCC, FADLM
Professor of Pathology, Microbiology and Immunology
Medical Director, Clinical Chemistry and POCT
Vanderbilt University Medical Center, Nashville, TN
james.h.nichols@vumc.org

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