AMPLIFY

It Is CLIA-Waived So Nothing Can Go Wrong. . .Right?

Norman Moore, PhD

Global Director of Medical Affairs at Abbott

Norman Moore, PhD

It is CLIA-Waived So Nothing Can Go Wrong. . .Right?

Financial Disclosures

- Employee of Abbott

Leading Causes of Deaths in the United States

1. Cardiac events
2.
3.

Makary MA, Daniel M. Medical error-the third leading cause of death in the US. BMJ. 2016 May 3;353:i2139.

Leading Causes of Deaths in the United States

1. Cardiac events
2. Cancer
3.

Makary MA, Daniel M. Medical error-the third leading cause of death in the US. BMJ. 2016 May 3;353:i2139.

Leading Causes of Deaths in the United States

1. Cardiac events
2. Cancer
3. Medical errors

Makary MA, Daniel M. Medical error-the third leading cause of death in the US. BMJ. 2016 May 3;353:i2139.

Medical Errors

200,000 American deaths each year are associated with preventable harm in hospitals

Cost associated with errors exceeds $17 billion annually

Up to 70% of clinical decisions influenced by laboratory results

Makary MA, Daniel M. Medical error-the third leading cause of death in the US. BMJ. 2016 May 3;353:i2139.

QUALITY IN THE POINT OF CARE

Changes in Medical Testing

Crisis In The Laboratory

Lack of medical scientists is a national issue

- Demand for med techs to increase by ~22% from 2012 to 2022, (U.S. Dept Labor, Bureau of Labor Statistics)
- < 5,000 people are graduating each year from accredited programs
  - Half of what is needed
  - Number of accredited programs is declining
- Educational requirements
  - Medical **technologist** requires baccalaureate and year of training in accredited or approved laboratory training
  - Medical **technician** requires associate degree and a year of training
- Money
  - Median salaries are below registered nurses, physical therapists, and pharmacists

Current medical scientists

- “Seniors” - ~50% of med techs are within 10 years of retirement
- On the job training

PassportUSA, US Demand for Medical Technologists Reaches Boiling Point. health carousel. https://passportusa.com/medical-technologist-shortage/. June 30, 2020.

More Tests Are Performed Outside the Laboratory

KEY POINT OF CARE FACTORS:

Rapid test result need

Easy and rapid test technology

Low risk of error

CLIA Waived test designation

CLIA Waived Tests and Requirements

- **WAIVED TESTS**
- "Simple tests with a low risk for an incorrect result"[1]

- **REQUIREMENTS[2]**

1. **Follow manufacturer instructions**
2. Assign lab director to oversee activities
   - **Ensure compliance with requirements**
3. Notify state agency of changes in ownership, name, address or laboratory director within 30 days

1. CDC. Clinical Laboratory Improvement Amendments (CLIA), Test Complexities. https://www.cdc.gov/clia/test-complexities.html, updated Aug 6, 2018.
2. Centers for Medicare & Medicaid Services (CMS). How to obtain a CLIA Certificate of Waiver. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf. March 2019.

CLIA Waived Tests and Requirements

- **WAIVED TESTS**
- "Simple tests with a low risk for an incorrect result"[1]

- **REQUIREMENTS[2]**

1. **Follow manufacturer instructions**
2. Assign lab director to oversee activities
   - **Ensure compliance with requirements**
3. Notify state agency of changes in ownership, name, address or laboratory director within 30 days

INSTRUCTIONS FOR USE MUST BE FOLLOWED FOR CLIA WAIVED TESTS

1. CDC. Clinical Laboratory Improvement Amendments (CLIA), Test Complexities. https://www.cdc.gov/clia/test-complexities.html, updated Aug 6, 2018.
2. Centers for Medicare & Medicaid Services (CMS). How to obtain a CLIA Certificate of Waiver. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf. March 2019.

CLIA Waived Tests and Requirements

- **WAIVED TESTS**
- "Simple tests with a low risk for an incorrect result"[1]

- **REQUIREMENTS[2]**

1. **Follow manufacturer instructions**
2. Assign lab director to oversee activities
   - **Ensure compliance with requirements**
3. Notify state agency of changes in ownership, name, address or laboratory director within 30 days

INSTRUCTIONS FOR USE MUST BE FOLLOWED FOR CLIA WAIVED TESTS

"Tests…that have been modified from the approved manufacturer's instructions default to ***high complexity****"*[1]

1. CDC. Clinical Laboratory Improvement Amendments (CLIA), Test Complexities. https://www.cdc.gov/clia/test-complexities.html, updated Aug 6, 2018.
2. Centers for Medicare & Medicaid Services (CMS). How to obtain a CLIA Certificate of Waiver. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf. March 2019.

CLIA-WAIVED TESTS

Quality and Appropriate Procedures for POC Testing

Sample Collection

Swab selection

- Appropriate swab used; Nasopharyngeal, mid-turbinate, nasal, throat, cheek, saliva (test and method dependent)
- Swab captures optimum amount of sample

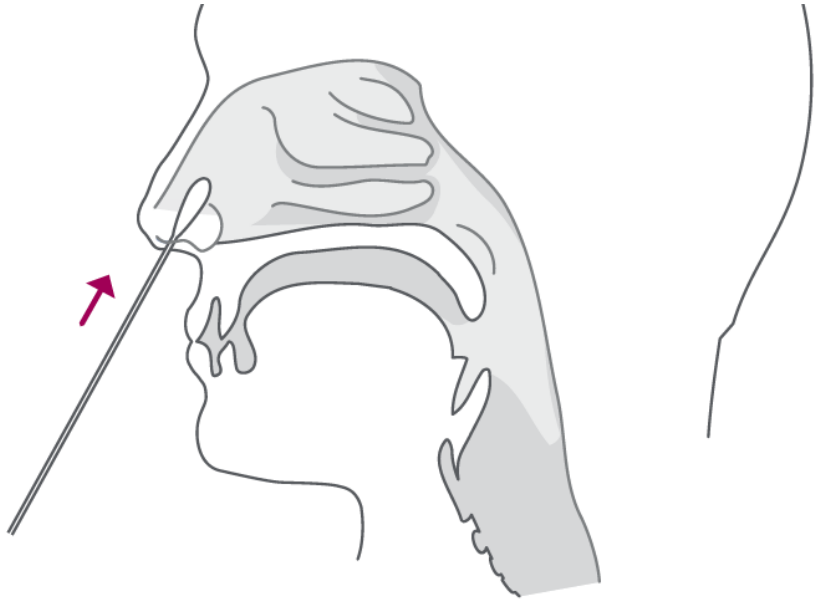
Sample collection technique

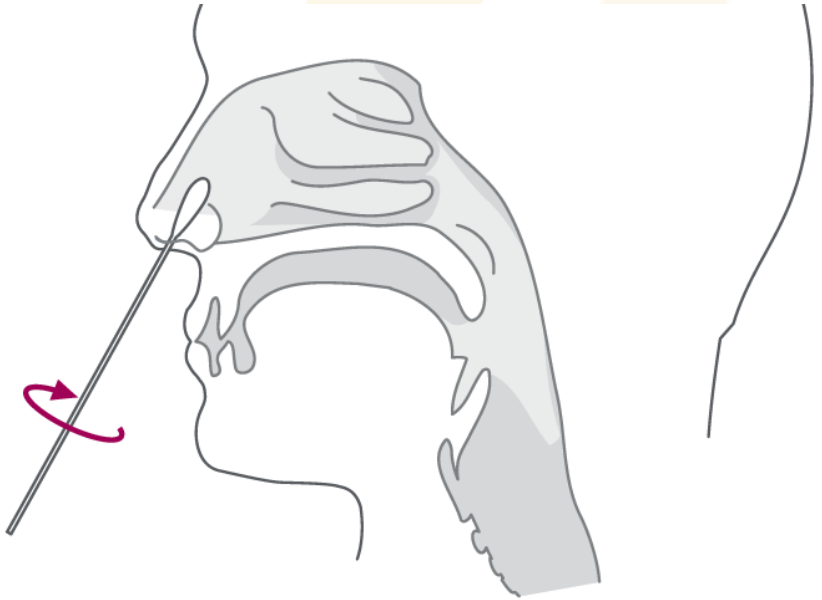
- Swab appropriate area and with correct technique

Patient

- May be decision between best swab and comfort
- Some patients are less inclined to be able to get a second swab, never mind one

Sample Quality is VERY Important - Nasal Swab (NS)





1 To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible.

2 Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril.

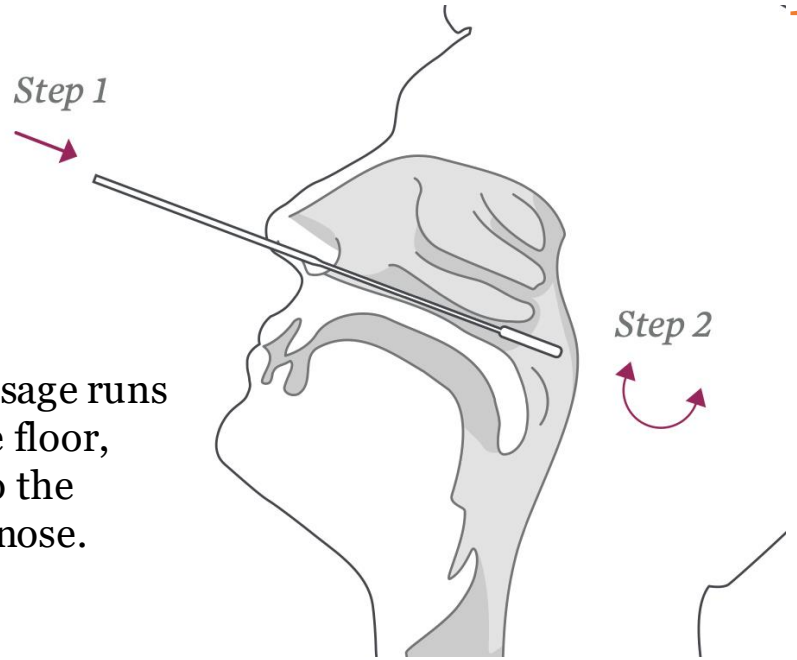
IMPORTANT REMINDERS

Products have specific requirements regarding specimen collection. Please refer to the specific product package insert.

For optimal performance, use the swabs provided in the test kit.

Sample Quality is VERY Important - NP Swab

Target the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible.



NOTE:
The nasal passage runs parallel to the floor, not parallel to the bridge of the nose.

1 Carefully insert the swab directly backwards into the anterior nare (parallel to the palate) without tipping the swab head up or down.

The swab should travel smoothly with minimal resistance.
DO NOT USE FORCE.

2 Gently rotate the swab into the anterior nare, parallel to the palate, and into the nasopharynx, halfway from the nose to the tip of the ear (about half the length of the swab). Leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

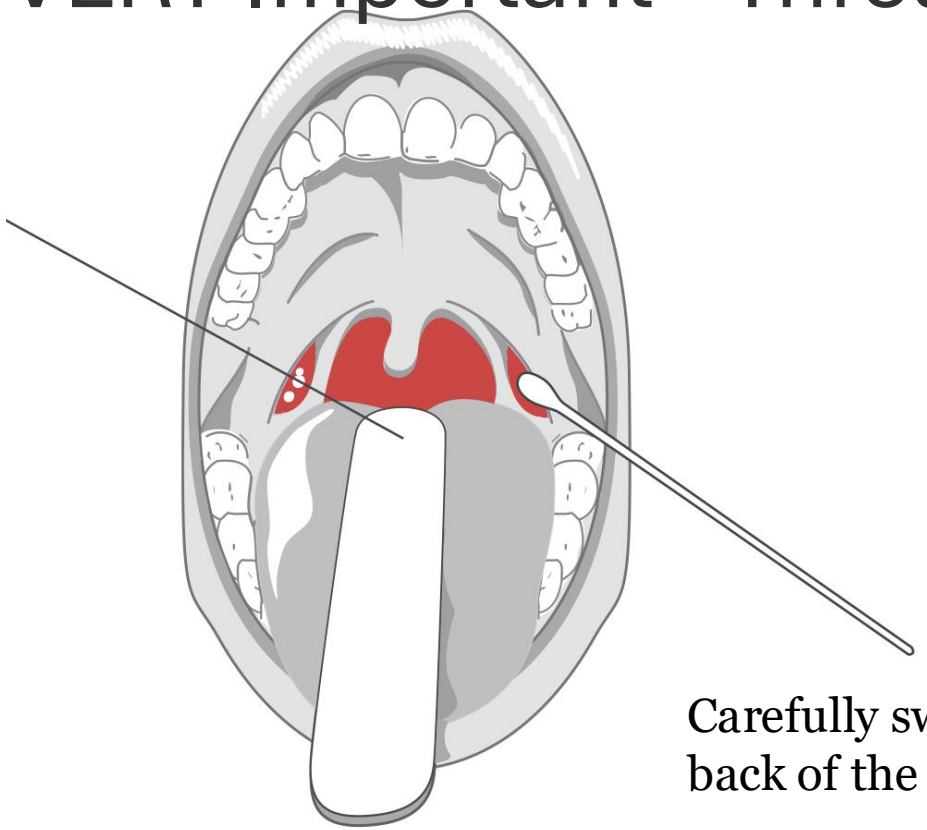
IF RESISTANCE IS ENCOUNTERED
Slightly withdraw the swab without removing it from the nostril. Elevate the back of the swab and move it forward into the nasopharynx.

IMPORTANT REMINDERS
Products have specific requirements regarding specimen collection. Please refer to the specific product package insert.
For optimal performance, use the swabs provided in the test kit.

Tech Tips: https://content.veeabb.com/1d09429b-8373-419f-8f1a-d28f9586863a/0658bb46-bb4c-4a30-a196-e03b4565f91b/0658bb46-bb4c-4a30-a196-e03b4565f91b_source__v.pdf

Sample Quality is VERY Important - Throat Swab

Use a tongue depressor to hold the tongue down, if necessary.



Carefully swab the tonsillar area and back of the throat beyond the uvula.

IMPORTANT REMINDERS

Swab the area with a back and forth motion — do not merely touch the area. Swabbing is required to remove organisms adhering to the surface of the throat.

Aim for white patches. Streptococcal bacteria are frequently found in white patches in the tonsillar area.

Avoid contact with the lips, teeth, cheek, gums, uvula and tongue. Contact with these areas may contaminate the sample.

When using dual swabs, collect bacteria on both sides of the swab head and rub the two swab heads together. Rubbing ensures even distribution of the sample.

Technical Bulletin: Throat Swab Collection: https://content.veeabb.com/1d09429b-8373-419f-8f1a-d28f9586863a/1114dc40-394b-4857-a386-aaef74ef5a41/1114dc40-394b-4857-a386-aaef74ef5a41_source__v.pdf

Improper Throat Swabs - Strep A

What happens with cheek swab?

Improper Throat Swabs - Strep A

What happens with saliva on the swab?

Improper Throat Swabs - Strep A

What happens with back of throat?

Fingerstick

Use the appropriate finger

Usually middle or ring finger. Ring finger has less pain

Don’t milk the finger as you get more interstitial fluid

Appropriate size lancet

Can massage up to first knuckle

Get right sample

Clean and disinfect site

Wipe away alcohol so it doesn’t dilute blood

Usually wipe away first drop (for Hgb, can be variable for first 3)

Pre- and Post-Analytical Quality Factors

Contamination

- Samples / controls placed on bench/countertop
- Hand contact with reagent bottles
- Hand contact with swab head and then touch other samples
- Workstation decontamination between samples
- Replace gloves between samples

Sample labeling

- Samples/Patient ID properly identified

Transport

- Direct samples or with transport medium

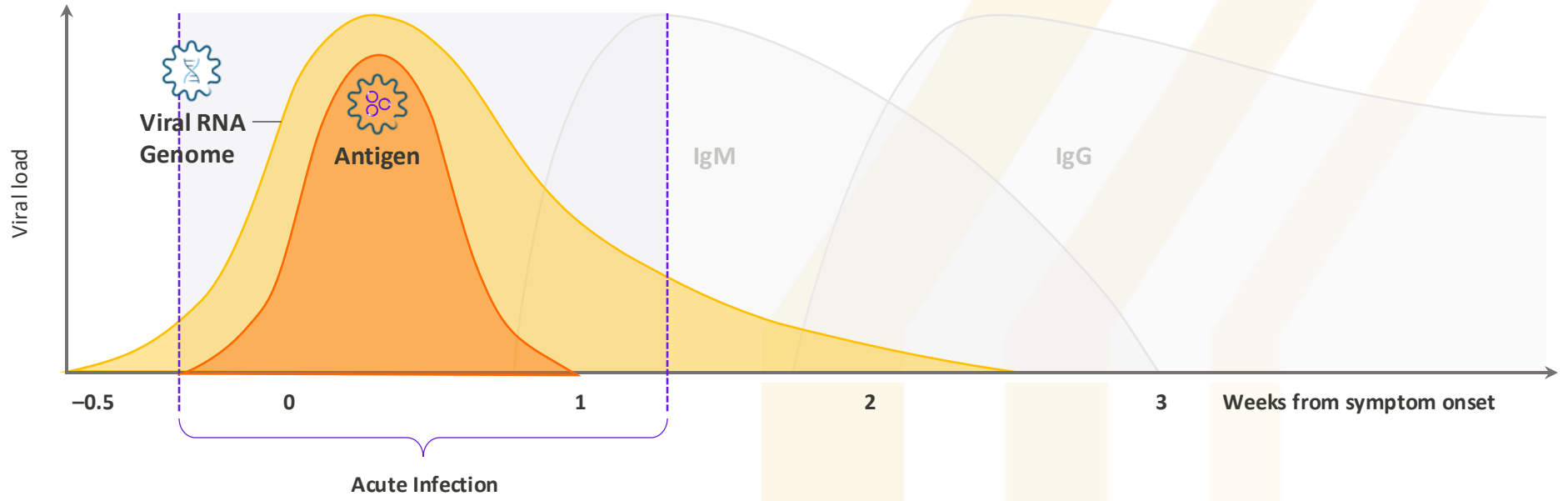
Transcription/Manual data entry

- Patient ID
- Test results

What about the type of test?

What Does the Patient Want to Know?

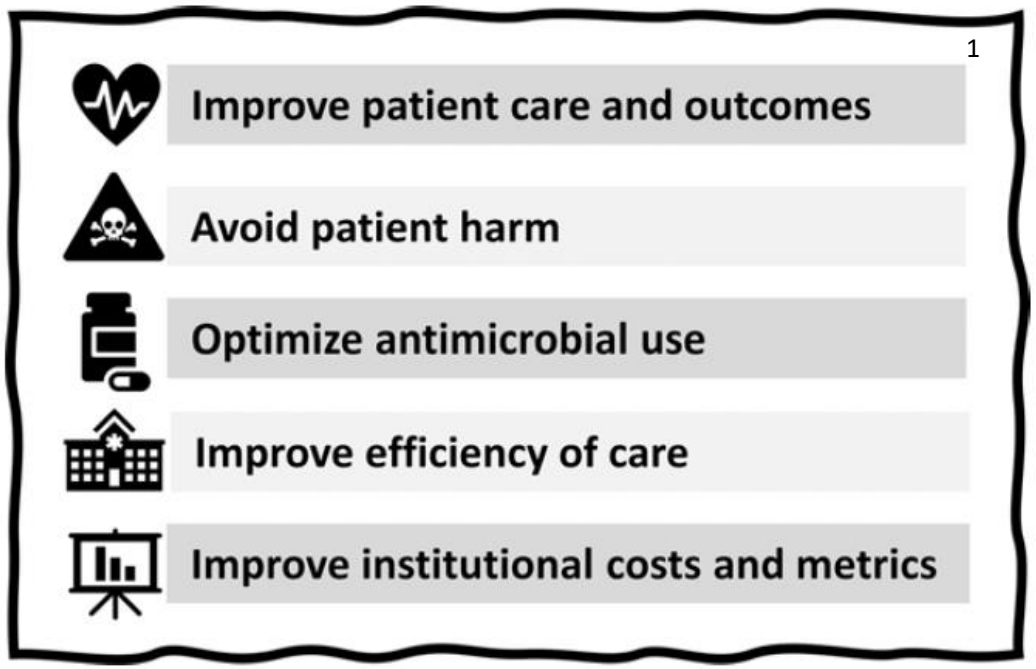
- RAPID ANTIGEN TESTS AND NUCLEIC ACID AMPLIFICATION TESTS (NAATs)



Generic viral patterns
Adapted from Mercer, T.R., Salit, M. Testing at scale during the COVID-19 pandemic. Nat Rev Genet 22, 415–426 (2021).

What is Diagnostic Stewardship

- ✓ Right test[1-4]
- ✓ Right patient[1-4]
- ✓ Right time[1-4]
- ✓ To prompt the right action[1-4]



1. Fabre V, Davis A, Diekema DJ, et al. Principles of diagnostic stewardship: A practical guide from the Society for Healthcare Epidemiology of America Diagnostic Stewardship Task Force. Infect Control Hosp Epidemiol. 2023 Feb;44(2):178-185.
2. ASM. Article: Diagnostic Stewardship Interventions That Make a Difference. https://asm.org/articles/2021/august/diagnostic-stewardship-interventions-that-make-a-d, Aug 3, 2021.
3. Claeys KC, Johnson MD. Leveraging diagnostic stewardship within antimicrobial stewardship programmes. Review. Drugs Context. 2023;12:2022-9-5.
4. Curren EJ, et al. Advancing Diagnostic Stewardship for Healthcare-Associated Infections, Antibiotic Resistance, and Sepsis. Clin Infect Dis. 2022 Mar 1;74(4):723-728.

Example Clinical Factors Impacting Testing / Test Selection

COVID-19

- Affects all ages; risk of serious illness varies by age/co-morbidities
- Initiate antiviral treatment ≤ 5 days
- Testing may be appropriate recommended in symptom and asymptomatic
- Currently, not seasonal

INFLUENZA

- Affects all ages; risk of serious illness varies by age/ co-morbidities (i.e., ≥ 65 years, pediatric/infants, chronic conditions, pregnancy.
- Initiate antiviral treatment ≤ 48 hours
- Test when results will impact clinical decisions
- Seasonal, test when circulating; low prevalence can reduce PPV and add unnecessary costs

RSV

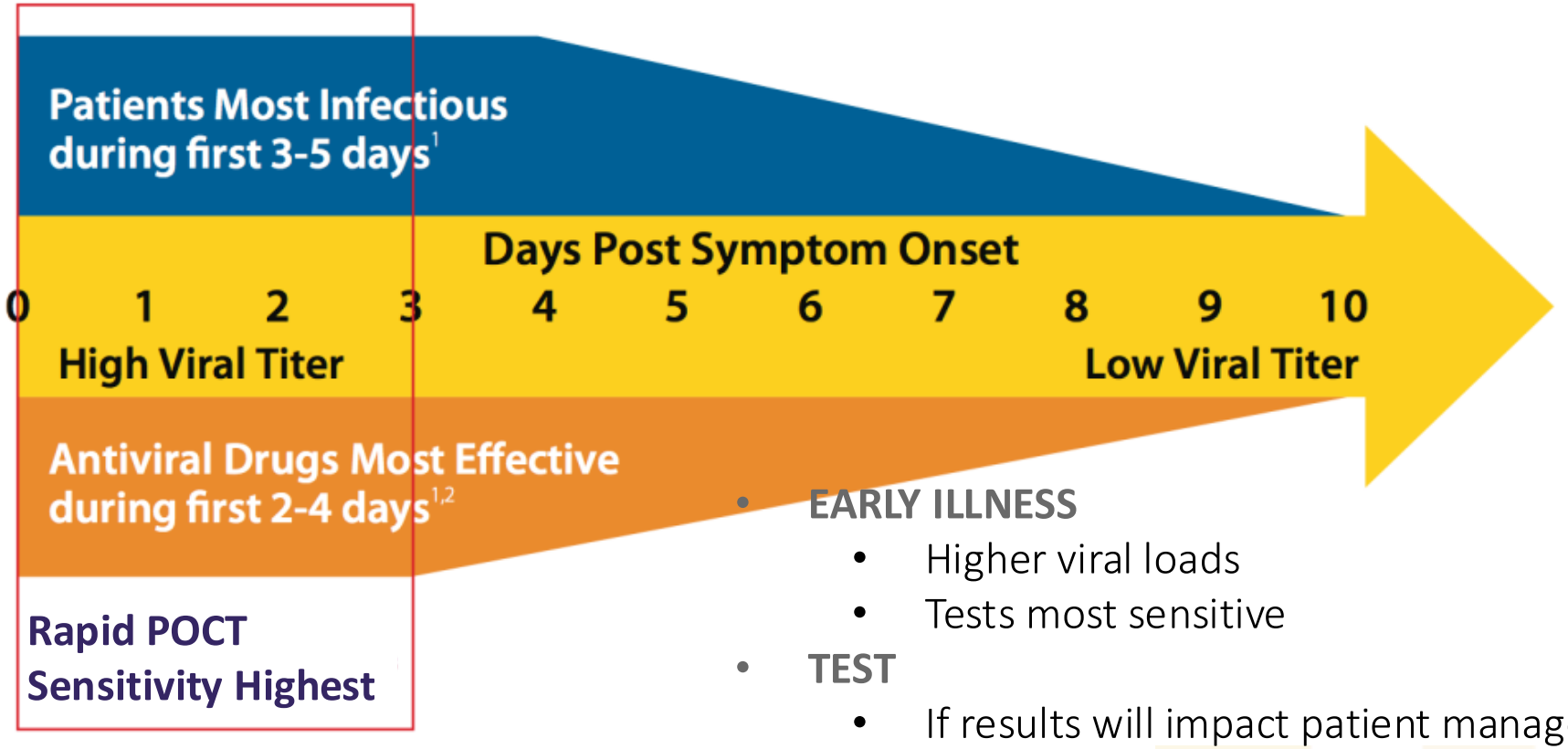
- Can be serious disease in patients aged < 5 and ≥ 65 population, most serious in ≤ 1 year
- No treatment
- Seasonal, test when circulating; low prevalence can reduce PPV and add unnecessary costs
- Consider testing in hospitalized infants, elderly, and immunocompromised/ comorbid patients[1]
- **Antigen tests not recommended in older children and adults.**

FOLLOW-UP TESTING IF INITIAL PATHOGEN IS NEGATIVE AND WARRANTED

COVID-19

- Guidelines recommend molecular testing if sick enough to seek medical care
- Antigen testing is available both OTC and for medical use
  - Some recommendations call for 2 separate tests if symptomatic and 3 if asymptomatic

Influenza A & B



- **EARLY ILLNESS**
  - Higher viral loads
  - Tests most sensitive
- **TEST**
  - If results will impact patient management and infection control decisions
  - ≤ 48 hours, for effective treatment
- **SELF-ISOLATE**
  - When symptomatic, avoid exposure with others

RSV

Under 5?

- Rapid antigen and NAAT tests acceptable

Over 65?

- Rapid antigen tests perform poorly in elderly, not recommended[1]

1. CDC. Respiratory Syncytial Virus Infection (RSV), For Healthcare Providers. https://www.cdc.gov/rsv/clinical/index.html, updated October 28, 2022.

GAS

Cannot diagnose clinically[1]

- Do not diagnose without laboratory confirmation
- Do not treat without laboratory confirmation

Test in appropriate patients[1]

- ≥ 3 years
- Symptoms of bona fide GAS pharyngitis infection

Know test sensitivity

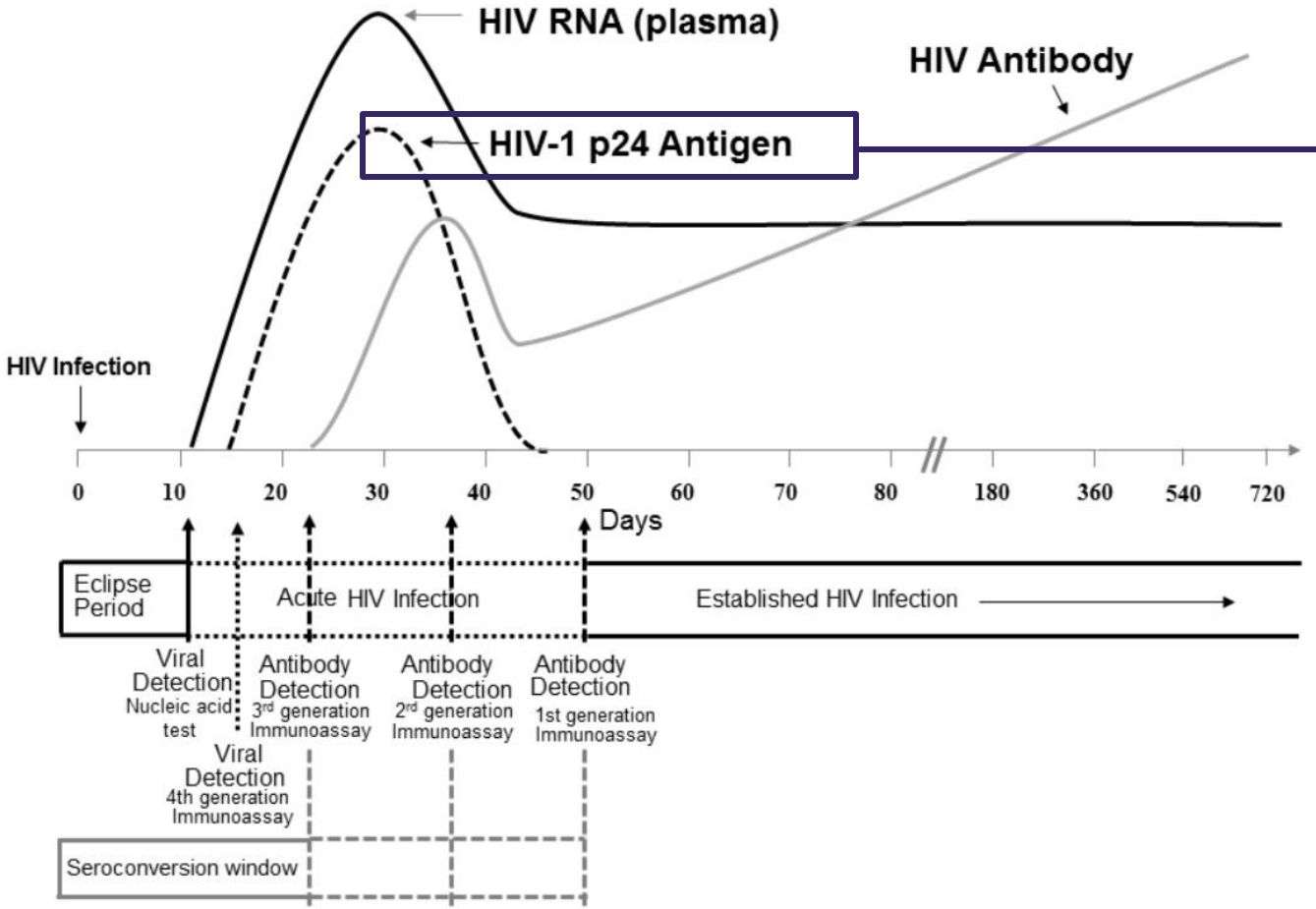
- Rapid antigen tests – Cohen, et al. 2016 meta-analysis – **85.6%**[2]
- NAATs – Thompson, et al. 2019 meta-analysis – **95% - 99%**[3]

Confirm negative rapid antigen with culture?

- "Negatives SHOULD be cultured" - Follow product insert for CLIA waived tests
  - Documentation required for JCAHO and CAP inspections
  - COLA treats as a recommendation not requirement

1. Red Book, 2021-2024. Report of the Committee on Infectious Diseases. Group A Streptococcal Infections. https://publications.aap.org/redbook/book/347/Red-Book-2021-2024-Report-of-the-Committee-on
2. Cohen JF, et al. Rapid antigen detection test for group A streptococcus in children with pharyngitis (Review). 2016, Issue 7. Art. No.: CD010502.
3. Thompson TZ, McMullen AR. J Clin Microbiol. 2020;58(6):e01494-19.

HIV



p24 antigen

enhances detection during acute phase of infection to help reduce risk of missing recently infected individuals / unrecognized acute infections.[1,2]

Acutely infected individuals vs. chronically infected:

Up to **26x** more infectious.[2]

1. Branson BM, et al. Laboratory testing for the diagnosis of HIV infection : updated recommendations. June 27, 2014. https://stacks.cdc.gov/view/cdc/23447.
2. Miller WC, Rosenberg NE, Rutstein SE, Powers KA. Role of acute and early HIV infection in the sexual transmission of HIV. Curr Opin HIV AIDS. 2010;5(4):277-282.

Pre-Analytical and Peri-Analytical Factors

Reagent Storage

- Reagents stored correctly (refrigerated or room temp)?
- Room temp warm up required?

Reagent use and application

- Reagents used within expiration date
- Proper use of reagents; # of drops, recapping

Test procedures

- Instructions followed?

Factors Impacting Rapid Antigen Tests

Read time	• Consistent use of a timer? • Reading at proper time? (Multitasking can interrupt process) • Potential errors when read too early? Too late?
Visual Interpretation	• User visual read (faint lines can be missed)
Test Performance	•Sensitivity? Antigen test less sensitive than molecular technology •Prevalence?

Factors Impacting Rapid NAATs

BEFORE Testing	• Ensure area is clean especially after a positive test
DURING Testing?	• Anything that interacts with enzymes • Point mutations
AFTER testing?	• Dispose of properly

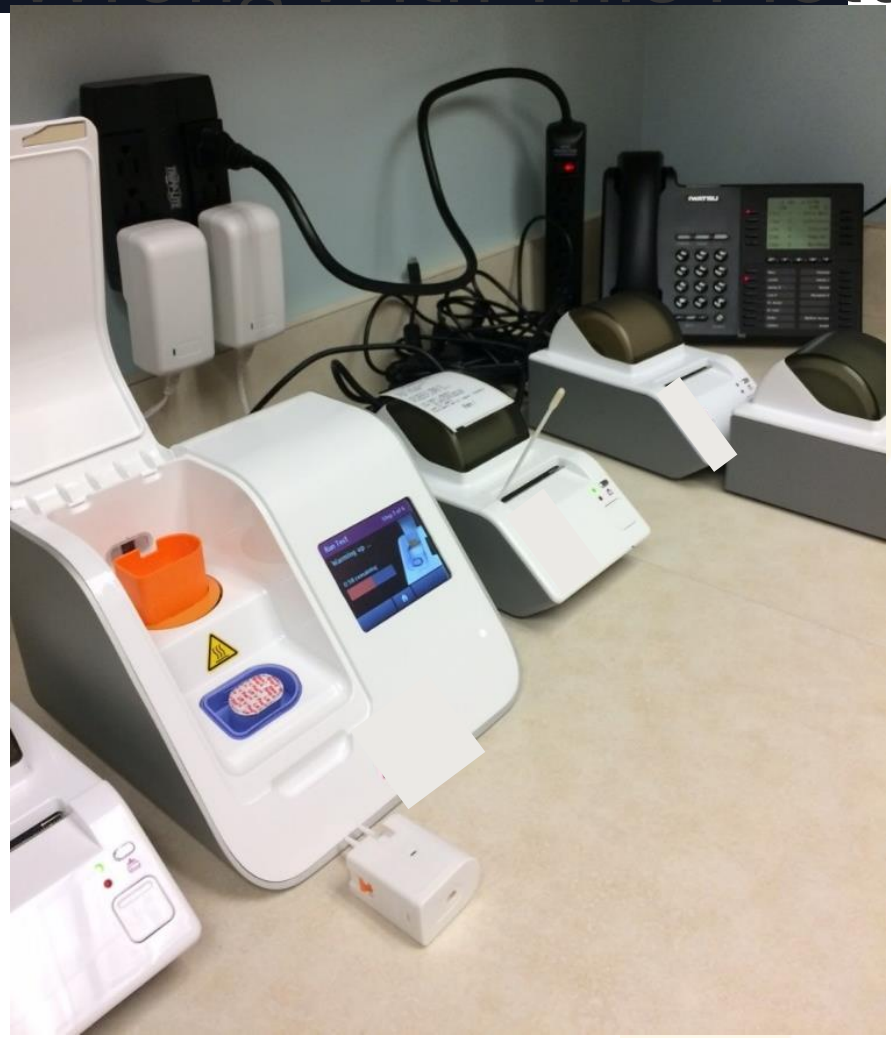
Can the Patient Be A Source of Error?

- Not staying still while taking clinical samples
- Maybe they are embarrassed to answer questions appropriately
- Maybe they aren't understanding how to answer the question
- Maybe they know the prescription they want and will build their answers around that
- Dr. Google can cause a lot of confusion

CLIA-WAIVED TESTS

What Might You Look For at a POC Test Site?

What is Wrong With This Picture?



Or This One?

Or This One?

CLIA-WAIVED TESTS

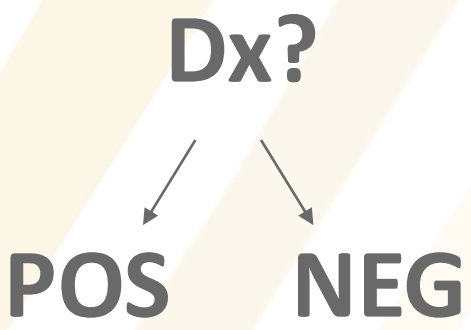
Why Support CLIA-Waived POC Tests?

Drivers for Rapid Accurate Test Results?

- **TRANSITION TO "PATIENT-CENTERED" VALUE BASED HEALTH SERVICE DELIVERY[1]**
  - Improve diagnostic accuracy at initial encounter
  - Diagnose in an actionable timeframe
  - Early optimal treatment selection

  - Avoid the waste of unnecessary investigations
  - Avoid the waste of over treating, improving antimicrobial stewardship
  - Avoid the consequences of incorrect patient management

  - Better health outcomes and reduced healthcare costs



The results of diagnostic tests are immensely influential,
affecting around 60–70% of all clinical decisions,
although they still amount for only 4–5 % of healthcare costs.[1]

1. Akhmetov, I. and Bubnov, R.V. Assessing the value of innovative molecular diagnostic tests in the concept of predictive, preventive, and personalized medicine. The EPMNA Journal (2015) 6:19.

Advantages of Rapid Testing for Infectious Respiratory Illnesses

Increased **appropriate use of antivirals** with positive viral test [1-4]

195% improvement [2]

Better outcomes [9-11]

Including, shorter duration of symptoms[9] and faster return to work or school[10]

Antimicrobial stewardship [1,5-8]

25% reduction in unnecessary antibiotic use

Infection control

66% reduction in uninfected patient exposure time [13]

82% reduction in hospital acquired respiratory infections (HAI) [14,15]

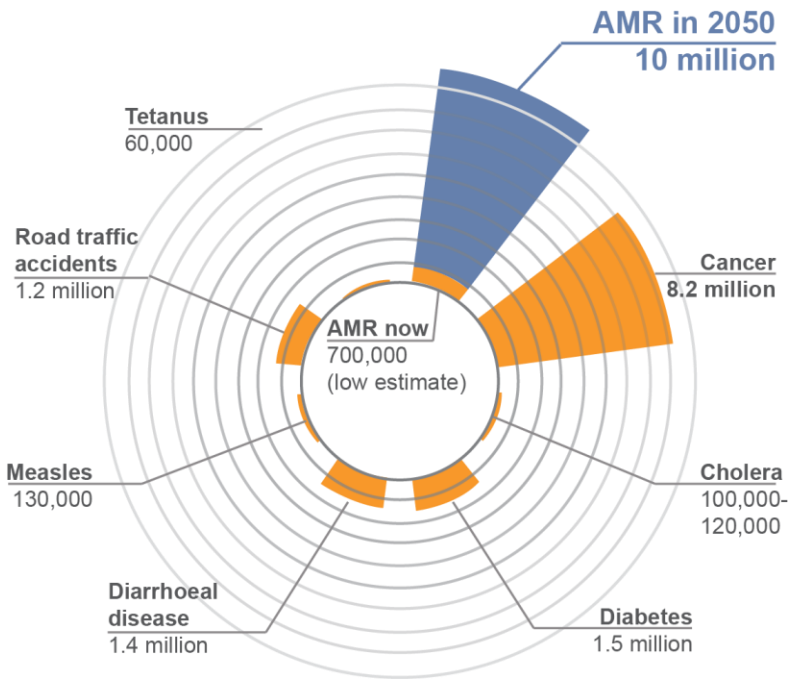
Reduced length-of-stay in Emergency Department[12]

Increase in real-time **patient consultations** (with higher physician and patient satisfaction)[16, 17]

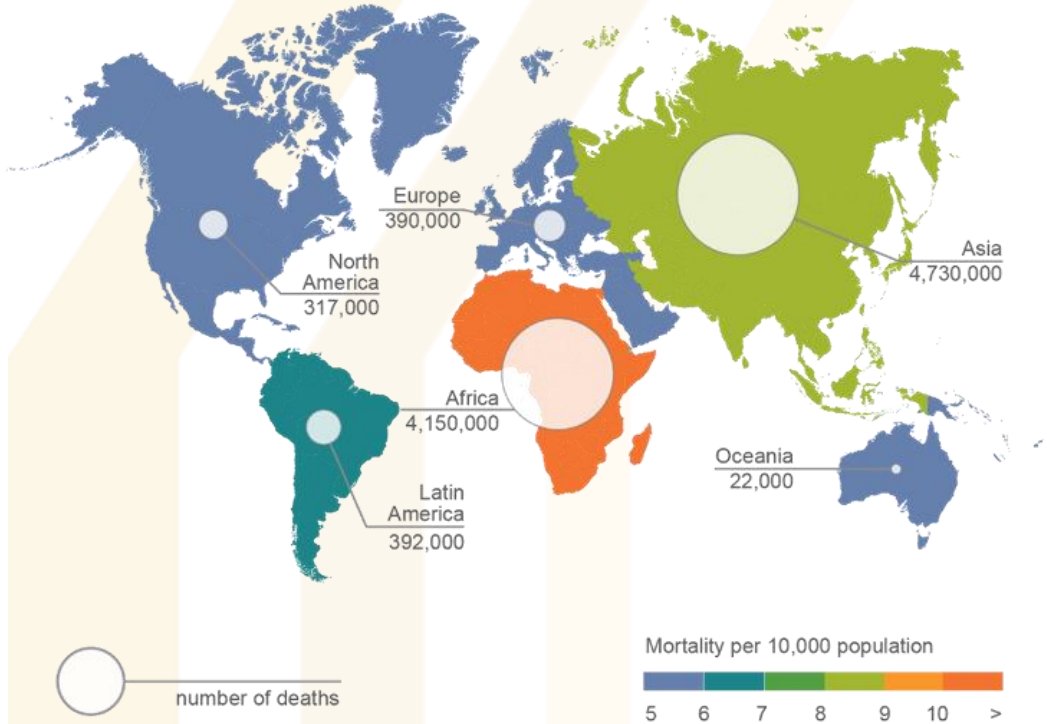
See additional citations

Antimicrobial Resistance: If We Don't Take Action Now

DEATHS ATTRIBUTABLE TO AMR EVERY YEAR
compared to other major causes of death



DEATHS ATTRIBUTABLE TO AMR EVERY YEAR
by 2050



Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations. 2014.

I Need Your Feedback – Scan the QR

Scan the QR code to submit your feedback digitally.

Prefer paper?

On the form in front of you, please score me and the content I shared with you today.