Challenges and Practical Solutions in Implementing Point-of-Care Testing

Joe Wiencek, Ph.D., DABCC, NRCC, FAACC
Associate Professor of Pathology, Microbiology and Immunology
Service Line Medical Director, VUMC Core Laboratory
Medical Director of Clinical Chemistry, VUMC Core Laboratory
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VANDERBILT UNIVERSITY School of Medicine

Disclosures for Joe Wiencek, Ph.D.

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- Board/Committee: Chair, CLSI Document on External Specimen Transport (PRE06)

Learning Objectives

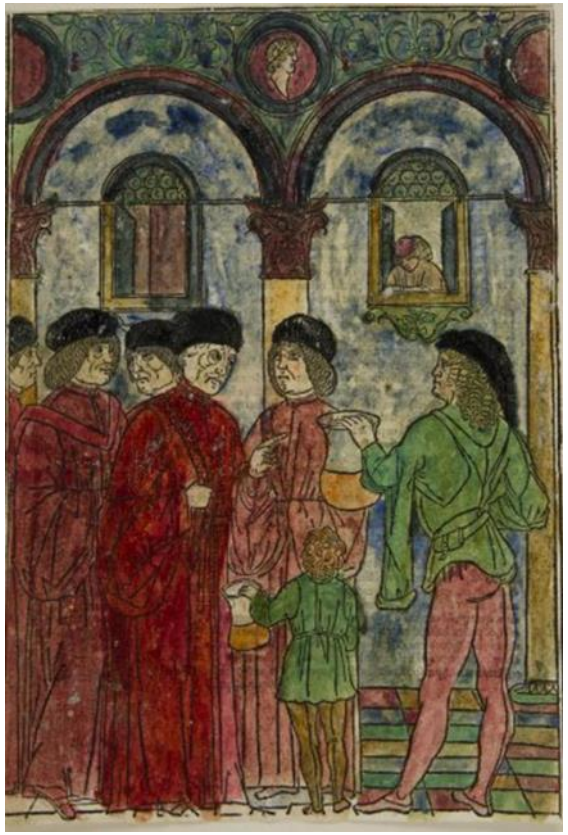
At the conclusion of this activity, learners will be able to…

1. Describe test complexity and their respective accrediting requirements needed to perform point-of-care testing.
2. Cite an example of a practical issues involved in the implementation of point-of-care testing
3. List potential solutions and resources to many challenges encountered in implementing point-of-care testing.

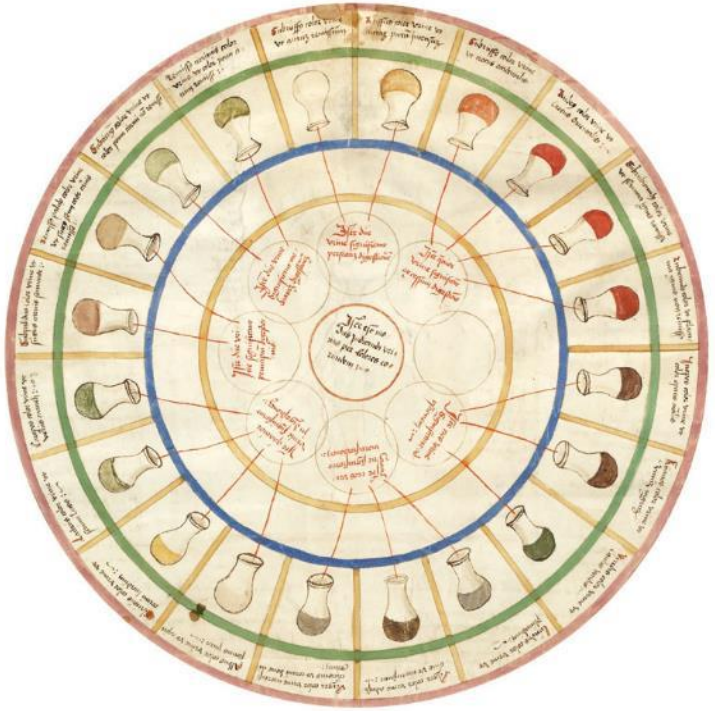
Outline

- History of POCT
- New innovations
- Advantages and Disadvantages
- POCT Challenges and Solutions
- Pandemic Lessons

History of POCT



From Fasciculus Medicinae, Venice, C. Arrivabenus, 1522 Harvard Art Museums/Fogg Museum, Gray Collection of Engravings Fund, G5121.2



Urine wheel was published in 1506 by Ullrich Pinder, in his book *Epiphanie Medicorum*. It describes the possible colours, smells and tastes of urine, and uses them to diagnose disease.

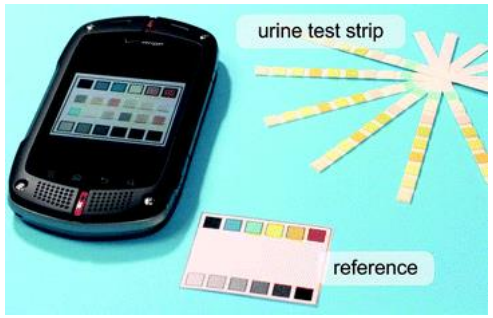
POCT is everywhere…

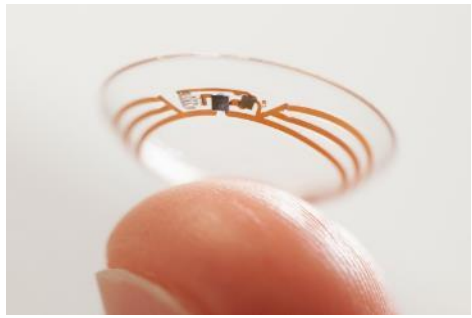
POCT IS STRETCHING THE LIMITS…

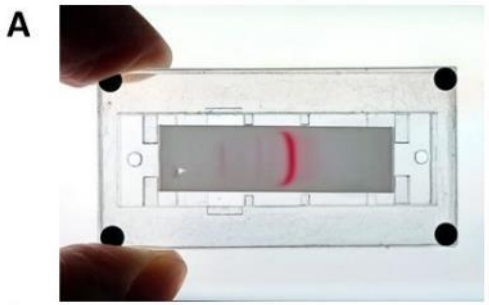
Wiencek J., et al. Lab Medicine in Space. Clin Chem. 2023

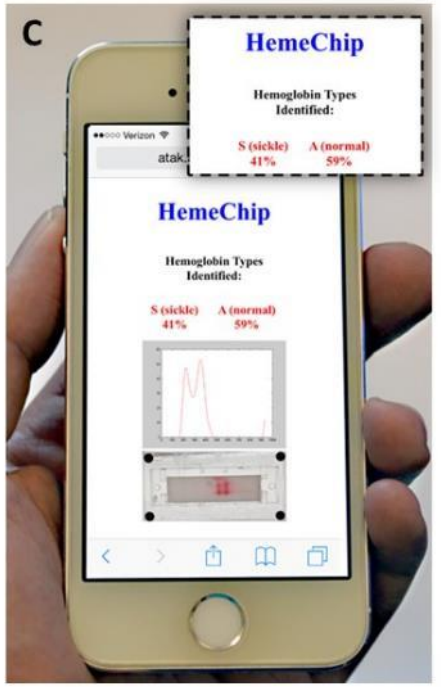
New and innovative technologies

- Smartphone technologies
- Lab-on-a-chip
- Paper-based assays
- Microfluidics
- Miniaturization of IA









Continuous Glucose Monitoring

J Diabetes Sci Technol. 2020 Nov; 14(6): 1035–1064.

Wearables to the rescue

- Heather Hendershot, 25, thought her **Apple Watch** must be defective when it said her heart rate was too high, but it correctly identified a symptom of her undiagnosed hyperthyroidism

https://www.today.com/health/woman-s-apple-watch-alerted-her-high-resting-heart-rate-t126921

Wearables to the rescue… again

Apple Watch comes to the rescue again! Saves owner's life suffering from 'blood clots'

An Apple Watch is once again being credited with saving the life of its wearer, owing to its advanced health features.

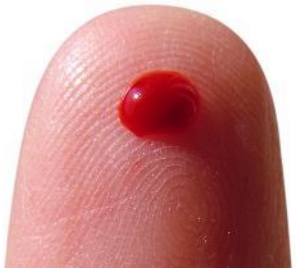
By: HT TECH | Updated on: Mar 20 2023, 12:33 IST

Apple Watch is equipped with health-tracking features such as heart rate tracking, SpO2 monitoring, ECG and more. (Representative Image) (Pixabay)

https://tech.hindustantimes.com/wearables/news/apple-watch-comes-to-the-rescue-again-saves-owner-s-life-suffering-from-blood-clots-716792904600 20.html

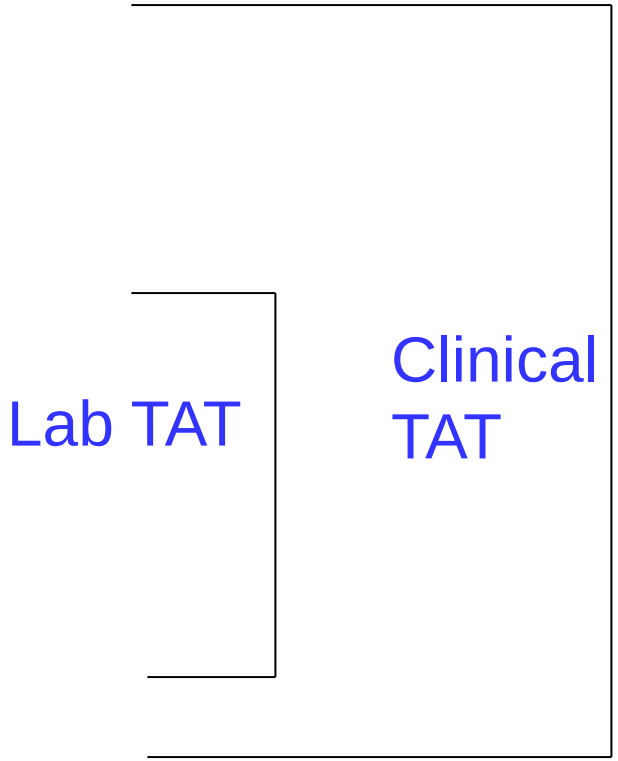
Advantages of POCT

- Turn-around-time
- Volume of specimen
- Faster patient management
- Wide test menu
- Enhanced satisfaction
- Whole blood and other specimen types
- Works within clinical patient flow while patient is still being examined



Turn around times

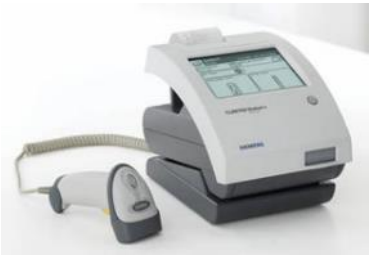
- Order
- Collection
- Transport to lab or testing location *
- Receipt in lab *
- Specimen clotting *
- Centrifugation *
- Aliquoting *
- Analysis
- Result reporting
- Acknowledgment of result
- Clinical Action



* Steps eliminated with POCT

Disadvantages of POCT

- Dozen of sites
- Hundreds of devices
- Thousands of operators
- Non-laboratorians



POCT Challenges

Challenges	Possible Solutions
Meeting federal and accreditation agency requirements	
Documenting manual POCT results	
Training/competency for large number of staff	
Misuse of POCT reagents	
Ensuring QC performed and documented	
Cleaning and disinfection of multiuse POCT devices	
Harmonization of POCT with central laboratory	

Wiencek J. et al. Expert Rev Mol Diagn. 2016;16(4):415-22.

Regulations and Test Categories

Regulation Challenges

- *The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulates all laboratory tests conducted for patient care on humans, including those tests that are performed at the* ***point of care****.*


False Negative

Medical Labs, Trusted As Largely Error-Free, Are Far From Infallible

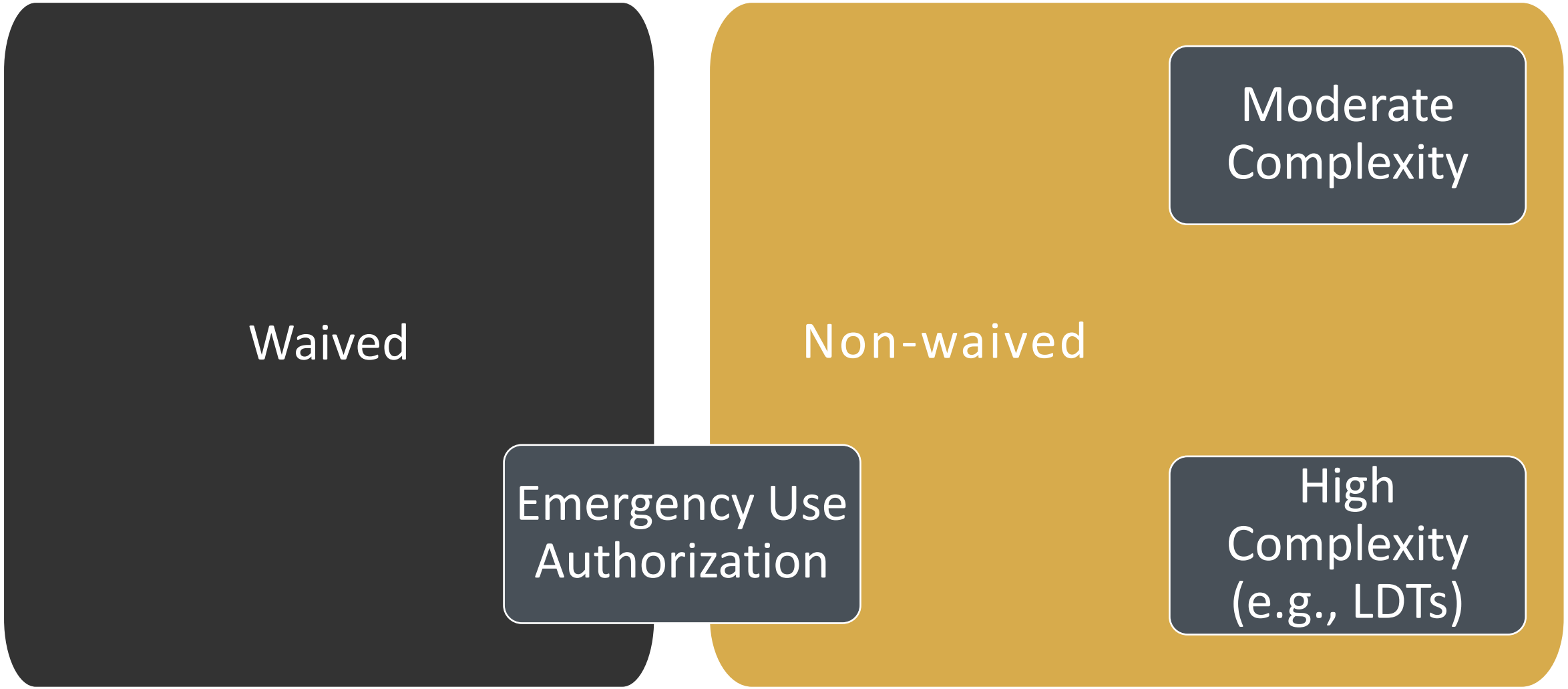
Haste, Misuse of Equipment, Specimen Mix-Ups Afflict Even Best Labs at Times

Regulation: Weak and Spotty

By Walt Bogdanich
Staff Reporter of The Wall Street Journal

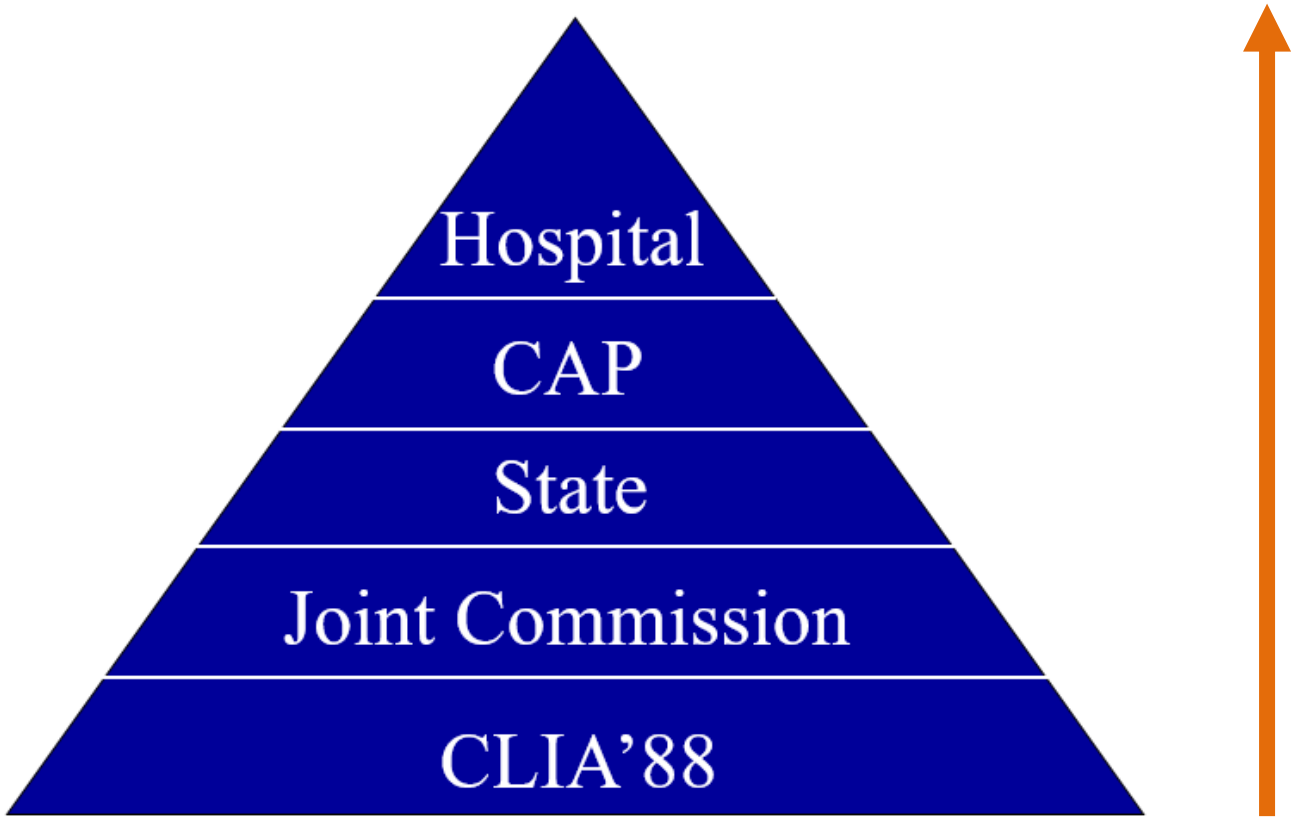
CLIA. Final Rule. Fed Regist. 2003, 42 CFR Part 493

CLIA Defined Test Categories



CLIA. Final Rule. Fed Regist. 2003, 42 CFR Part 493

Regulatory Hierarchy



Adapted from James H. Nichols, PhD, DABCC

CLIA Waived Testing Requirements

- *Pay biennial fee for "Certificate of Waiver"*
- *Follow manufacturers instructions*
- *Allow unannounced inspections*
- *No other additional requirements*
    - *Operator training/competency*
    - *Test verification*
    - *QC beyond manufacturers instructions*
- ***The Joint Commission/CAP both require documentation of QC and operator training***

CLIA Non-Waived Testing Requirements

Differ on requirements of education and training level

General Requirements

- *Proficiency testing*
- *Daily QC*
- *Instrument maintenance/cleaning*
- *Quality assurance*

CLIA Non-Waived Testing Requirements

- Before patient testing
  - Analytical performance
  - Written procedure
  - Defined reference intervals
  - Ongoing training/competency

Completed

- Must be inspected every other year by either CMS or another accreditation agency (Joint Commission or CAP)

Know Your Accreditation Organization

Accreditation organizations have additional requirements beyond CLIA

- *Different checklists*
- *Additional requirements for waived testing*

Different inspection approaches

- *CAP utilizes peer laboratory directors and staff*
- *The Joint Commission utilizes administrators, physicians, nurses and other clinical staff*
- *Announced vs. unannounced*

Documentation

Documentation is essential for compliance

POCT Documentation Challenges

- Greater than 50% of POCT are visually interpreted
- Some produce printed results
- Manually entry into EHR
- Written logs for QC

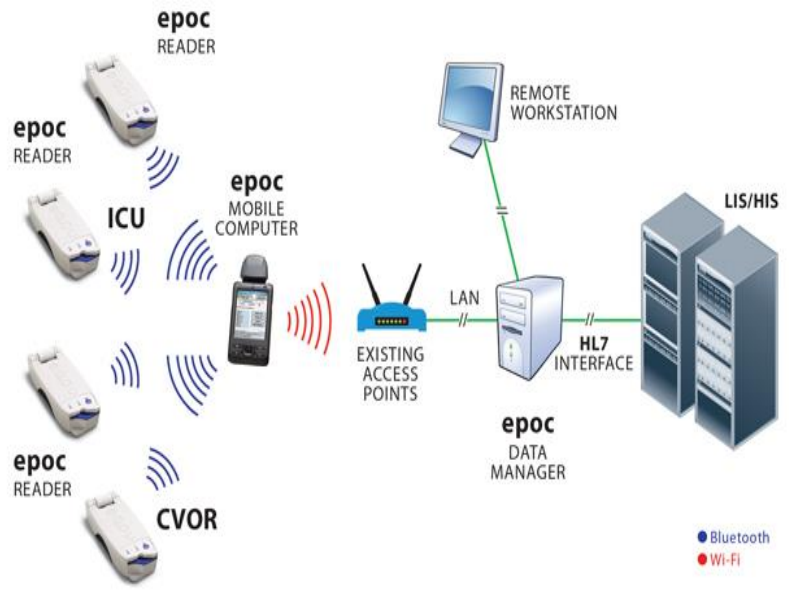
Possible Solutions

- Assign staff to review data logs
- Implement POCT data capture

Kohle-Ersher A et al. Comput Inform Nurs. 2012;30(3):126-133.

There is no single POCT interface

- Electronic data connections
  - Different manufacturers
  - Costly to setup
  - IT time/support
- POCT middleware
  - Interface multiple devices
  - One computer
  - Track QC, reagent lot, calibrators, operator training/competency, instrument maintenance and cleaning



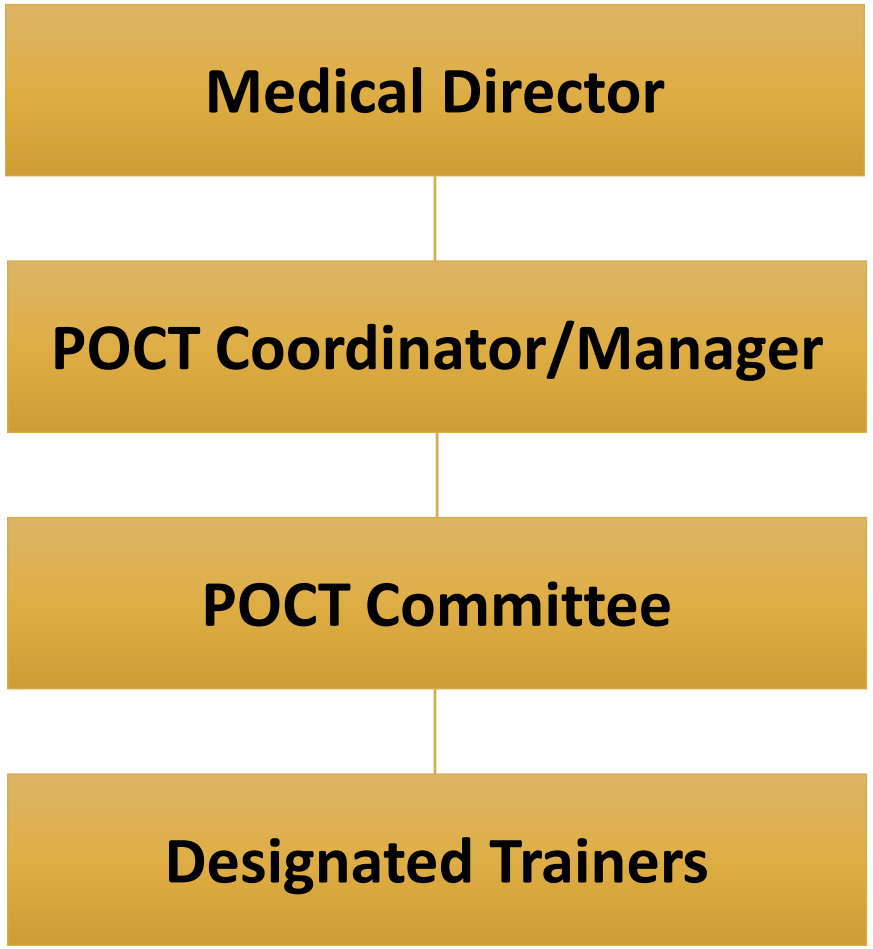
Dyhdalo KS et al. Arch Pathol Lab Med. 2014;138(11):1444-1448.

Training and Competency

What to do with all these operators?

https://nissanstadium.com/events/cma-fest-reveals-initial-2022-lineup/

Develop a POCT management structure



Main RI et al. Lab Med. 2000;31(8):453-460.

POCT training & competency solutions

POCT Education/Training Solutions

- Develop a POCT management structure
- Annual competency fairs
- Monthly training sessions
- One-on-one

Limitations

- Staff availability
- Certified trainers

www.pointofcare.net

Mismanagement of POCT Materials

Improper expiration dating leads to waste

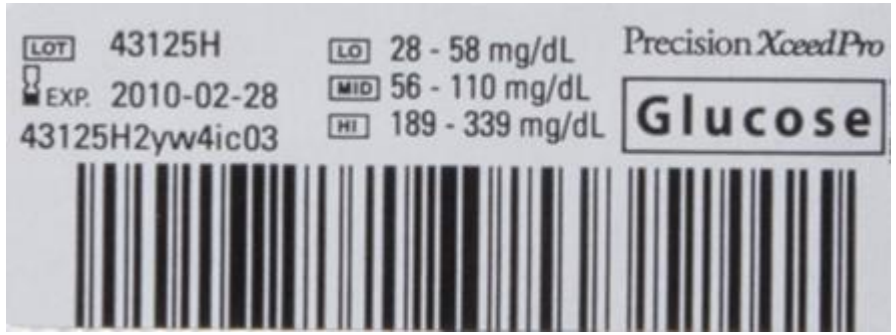
- Manufacturer expiration dates are checked by an operator
- Vials/strips/controls must be manually dated once opened
- Undated, opened containers must be thrown away

Discarded strips due to no date

Howerton D et al. Morb Mortal Wkly Rep. 2005;54(RR-13):1-4.

Barcoded reagents offer additional checks

- Reagent expiration embedded into barcodes
- Operator must scan before use
- Starts a timer that warns the operator after 30, 60, or 90 days
  - Locks out usage of the material after countdown
- Some devices can also recognize exposure to humidity (few hours), wet or reused strips as additional control measure



Inappropriate use of refrigerated controls

- Urine controls will deteriorate within 30 days if not refrigerated after opening
- However, urine controls must be warmed to room temperature before use (15-30min)
- Testing cold controls or not returning them to the fridge

Package Insert. AN30516D. Elkhardt (IN): Bayer Healthcare, LLC; 2005.

Problems of open containers

- Test strips are affected by light, humidity, and temperature
  - 2 hours of open container lead to a 26% bias in glucose measurement
- Strips spread out on the counter poses a huge risk for reuse…
- Some meters have reuse "checks"

Nichols JH et al. J Diabetes Sci Technol. 2011;5(1):173-177.

Solutions to stop misuse of POCT materials

Solutions for Misusing POCT Reagents

- Emphasize manufacture expiration, storage conditions, and open-bottle expiration during training
- Use manufacturers with barcoded expiration dates on individual vial and cartridge packaging
- Have unannounced inspections/quality checks

QC Issues

Frequency, documentation of QC

Operators who perform POCT are responsible for the success or failure of their devices.

Challenges of POCT QC

- Nonlaboratory mindset
- Manual documentation of QC performance
- System lockouts are not completely foolproof

Manual documentation of QC

- Manufacturers require daily QC on manual, visually interpreted POCT kits
  - Pregnancy, rapid strep or urine dipstick
- Patient testing could occur without proper QC documentation
- Newer devices have electronic data capture

Lewandrowski K et al. Arch Pathol Lab Med. 2011;135(11):1405-1414

Operator lockout is not fool-proof

- Newer devices have operator lockout
  - Untrained operators
  - Failed renewals for semi or annual competency/training
- Sharing
- Patient tested as QC

Clark KS. Point Care. 2008;12(2):97-98.

Ensuring QC performance and documentation

Solutions for POCT QC Docmentation

- Use devices with operator and QC lockout features
- For manual testing, provide easy to use logs
- Emphasize the importance of QC during training
- Assign staff to have regularly scheduled QC review

Proper care

Proper care of POCT devices

Sanitation and maintenance of high-touch and multiuse devices is essential in preventing harmful transmission of diseases.

Challenges of POCT cleaning/disinfection

- Device sharing between patients
- Proper cleaning of a sensitive device

Taylor BM et al. Am J Infection Control. 2013;41(6):S130

Hidden dangers of POCT

- Poor sanitation of POCT devices is becoming an emergent concern in infection control.
- Numerous nosocomial and antibiotic resistant organisms
- Several states report patients were exposed to infectious organisms after POCT
  - Glucose meters
  - Urinometers
  - Blood gas analyzer

Louie RF et al. Point Care. 2005;4:158-163

POCT devices are not waterproof

- POCT devices are electronic devices that should be protected from moisture
- Cleaning and disinfection as recommended by manufacturers instructions
- Directions are not always followed

Gentile NL et al. J Diabetes Sci Technol.. 2009;3(4)971-980.

Proper cleaning and maintenance of POCT

Solutions for cleaning and maintaining POCT devices

- Incorporate manufacturer cleaning recommendations into POCT policies
- Use POCT devices validated for exposure to cleaning chemicals and moisture
- Dedicate a POCT device to one patient if possible
- Do **NOT** submerged your POCT device in a sink full of water/soap

Harmonization and Methods

Harmonization in POCT

There is a demonstrated lack of harmonization between test results of the central laboratory instruments and POCT.

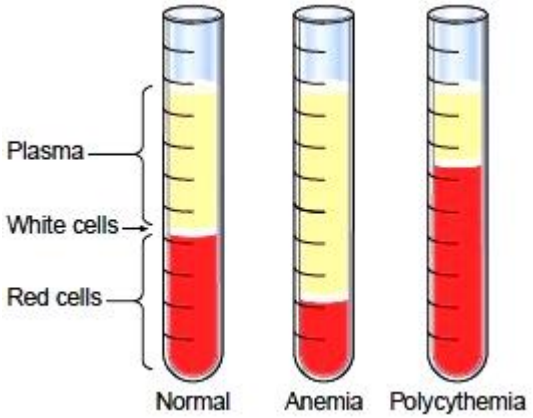
Challenges of harmonizing POCT and the central laboratory

- Whole blood versus serum/plasma
- Sampling problems (how much is enough)
- Lack of comparison agreement between tests and between devices
- Electronic test ordering

Gentile NL et al. Point Care. 2008;7(3):110-112.

POCT methodology

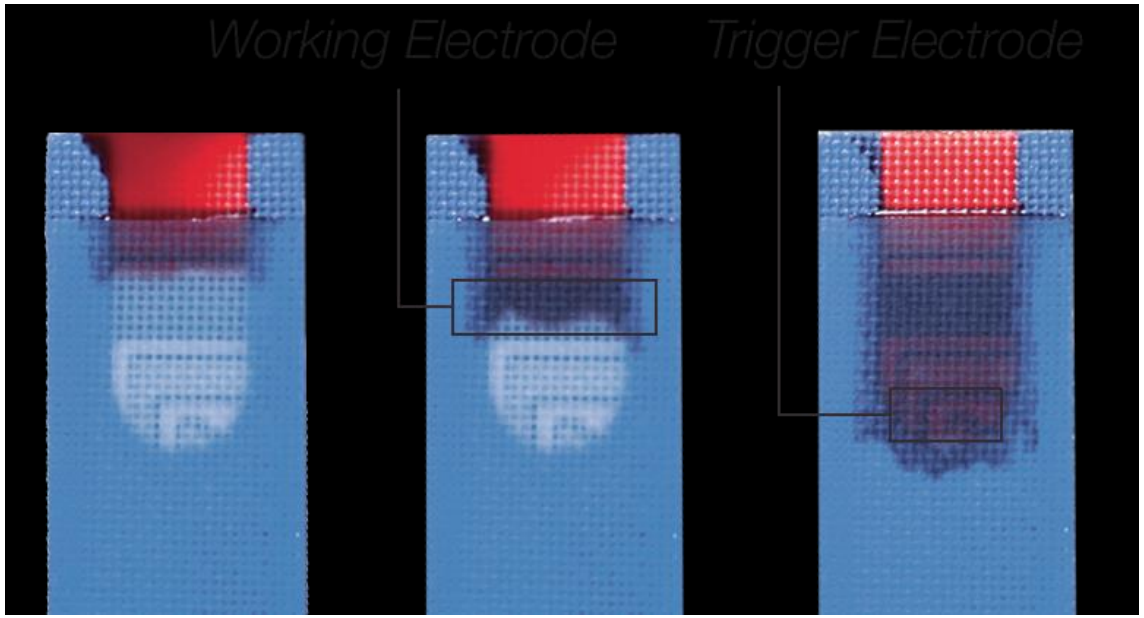
- POCT is a different methodology
  - With unique biases, interferences, and limitations
  - Primarily conducted on whole blood
  - Sample matrix due to plasma/serum calibrators
- Glucose meters have demonstrated limitations
  - Variable Hct in whole blood
  - Maltose/xylose/galactose interferences
  - Erroneously low results in critically ill



Armbruster D et al. Clin Biochem Rev. 2007;28(3):105-114

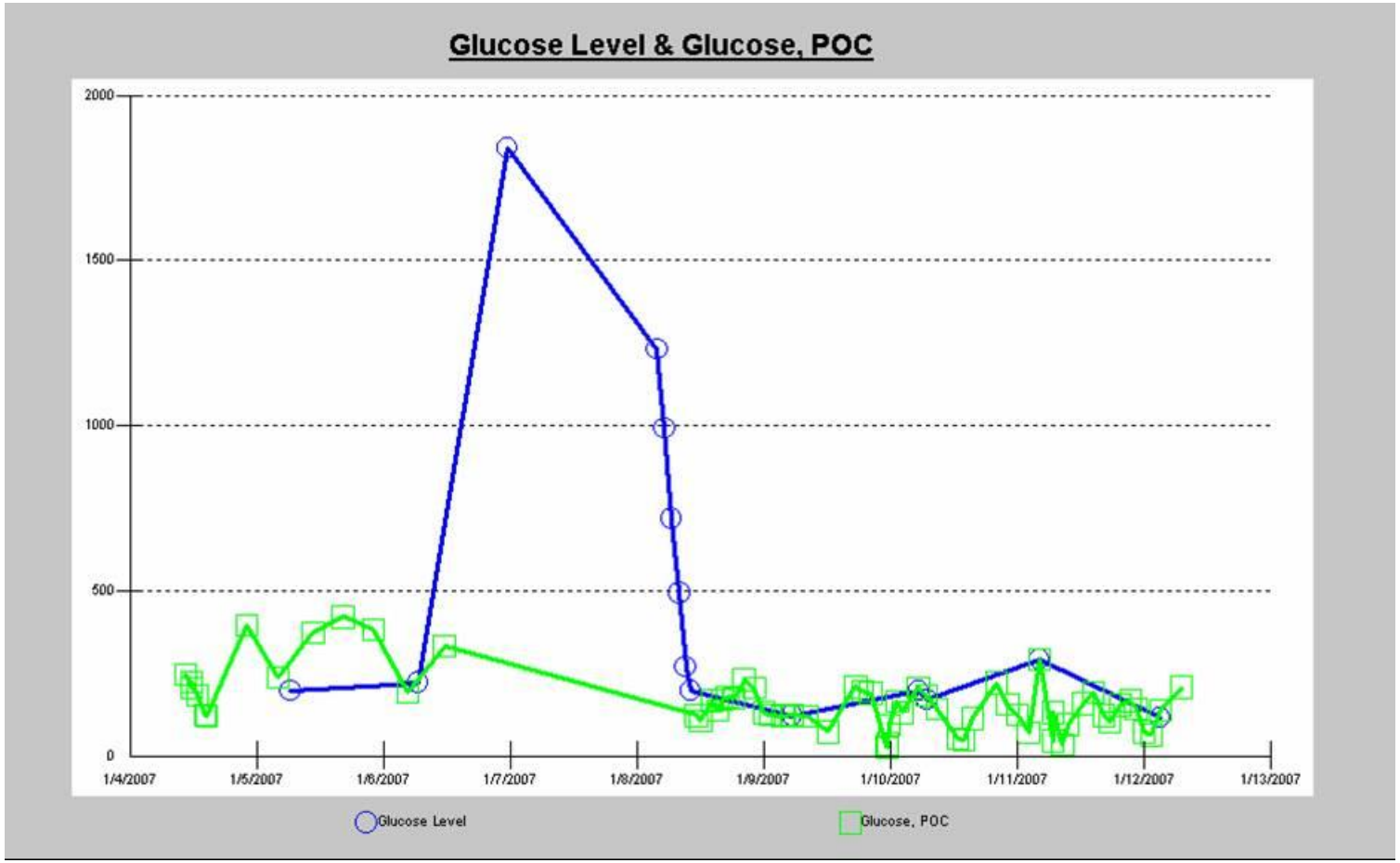
How much sample is enough?

- Test will only start when enough blood is applied



- But what about over application or under application…

POCT vs Core Lab



Adapted from James H. Nichols, PhD, DABCC

POCT test management

- POCT technology is different from other laboratory methods
- Results from both technologies **MUST** not be overlaid and should always be kept separate
- VUMC reports glucose
  - **BedGlu, Glu-WB, GluI for POCT**
  - **Gluc for Central Laboratory**

Resource Limited Settings

POCT in resource limited settings

The size, portability, and self-contained nature of POCT is what makes it ideal for resource-limited settings

Challenges of POCT in global terrain

- Shipping & environment exposure
- Program oversight
- Preparedness/staff training/competency

Gentile NL et al. Point Care. 2008;7(3):110-112.

POCT in adverse environmental conditions

- Reagents are susceptible to environmental conditions
  - Heat, cold, humidity, sunlight, altitude, sand, dust, and salt (ocean locations)

- Exposure to heat and humidity during hurricane Katrina (72 hours)
  - Consistently elevated glucose results (1 meter)
  - Variable results in the other meters

www.usnews.com

Louie et al. Disaster Med Public Health Prep. 2012;6:232-240.

POCT freeze/thaw cycles

- Colder climates can cause kits to freeze/thaw repeatedly
  - Adverse performance reported
- Glucose meter test strips and blood gas cartridges exposed to cold temps
  - Complete failure
  - Partial recovery of results

Louie et al. Disaster Med Public Health Prep. 2012;6:232-240.

POCT oversight in resource limited areas

- Skilled medical technologists may be limited
  - Various educational backgrounds
- Must have a quality management system
  - Ongoing training/validation
  - Competency
  - Test validation & performance
- International resources available
  - CLSI
  - WHO

Louie et al. Disaster Med Public Health Prep. 2012;6:232-240.

Military and disaster rescue

- Staff readiness & preparedness
  - Perform testing regularly
  - Just-in-time training
  - Ongoing validations
- Reagents must not be stockpiled
- QC must be performed on each test lot
  - Weekly or monthly basis
- Stocking sufficient supply

File:US Navy 050225-N-7422B-002 An MH-60S Seahawk helicopter lifts two pallets of supplies from the flight deck

Louie et al. Disaster Med Public Health Prep. 2012;6:232-240.

POCT in the global terrain

Solutions for POCT in resource-limited settins

- Considerations must be made for shipping, environmental exposure, staff training/competency and program oversight
- Tasks and management will need to be handled by clinical staff
- Know the international resources available
- Do not overstock supplies
- Know your warehouse (temperature, humidity etc.)

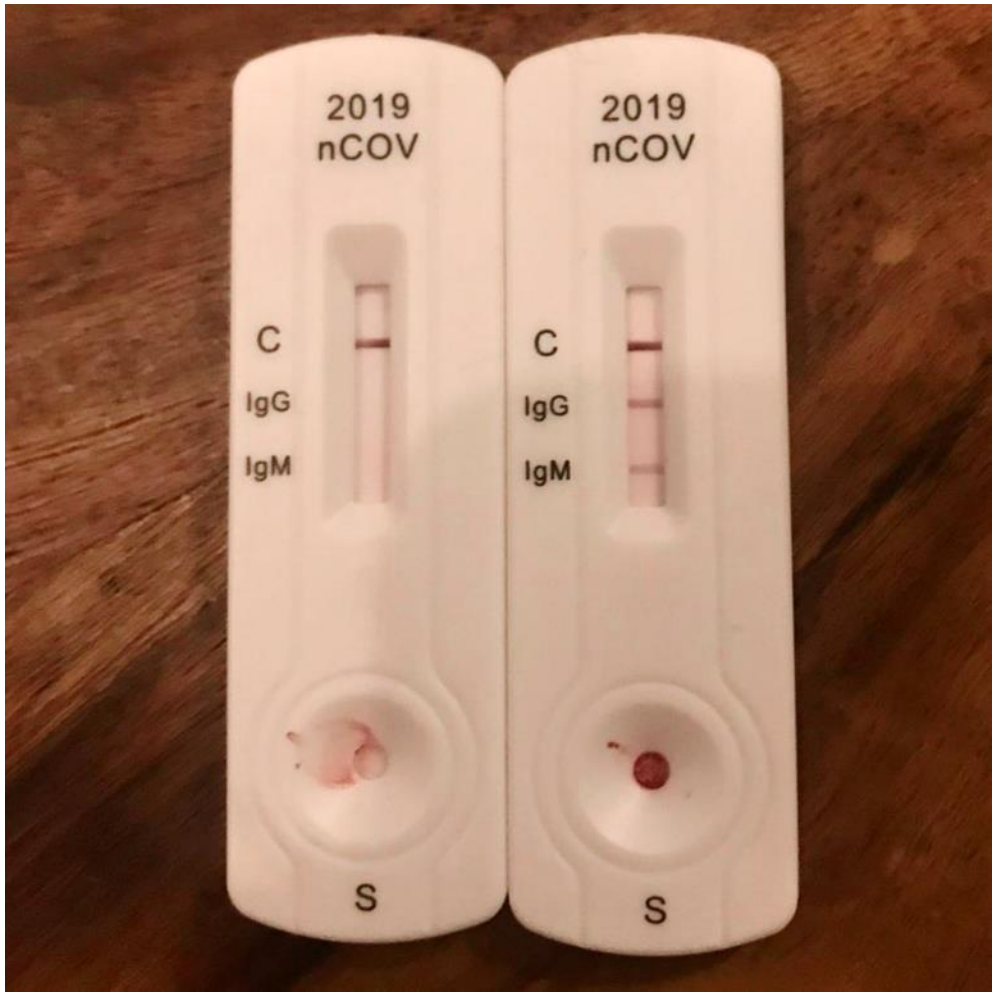
Challenges and Solutions Summary

Challenges	Possible Solutions
Meeting federal and accreditation agency requirements	• Form a POCT Committee • Create a POCT Coordinator position • Stay current on regulatory issues
Documenting manual POCT results	• Use data entry logs – assign staff to verify use • Implement POCT with electronic data capture
Training/competency for large number of staff	• Offer annual competency fairs • Schedule monthly training meetings • Hold one-on-one sessions
Misuse of POCT reagents	• Use manufacturers with barcoded expiration dates on individual vial/cartridge • Emphasize manufacturer expiration, storage conditions, and open-bottle expiration during training
Ensuring QC performed and documented	• Use devices with operator and QC lockout features • For manual testing, provide easy to use logs
Cleaning and disinfection of multiuse POCT devices	• Incorporate manufacturer cleaning recommendations into POCT policies • Utilize POCT devices validated for exposure to cleaning chemicals and moisture
Harmonization of POCT with central laboratory results	• Educate on method differences and interferences

Wiencek J. et al. Expert Rev Mol Diagn. 2016;16(4):415-22.

Pandemic Lessons

Early Lateral Flow (LFAs) Serologic Assays



Welcome to the Wild, Wild West…

- March 16, 2020 – FDA opens serology testing fluid gates
    1. Vendors could misrepresent how good their test was
    2. Vendors could offer their tests to the public

- Many tests exhibited abysmal quality…

"FDA issued a letter to health care providers to explain that some developers had misused the serology test-kit notification list to falsely claim that their tests were approved or authorized by the agency."

Kasten J. Clin Lab News 2020. & N Engl J Med 2021; 384:592-594

THE TEXAS TRIBUNE-PROPUBLICA INVESTIGATIVE UNIT

A Laredo ER spent $500,000 on coronavirus tests. Health officials say they're unreliable.

> A private emergency room owner bought 20,000 rapid COVID-19 tests, but a week later they were seized by the federal government. It's a bitter example of what can go wrong when local governments try to buy supplies on the open market from unknown manufacturers.

BY **JEREMY SCHWARTZ**, THE TEXAS TRIBUNE AND PROPUBLICA APRIL 10, 2020 2 PM CENTRAL

U.K. Paid $20 Million for New Coronavirus Tests. They Didn't Work.

Facing a global scramble for materials, British officials bought millions of unproven kits from China in a gamble that became an embarrassment.

Kirkpatrick DD, Bradley J. The New York Times, April 4 2020

FDA Sets Standards for Coronavirus Antibody Tests in Crackdown on Fraud

At least 160 antibody tests for Covid-19 entered the U.S. without prior FDA scrutiny

> "People are just trying to get a piece of this pandemic money pie, and they're willing to do anything," said Joseph Wiencek, a lab director at the University of Virginia's health system.

Burton TM. The Wallstreet Journal, May 4 2020

American Association for Clinical Chemistry's COVID-19 Serologic Task Force

Zhang YV, Wiencek J, Meng QH, et al. Clin Chem. 2021;67:1188-1200.

Public Statement from Task Force

AACC Better health through laboratory medicine.

AACC Recommendations for SARS-CoV-2 Serology Testing

This AACC statement seeks to provide clarity and guidance on serology testing and to raise awareness of its utility and limitations in the management of the COVID-19 pandemic.

There is broad recognition that the unprecedented COVID-19 pandemic requires clinical laboratory testing as part of the worldwide response to this health crisis. To detect SARS-CoV-2—the virus that causes COVID-19—in infected individuals, the primary laboratory tool has been molecular diagnostic tests. While these tests inform clinicians of individuals who are currently infected by identifying the presence of SARS-CoV-2 genetic material, there is a need to gain insight into the prevalence of SARS-CoV-2 in the general public. Serologic testing, which looks for antibodies specific to SARS-CoV-2, can identify individuals who have been infected and may assist in epidemiologic initiatives and contact tracing. Clinical laboratory professionals are invaluable for the evaluation, use, and interpretation of these clinical tests and can help policy makers and public health officials develop strategies to constrain the pandemic.

Utility of Serology Testing in COVID-19

Serology tests are blood-based tests that can be used to determine whether people have been infected by particular pathogens. The immune system recognizes pathogens as foreign and mounts a protective response involving the development of antibodies. The presence or absence of SARS-CoV-2 specific antibodies can determine whether a person has been infected by the virus.

Diagnosis and management

Serologic testing may play a role in vaccine development and identification of recovered patients who can donate blood to help others fight the infection. Serologic testing may also be a useful diagnostic tool in patients who have a longer (i.e. greater than 1-2 week) history of COVID-19 symptoms but have a negative molecular test. In such cases, the patient may have stopped producing virus and therefore may no longer be infectious. **Serologic testing may be complementary to PCR-based diagnostic testing for management of SARS-CoV-2 infection.**

Surveillance and prevalence

Serologic testing has limited utility for surveillance and identification of the prevalence (i.e. the percent of people infected within a population) of disease. The time required for antibody production after infection by SARS-CoV-2 must be considered when surveillance testing is utilized. **While serologic testing can provide insight into the level of SARS-CoV-2 exposure within our communities, there are limitations for its use, and test results must be interpreted judiciously.**

Limitations of Serology Testing

Serologic testing should not be used as a primary method of diagnosing an acute infection or exclusion of SARS-CoV-2 infection when a patient is experiencing symptoms. SARS-CoV-2 can be detected in infected individuals before antibodies are detected. While research into the course of SARS-CoV-2 infection is ongoing, it is known that antibodies take time to be produced by the immune system. Serology tests that are performed too early during infection will likely be negative, despite the presence of active infection.

Most importantly, it is unclear whether the antibodies produced after infection by SARS-CoV-2 result in lasting protective immunity. Research is underway to elucidate the protective effects of SARS-CoV-2 antibodies and duration of immunity.

SARS-CoV-2 Testing Performance

Serologic test performance, like all laboratory tests, can be evaluated using the following metrics:

Cross Reactivity

Ideally, serological tests detect only the antibodies for the particular virus being tested, in this case SARS-CoV-2. However, there are many viruses, including other coronaviruses, that people may have been infected with in the past. Some serological tests may not be able to distinguish between antibodies produced against these viruses versus the antibodies specific to SARS-CoV-2. This phenomenon is called cross-reactivity and can cause false positive results. Clinical laboratories play a critical role in the evaluation of serological tests to safeguard against these limitations and minimize false positive results that may undermine disease prevention strategies.

Sensitivity and Specificity

The sensitivity of a test refers to how frequently a test correctly identifies the presence of antibodies following infection (i.e. does detect the antibodies when they are there). Specificity indicates the frequency with which a test correctly identifies the absence of antibodies in a person who has not been infected (i.e. does not mistakenly detect antibodies that are not there). A test that has high sensitivity may have reduced specificity, resulting in some degree of false positive results.

Predictive Values

Positive and negative predictive values are two essential calculations that provide insight into the accuracy of positive or negative test results within the population tested. These values are based on the test sensitivity and specificity, but also incorporate and are dependent on the prevalence of SARS-CoV-2 in the population.

Positive predictive value (PPV) indicates the number of positive cases that a test accurately identifies out of the total number of positive cases within a given population. Negative predictive value (NPV) defines the accurate detection of negative cases. PPV increases with increased disease prevalence, whereas NPV decreases with increased disease prevalence.

Serology tests are manufactured by many companies that report a wide range of sensitivity and specificity values. If a serologic test that is 95% sensitive and 95% specific is used to test a population of 10,000 people in which 20% (2000) of individuals have antibodies, the test would correctly identify antibodies in 1,900 of those 2000. However, it would incorrectly identify antibodies in 400 people of the remaining 8000 who do not have antibodies. If that same test is used to test a population of 10,000 people in which only 5% (500) have antibodies, the test would correctly identify antibodies in 475 of those 500. However, it would also incorrectly identify the presence of antibodies in 475 people among the 9,500 individuals who do not have

them. In the first situation out of the 2300 people who tested positive, 82% would actually have antibodies, whereas in the second situation, out of the 950 who tested positive, only half would have antibodies.

Until a clear picture emerges regarding prevalence, serologic test results should not be used as the sole basis for clinical or public health policy decisions.

Regulatory Aspects

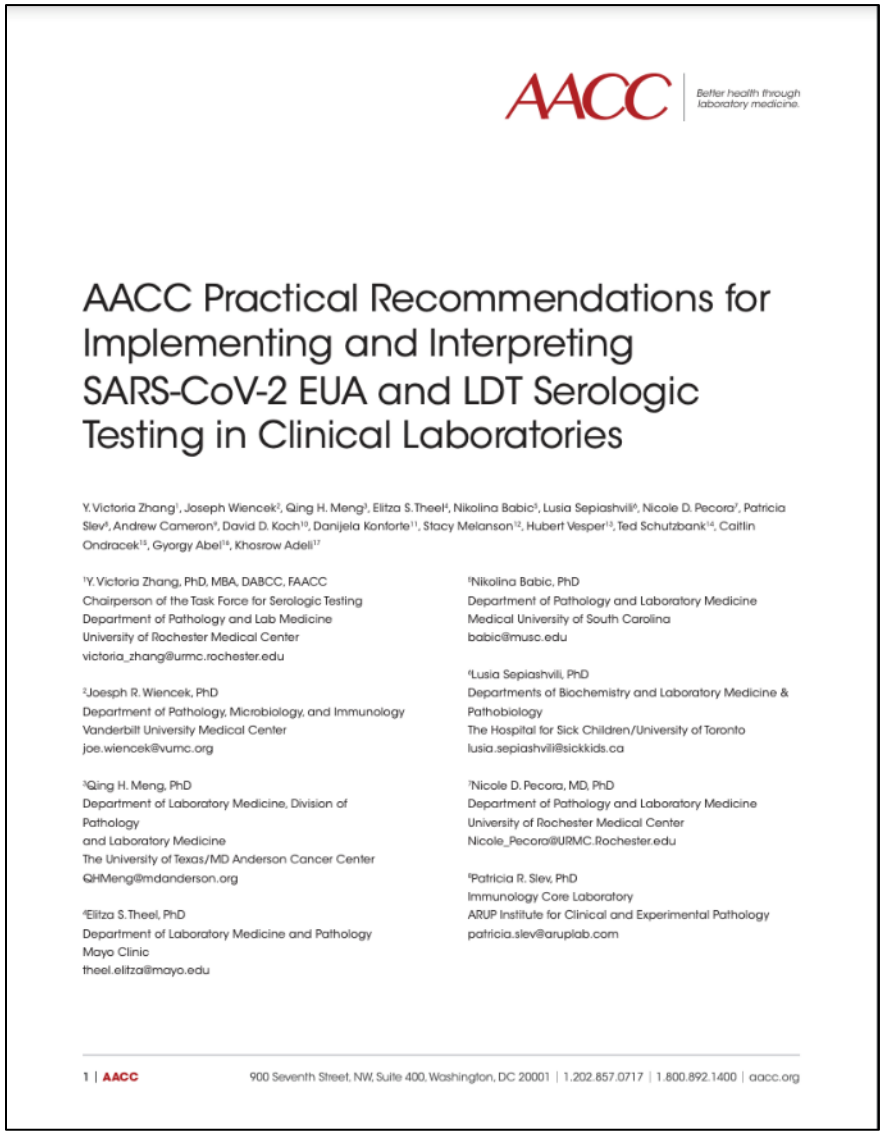
Clinical laboratory tests are regulated to ensure that they provide accurate results. A number of commercially produced serological tests for SARS-CoV-2 antibodies have received FDA Emergency Use Authorization (EUA) for clinical use and some laboratories are now beginning to use these tests. Other laboratories are choosing to develop their own serologic assays as laboratory developed tests (LDTs). **It is AACC's position that clinical laboratories should only use assays that have received an EUA by the FDA, or LDTs that have been developed and clinically validated by a laboratory certified to perform high complexity testing.** Clinical laboratories are responsible for validating and implementing all tests, regardless of FDA EUA status or LDT and AACC does not support at-home serology testing at this time.

There is significant interest in using rapid response tests broadly in hospitals, clinics, and physicians' offices, particularly in medically underserved areas. In these settings, a test performed at the point of care (near patient) by non-laboratory personnel requires designation as a waived test. As of May 5, 2020, there are no FDA EUA serologic tests for SARS-CoV-2 that may be used in a waived setting. At this time, all rapid response tests must be performed within a moderate or high complexity setting of a certified clinical laboratory.

In summary, serology testing is complementary to molecular diagnostic testing in managing the COVID-19 pandemic. It may play an important role in assessing the prevalence of the disease and may support epidemiological efforts such as contact tracing while research into anti-viral therapies and vaccines continues. **Although there are many various serologic tests coming to market, their accuracy, reliability, and interpretation must be evaluated by laboratory medicine professionals before these tests can be used effectively.** The FDA continues to adapt its guidelines based on real-world experience and new data to balance the risks and benefits of granting test authorization. AACC commends the FDA for its continued diligence in holding manufacturers accountable for their tests and marketing practices.

Our understanding of COVID-19 and the tests used to detect and manage infection will increase as our global scientific and clinical communities work together to understand this novel virus. Laboratory professionals play an indispensable role in developing and performing diagnostic and serologic tests and providing guidance in their proper use and interpretation.

AACC supports the efforts to expand testing in an evidence-based manner as this pandemic continues to unfold. The association advocates for vigilance in implementing serologic testing to provide better patient care through laboratory medicine. ■



AACC Better health through laboratory medicine.

AACC Practical Recommendations for Implementing and Interpreting SARS-CoV-2 EUA and LDT Serologic Testing in Clinical Laboratories

Y. Victoria Zhang[1], Joseph Wiencek[2], Qing H. Meng[3], Elitza S. Theel[4], Nikolina Babic[5], Lusia Sepiashvili[6], Nicole D. Pecora[7], Patricia Slev[8], Andrew Cameron[9], David D. Koch[10], Danijela Konforte[11], Stacy Melanson[12], Hubert Vesper[13], Ted Schutzbank[14], Caitlin Ondracek[15], Gyorgy Abel[16], Khosrow Adeli[17]

[1]Y. Victoria Zhang, PhD, MBA, DABCC, FAACC
Chairperson of the Task Force for Serologic Testing
Department of Pathology and Lab Medicine
University of Rochester Medical Center
victoria_zhang@urmc.rochester.edu

[2]Joesph R. Wiencek, PhD
Department of Pathology, Microbiology, and Immunology
Vanderbilt University Medical Center
joe.wiencek@vumc.org

[3]Qing H. Meng, PhD
Department of Laboratory Medicine, Division of Pathology
and Laboratory Medicine
The University of Texas/MD Anderson Cancer Center
QHMeng@mdanderson.org

[4]Elitza S. Theel, PhD
Department of Laboratory Medicine and Pathology
Mayo Clinic
theel.elitza@mayo.edu

[5]Nikolina Babic, PhD
Department of Pathology and Laboratory Medicine
Medical University of South Carolina
babic@musc.edu

[6]Lusia Sepiashvili, PhD
Departments of Biochemistry and Laboratory Medicine & Pathobiology
The Hospital for Sick Children/University of Toronto
lusia.sepiashvili@sickkids.ca

[7]Nicole D. Pecora, MD, PhD
Department of Pathology and Laboratory Medicine
University of Rochester Medical Center
Nicole_Pecora@URMC.Rochester.edu

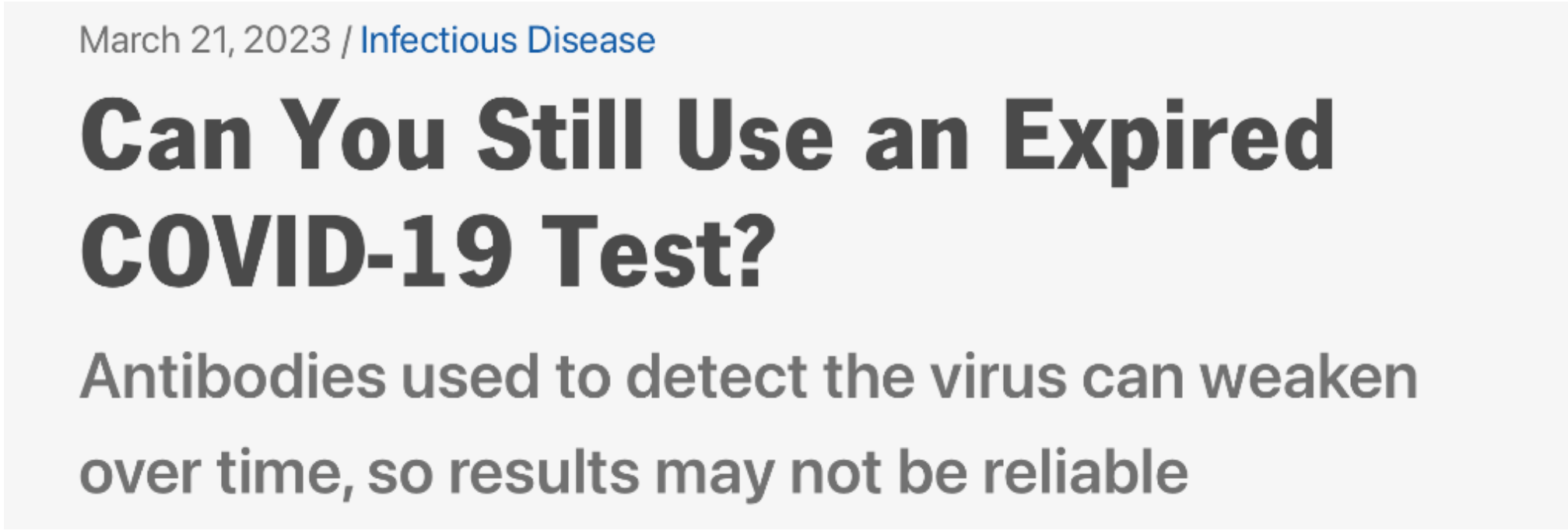
[8]Patricia R. Slev, PhD
Immunology Core Laboratory
ARUP Institute for Clinical and Experimental Pathology
patricia.slev@aruplab.com

AACC Practical Recommendations for Implementing and Interpreting SARS-CoV-2 Emergency Use Authorization and Laboratory-Developed Test Serologic Testing in Clinical Laboratories

Y. Victoria Zhang,[a,*,†] Joesph Wiencek,[b,†] Qing H. Meng,[c,†] Elitza S. Theel,[d] Nikolina Babic,[e] Lusia Sepiashvili,[f] Nicole D. Pecora,[a] Patricia Slev,[g] Andrew Cameron,[h] and Danijela Konforte,[i] on behalf of the AACC COVID-19 Serologic Testing Task Force

Zhang YV, Wiencek J, Meng QH, et al. Clin Chem. 2021;67:1188-1200.

Still fielding questions…



March 21, 2023 / Infectious Disease

Can You Still Use an Expired COVID-19 Test?

Antibodies used to detect the virus can weaken over time, so results may not be reliable

https://health.clevelandclinic.org/expired-covid-test/

“There are currently more immunoassays on the market for SARS-CoV-2 testing than for any other pathogen”

- Elizabeth Smerczak, MLS, ASCP^{CM}, MA

Smerczak E. Lab Med. 2021;lmab061.

email: joe.wiencek@vumc.org @DxSteward