



# STI Testing Technology

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# Disclosures

(Research Support, Consulting or Honorarium)

## Research Grants to my Institution

- NIH
- Abbott Molecular
- BD Diagnostics
- binx health
- BioFire
- Cepheid
- Hologic
- Roche Molecular

## Salary/Consulting Honoraria

- UAB
- NIH
- FDA
- Abbott Molecular
- Applied BioCode
- BD Diagnostics
- Roche Molecular

*It is a duty of academicians and experienced scientists paid using tax-payer dollars to advise industry in bringing forward new technologies to advance medicine and public health. Not doing so would be detrimental to the public interest by limiting access to expertise. I have several disclosures, but none represents a conflict of interest as my primary interest is public health.*

# Topics

- Central Lab-based
- Point-of-Care
- Non-clinical Settings

# CENTRAL LAB-BASED TESTING



# Classes of Tests (I)

- Serology      **Indirect evidence of infection**
  - *Excellent for viral infections and syphilis*
  - *Usually requires additional testing to confirm active infection*
  
- Antigen Detection      **Evidence of active infection**
  - *Detects proteins from the organism*
  - *Usually requires very high organism load (=poor sensitivity)*
    - New bio-sensing technologies are changing this

# Classes of Tests (II)

## Nucleic Acid Amplification Tests (NAATs)

- NAATs **Evidence of exposure, active infection or recently resolved infection**
  - *AKA Molecular assays, “PCR”*
  - *Most sensitive class of test*
    - Detection of exposure in absence of actual infection is possible
  - *Most commonly used class of test for CT/GC/TV/MG*
  - *Difficult for syphilis applications*

# Platforms

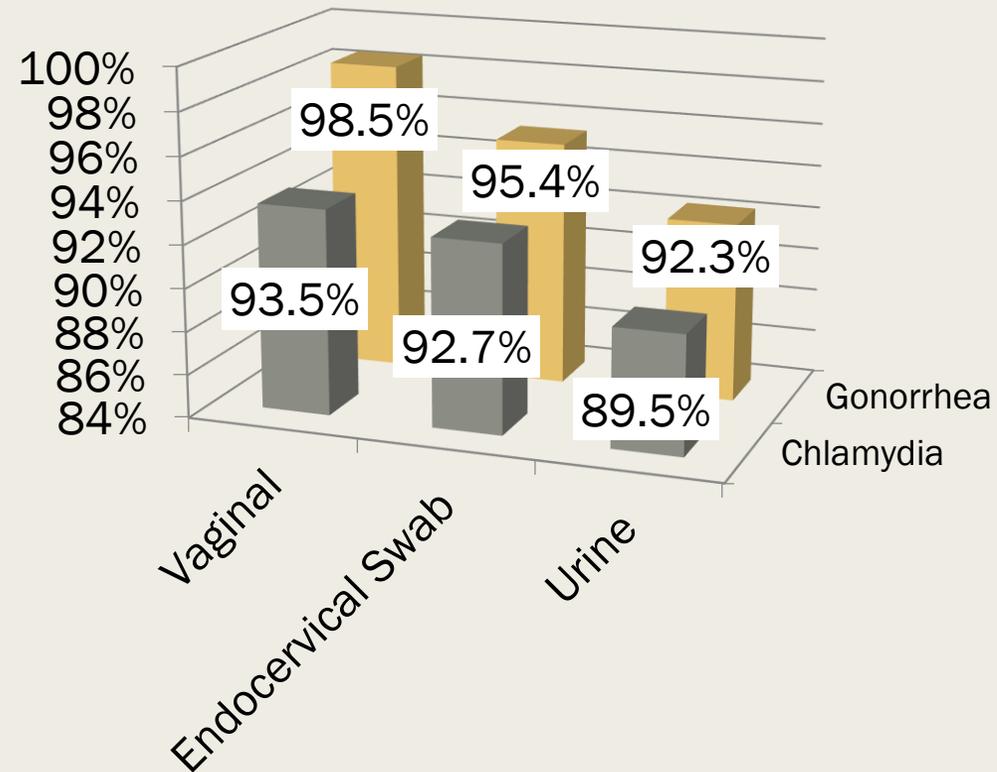
- Most CT/GC/TV/MG platforms can detect multiple pathogens per sample offering wide menu flexibility
  - *Be wary of multiplexed bundles (see Panel Session 2 on Wednesday!)*
- TAT is usually within 24 h of receipt
  - *Specimens and data must be transmitted from clinic to lab to clinic*

# Less than Optimal Screening

- Public Health Laboratories surveyed in 2017
- >50% of samples tested from women = URINE

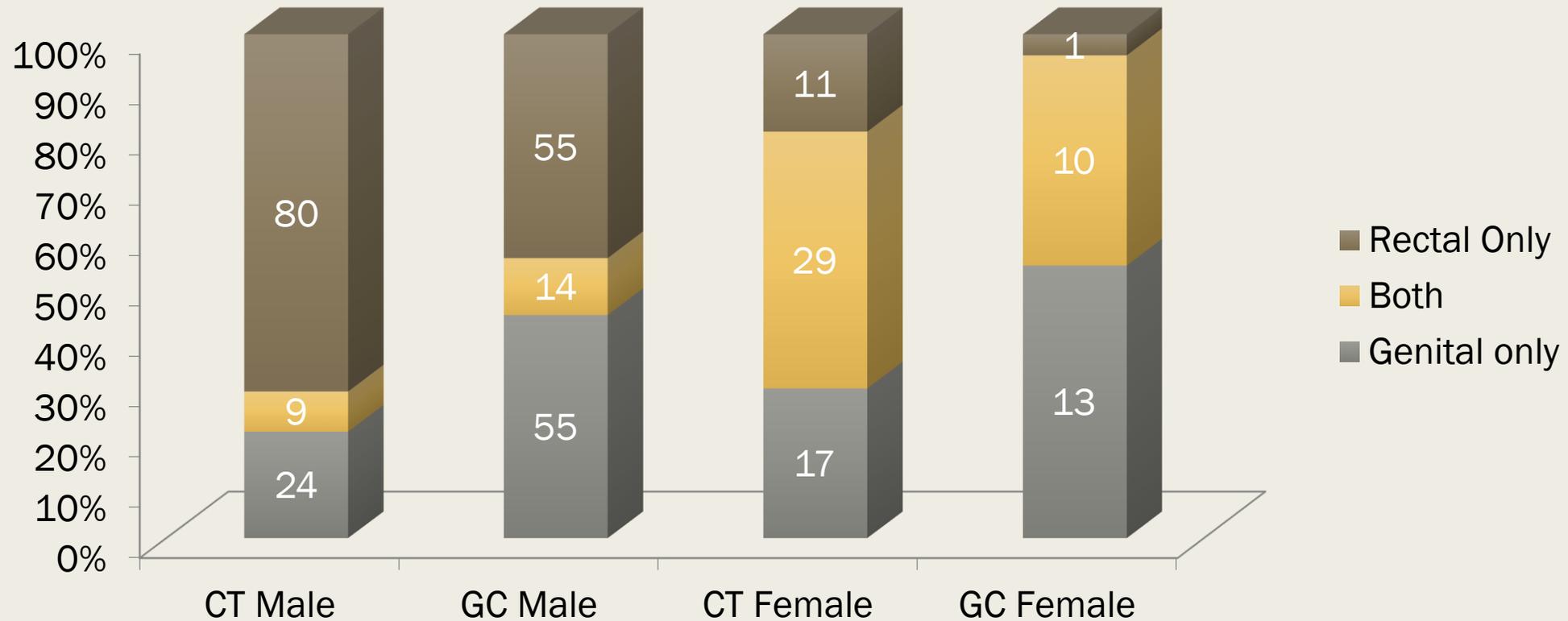
Can a Clean Catch Urine Sample Be Used to Diagnose Chlamydia and Gonorrhea in Adolescent Females?  
*Pickett L. 2021 J Adol H*

86.2% (64.8-93.1%) compared to vaginal swab=80.5%

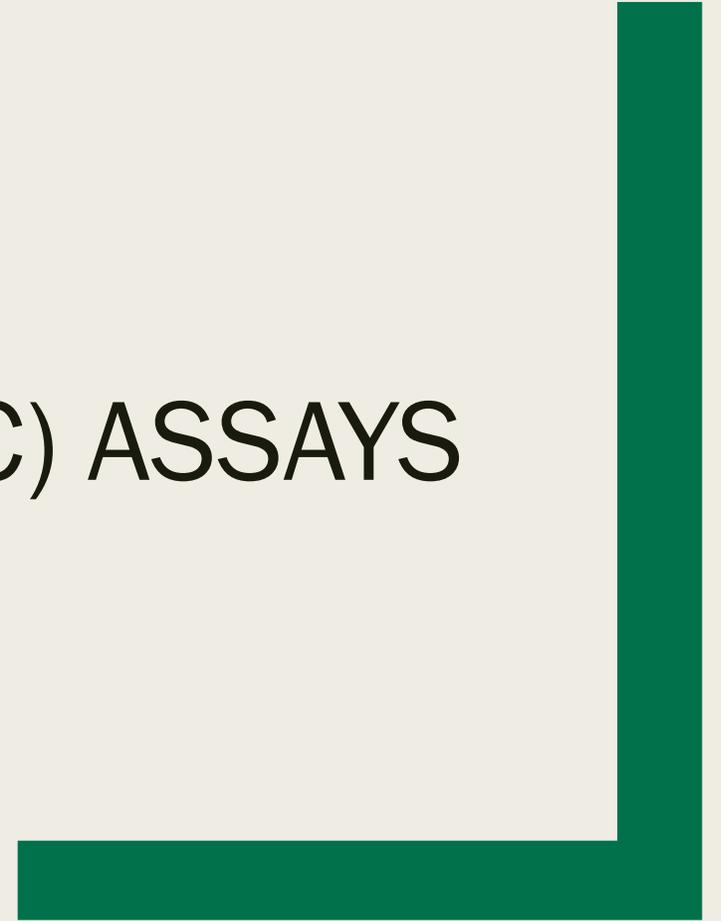


Davis et al, STD 2020  
Figure adapted from Van Der Pol, et al, 2013 STD

# Proportion of Infections Detected by Rectal or Genital Sampling



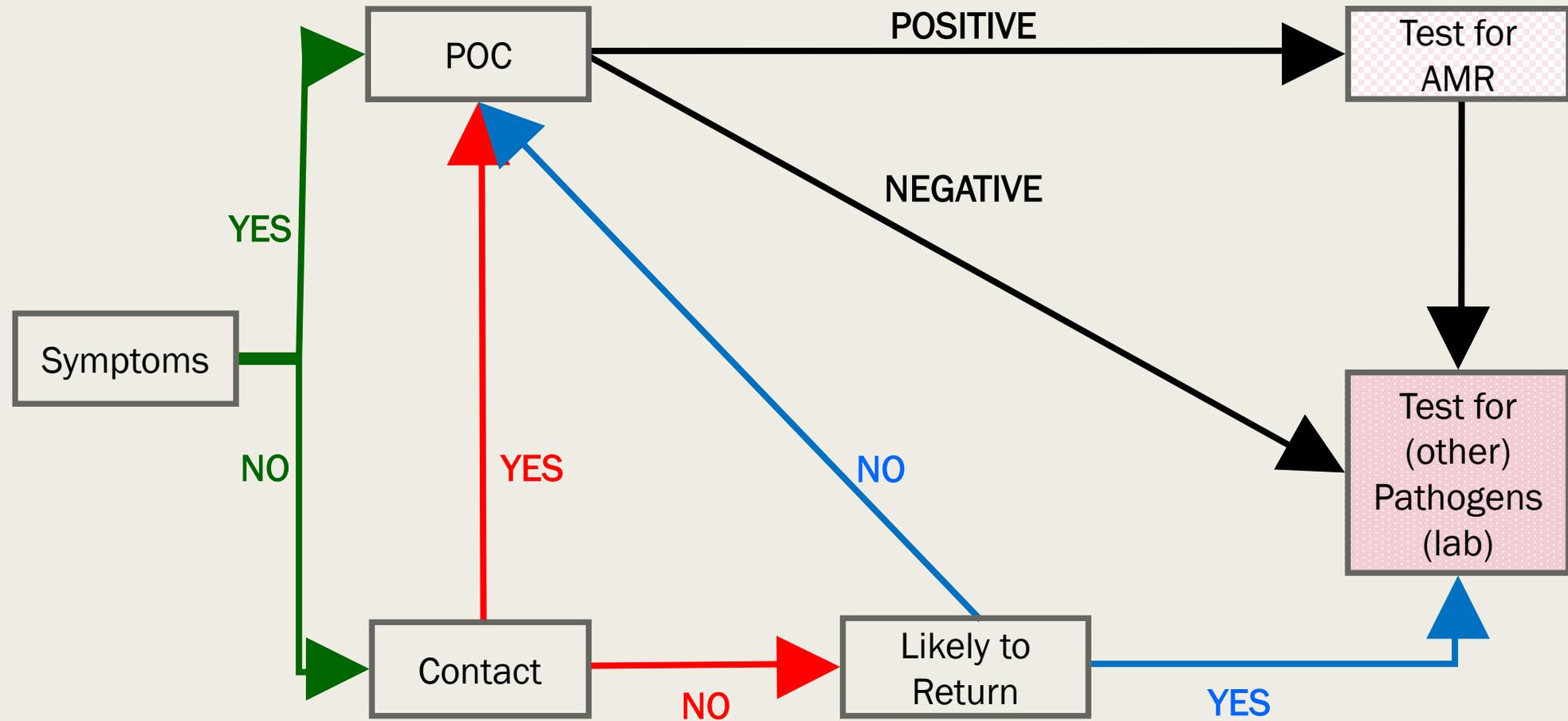
# POINT-OF-CARE (POC) ASSAYS



# Be Careful What You Ask For! (and when you use it)

- POC is often incorrectly associated with antigen testing (and low sensitivity)
- POC for HIV serology led the way
  - *Syphilis serology is here, but implementation has been challenging*
- 3 NAAT POC for CT/GC/TV are here
  - *Implementation is challenging*

# A Draft Decision Tree for Clinical Use



# Time to results

- 90 min test (SAMPLE FIRST)\*
  - *Added 46 min to a 2 h visit*
  - *21% waited for results*
    - 20% of these had change in Tx based on Dx
    - Time to result deliver decreased from 10 to 2 days!
  
- 30 min test (SAMPLE FIRST)\*\*
  - *Added 11 min to 30 min visit*
  - *83% able to wait for results*

\*Harding-Esch, et al. STD. 2020

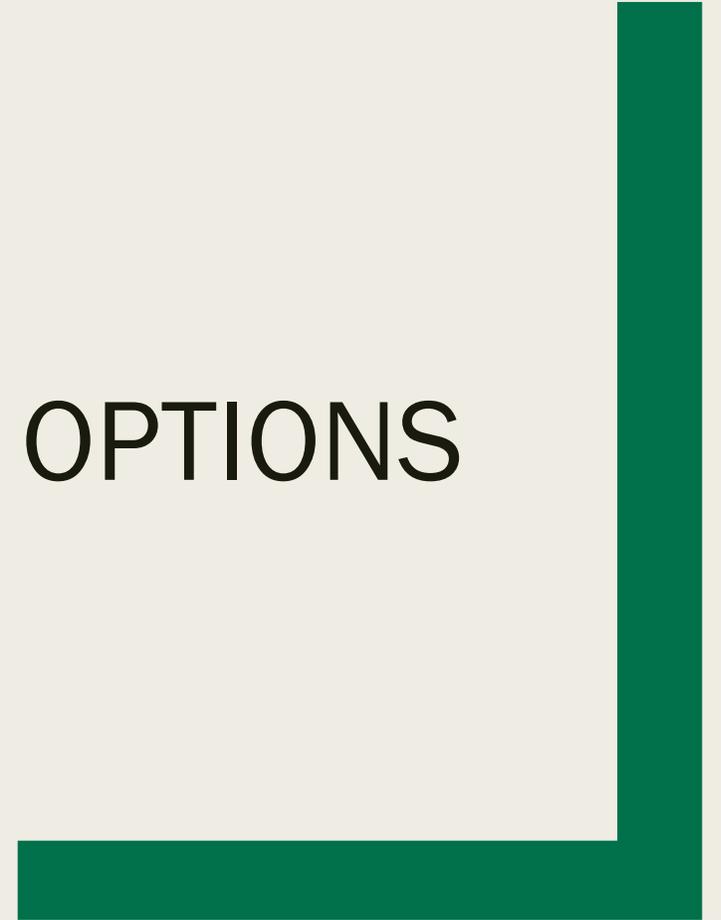
\*\*Gettinger, et al. STD. 2020

# Assay Comparisons for CT/GC/TV

Attribute	Assay 1	Assay 2	Assay 3
Sample types	Urine, Cervical Vaginal Anal and Pharyngeal swabs	Male urine, Vaginal swabs	Vaginal swabs
Targets	CT/GC, TV separate	<b>CT/GC</b>	CT/GC/TV multiplex
Time to Results	<b>90</b> min	30 min	30 min
CLIA Waived	<b>No?</b>	Yes	Yes
Instrument required	<b>Yes</b>	<b>Yes</b>	No ( <b>Power required</b> )
Throughput	1-16 per instrument	<b>1 per instrument</b>	As many as power & space permit
Cost	\$\$	\$\$\$	\$\$\$\$

- Which one is “best”?
  - *It depends!*
  - *The answer may be different tomorrow*

# NON-CLINICAL TESTING OPTIONS



# Hot Topic!!

## (see Sessions 3 & 6!)

- HIV is only STI for which there is an FDA-cleared at-home test
  - *No self-collection devices have intended use outside clinical settings for any other STI*
- BUT...
  - *DIS often test for syphilis in the field*
  - *Telemedicine and Direct to Consumer testing relies on collection in non-clinical settings (mostly)*

For more details from the American STD Association, see Exten et al. Direct-to-Consumer STI Testing Services, STD May 20, 2021 - doi: 10.1097/OLQ.0000000000001475

[https://journals.lww.com/stdjournal/Abstract/9000/Direct\\_to\\_Consumer\\_STI\\_Testing\\_Services\\_A.97656.aspx](https://journals.lww.com/stdjournal/Abstract/9000/Direct_to_Consumer_STI_Testing_Services_A.97656.aspx)

# Over-the-Counter: On the way?

- Consider the implications of Over-the-Counter tests
  - *The regulatory hurdles are currently a barrier for OTC assay development, but CoVID may have helped!*
- Tests must be accompanied with education efforts
- Linkage to care and reporting are critical (and POSSIBLE)
  - *Linkage to care may not work perfectly, but will there be a net benefit?*
- What to do about “confirming” results?

# We need solutions to effect a paradigm shift

- New technologies and data management solutions developed in response to CoVID need to be applied to the problem of STI
- Cost will ALWAYS matter
- Attend the sessions and join in the conversation!

