HIV/HCV Diagnostics Update:

Opportunities to Strengthen HIV and/or HCV Testing and Linkage Programs

July 8, 2025

NASTAD

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Housekeeping

- Please place yourself on mute
- Questions via chat, or please hold until the end
- Webinar will be recorded and link to access will be distributed

Learning Objectives

- Increase knowledge about the characteristics and performance of currently available HIV and HCV tests
- Identify opportunities for using technologies/strategies to optimize HIV and/or HCV testing and linkage programs

Agenda

- **HIV and HCV Testing**
  Linda Styer, PhD, Director, Bloodborne Viruses Laboratory
  Wadsworth Center
  New York State Department of Health
- **Evolution of Hepatitis C Testing in New York State**
  Colleen Flanigan, RN, MS
  Director, Bureau of Hepatitis Health Care and Epidemiology
  New York State Department of Health
- **Considerations and Resources for Optimizing Testing in Public Health Programs (time permitting)**
  - *Liisa Randall, PhD, Consultant, NASTAD*
  - *Sarah Buss, PhD, D(ABMM), APHL*
- **Questions and Discussion**

NEW YORK STATE | Department of Health
Wadsworth Center

HIV and Hepatitis C Virus (HCV) Testing

Linda Styer, Ph.D.
Director, Bloodborne Viruses Laboratory
linda.styer@health.ny.gov

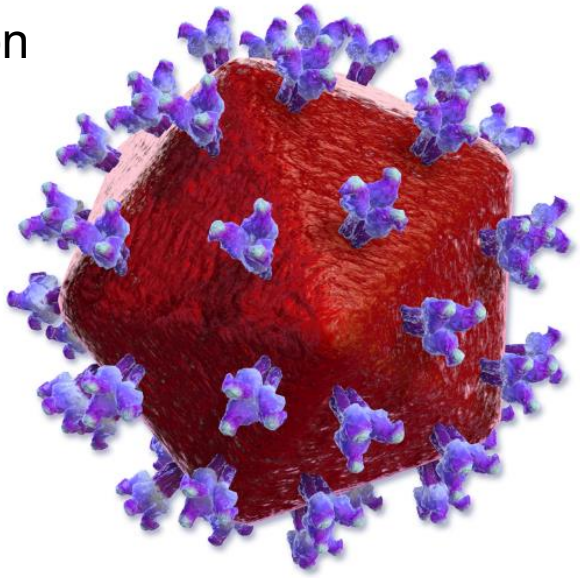
Outline

- Background on HIV/HCV infection cycles, diversity, & treatment
- HIV – infection markers, window periods, test algorithm, tests (lab & point-of-care)
- HCV – infection markers, window periods, test algorithm, tests (lab & point-of-care)
- Alternative specimens for HIV/HCV
- Considerations for HIV/HCV testing

HIV and HCV

Transmitted via sexual activities and blood exposure; cause chronic infections

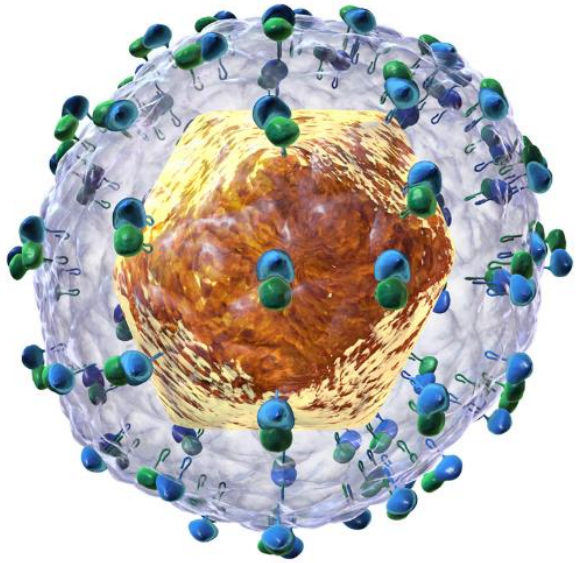
Mostly sexual transmission



Human Immunodeficiency Virus (HIV)

https://commons.wikimedia.org/wiki/File:HIV.png

Mostly blood transmission

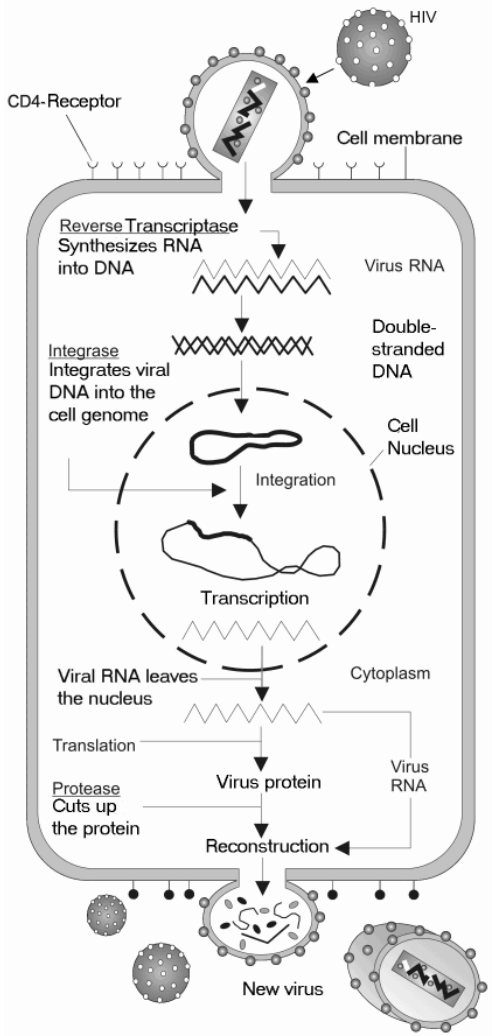


Hepatitis C Virus (HCV)

https://commons.wikimedia.org/wiki/File:HCV.png

NEW YORK STATE | Department of Health
Wadsworth Center

Infection Cycle



HIV

Two copies of RNA genome in virion

RNA to DNA to RNA

'Reservoir' of HIV DNA integrated into genome

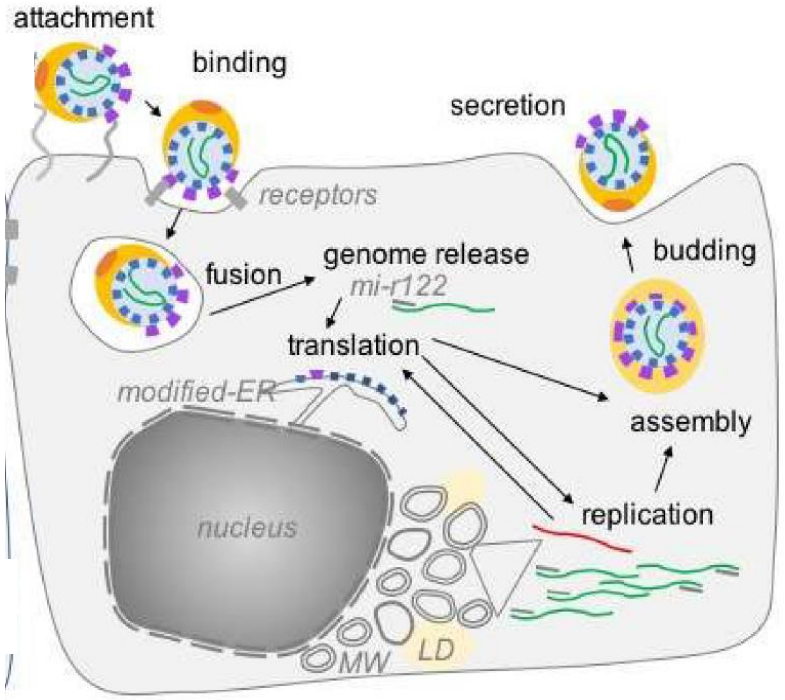
Recombination and error prone reverse transcription

https://commons.wikimedia.org/wiki/File:HIV_gross_cycle_only.png

HCV

Error prone viral polymerase

RNA to RNA

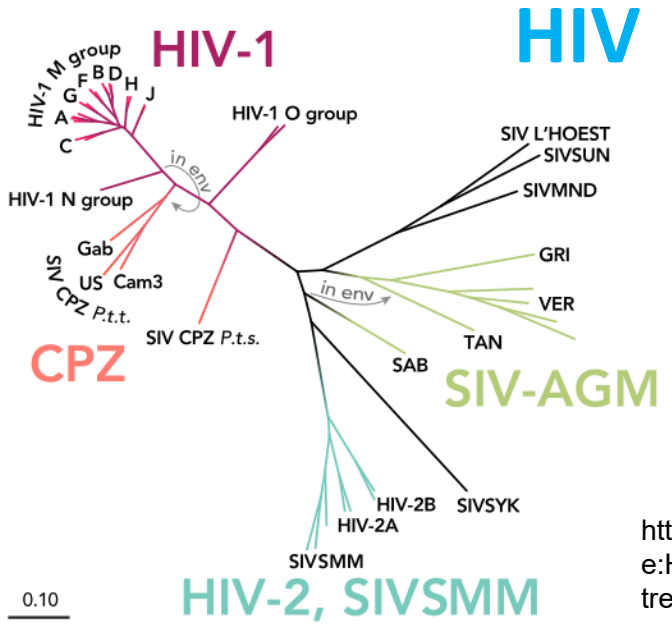


https://commons.wikimedia.org/wiki/File:Viruses-11-00030-g001.webp

NEW YORK STATE | Department of Health
Wadsworth Center

Viral Diversity

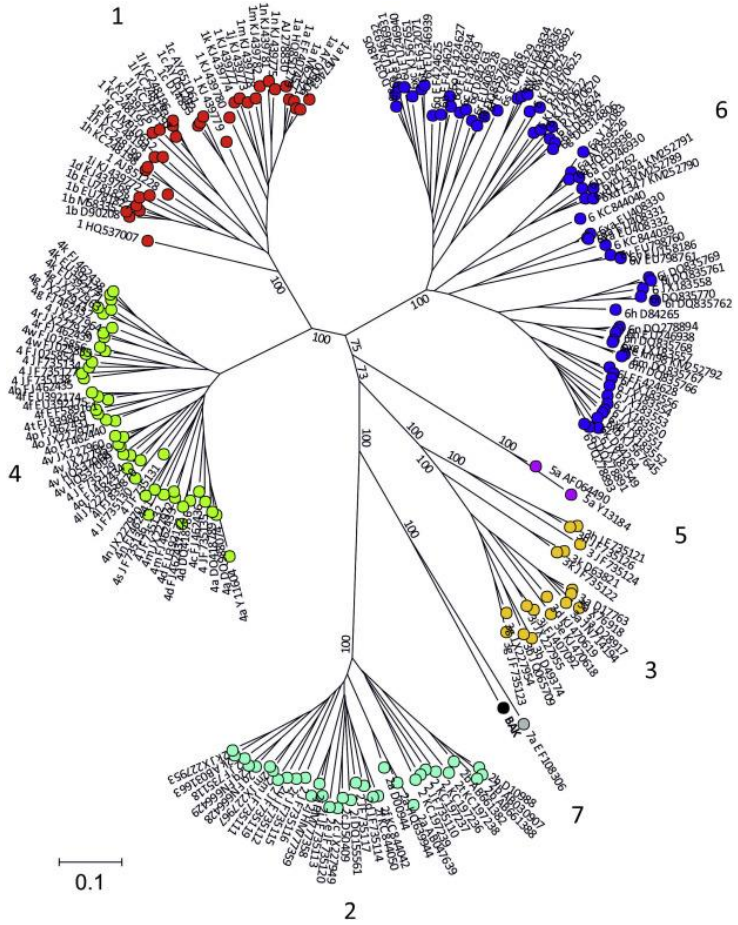
HIV



https://commons.wikimedia.org/wiki/File:HIV-SIV-phylogenetic-tree_straight.svg

- Types: HIV-1 and HIV-2 (rare)
- Groups: HIV-1 M,N,O,P HIV-2 A,B
- Subtypes: within HIV-1 Group M

HCV

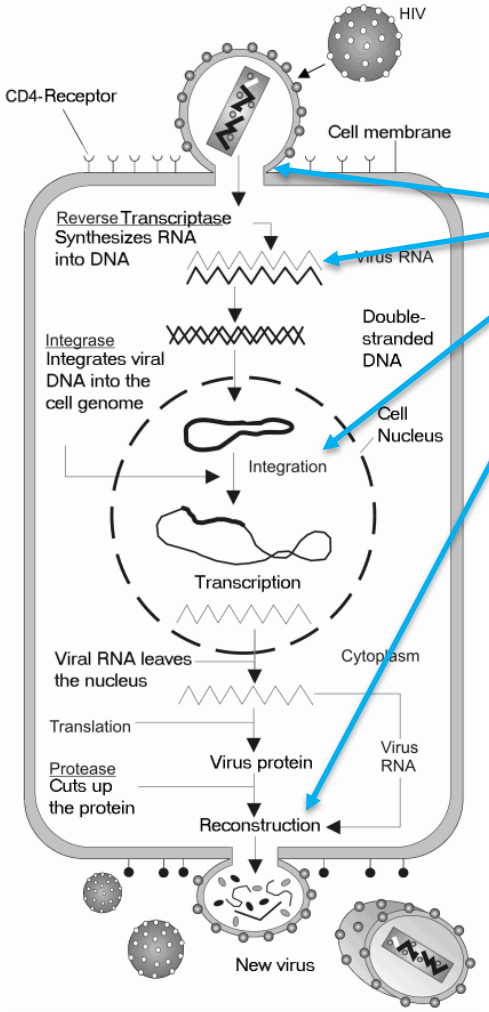


Salmona et al 2016 Clin Micro & Infect 22:947.e1947.e8.
https://doi.org/10.1016/j.cmi.2016.07.032

- 7 total genotypes
- Many subtypes

NEW YORK STATE | Department of Health
Wadsworth Center

Treatment



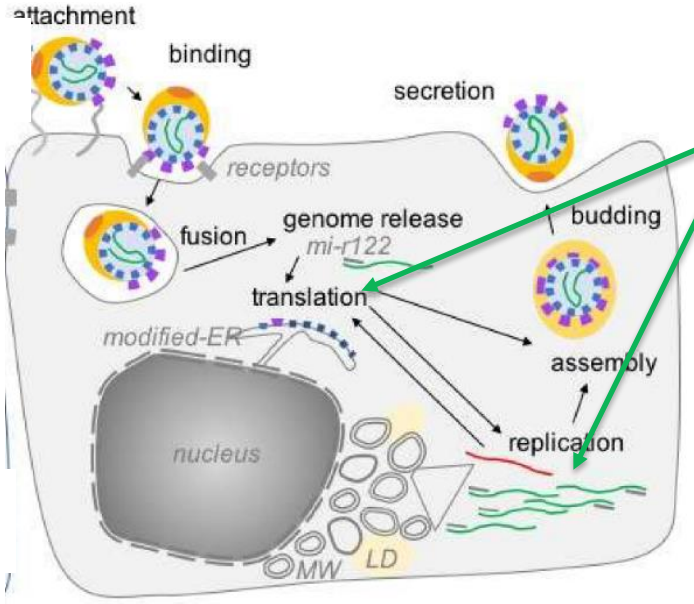
HIV

Multiple drug targets

- Not curative, stops viral replication
- Developed for HIV-1 but some treat HIV-2
- ‘Treatment as prevention’

HCV

- 15-45% clear HCV without treatment
- Direct acting antivirals (DAAs) >95% cure
- ‘Treatment as prevention’
- Can be re-infected with HCV



Multiple drug targets

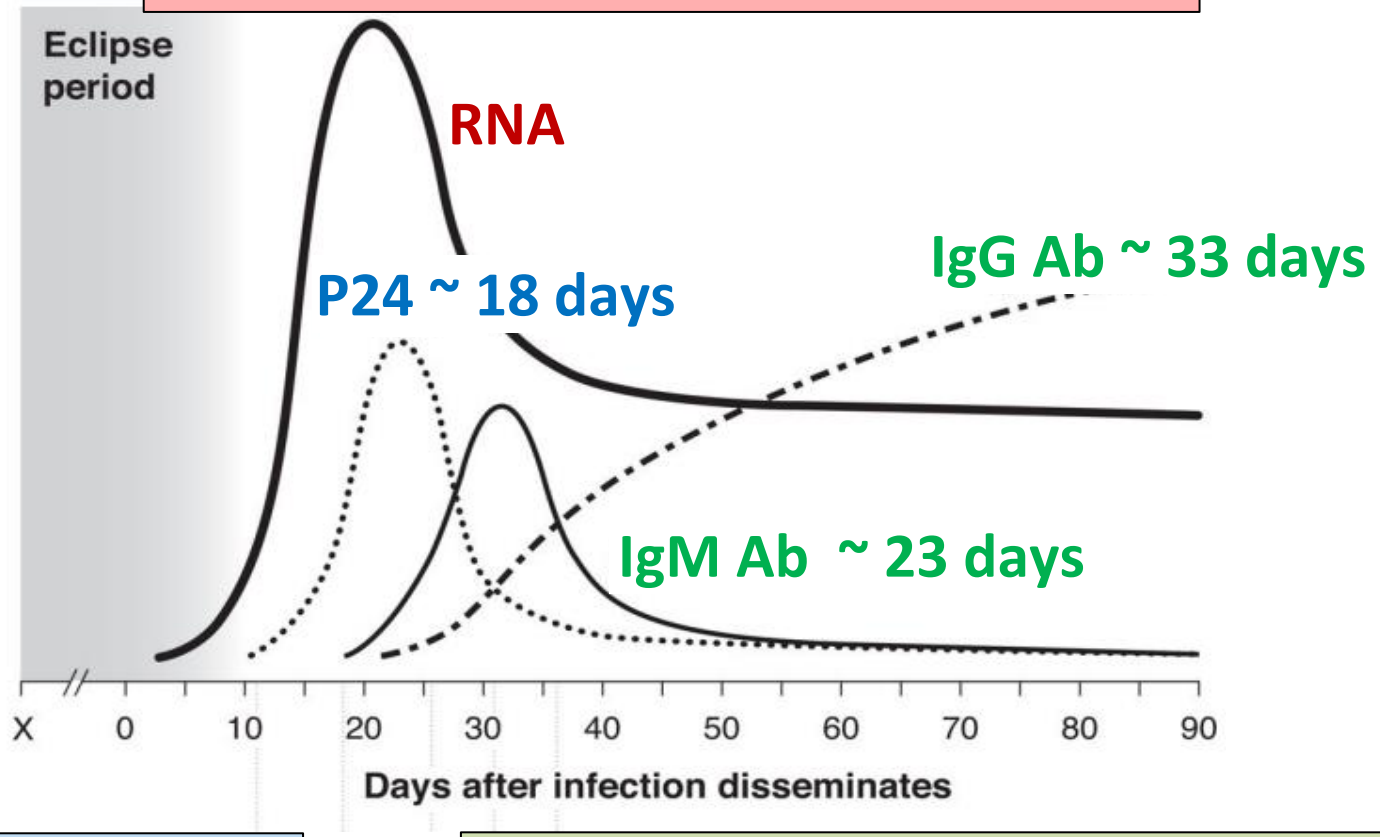
NEW YORK STATE | Department of Health
Wadsworth Center

Markers of Infection & Window Periods - HIV

Window periods depend on:

- **Test target**
- **Type of specimen**
- **Lab vs POC Test**
- **Random factors**

Window Period in PLASMA – Lab Testing



Window Period in BLOOD – Rapid Test
~ 1-2 months for IgM/IgG Ab

Window Period in ORAL FLUID – Rapid Test
~ 3 months for IgM/IgG Ab

NEW YORK STATE | Department of Health
Wadsworth Center

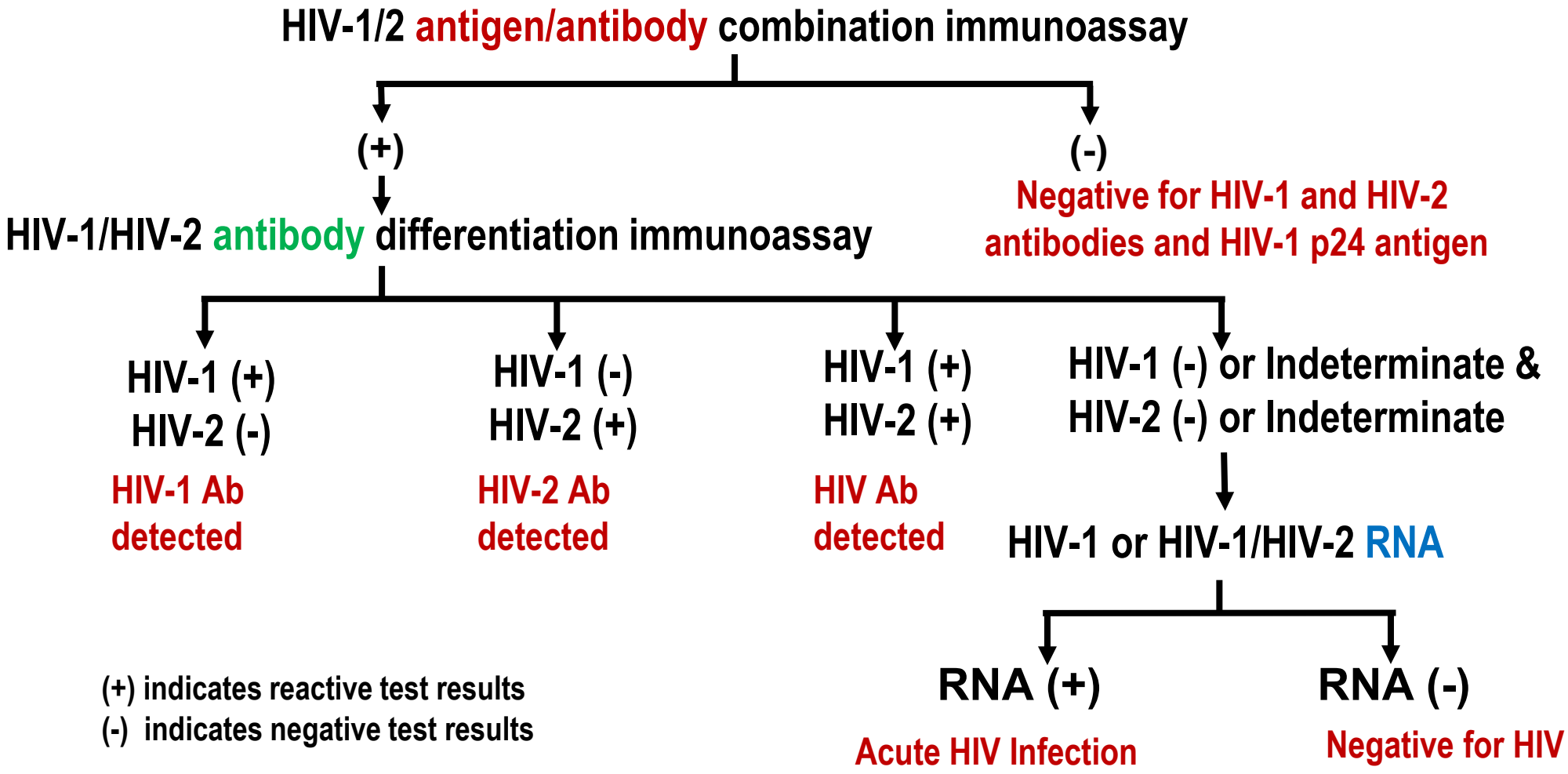
Median window periods (lab) from Delaney et al. Clin Infect Dis. 2017;64(1):53-59. doi:10.1093/cid/ciw666
Figure modified from Sexually Transmitted Diseases44(12):739-746, December 2017. doi: 10.1097/OLQ.0000000000000719

Laboratory Testing Algorithm- HIV

Step 1

Step 2

Step 3



(+) indicates reactive test results
(-) indicates negative test results

From CDC's Quick Reference Guide, Jan 2018
https://www.cdc.gov/hiv/testing/laboratorytests.html

Step 1: HIV-1/2 Ag/Ab Combo Immunoassays

HIV

Test (Manufacturer)	Yr FDA approved	Method
Architect HIV Ag/Ab Combo (Abbott)	2010	CMIA
GS HIV Ag/Ab Combo EIA (Bio-Rad)	2011	EIA
ADVIA Centaur HIV Ag/Ab Combo (Siemens) Centaur and Atellica instrument platforms	2015	CMIA
Elecsys HIV combi PT (Roche Diagnostics)	2017	ECLIA
VITROS HIV Combo (Ortho Clinical Diagnostics)	2017	Immunometric
Alinity i HIV Ag/Ab Combo (Abbott)	2019	CMIA
LIAISON XL MUREX HIV Ab/Ag HT (Diasorin)	2020	CMIA
Determine HIV-1/2 Ag/Ab Combo (Abbott)	2013	**LF rapid test**
BioPlex 2200 HIV Ag-Ab (Bio-Rad Laboratories)	2015	Multiplex flow
Elecsys HIV Duo (Roche Diagnostics)	2020	ECLIA
Access HIV Ag/Ab Combo (Beckman Coulter)	2023	CMIA

All are designed to detect HIV-1 p24 antigen and IgM/IgG antibodies to HIV-1 and HIV-2

No analyte differentiation

None are designed to detect HIV-2 antigen

Analyte differentiation

NEW YORK STATE | Department of Health
Wadsworth Center

Step 2: HIV-1/HIV-2 antibody differentiation immunoassay

HIV

Geenius HIV-1/2 Supplemental Assay (BioRad)

- Detects IgG Ab to HIV-1 & HIV-2
- Single cartridge with reader
- Individual results, overall interpretation

https://www.bio-rad.com/en-us/product/geenius-hiv-1-2-supplemental-assay?ID=NGUT8KE8Z

VioOne HIV Profile Supplemental Assay (Avioq)

- Detects IgG Ab to HIV-1 & HIV-2
- ELISA format on 96 well plate
- Individual results, overall interpretation

	1	2	3	4	5	6	7	8	9	10	11	12
A				No viral Ag								
B				HIV-1 p65 (*pol*)								
C				HIV-1 gp160 (*env*, low)								
D				HIV-1 gp160 (*env*)								
E				HIV-1 gp41 (*env*, M,O)								
F				HIV-1 p24 (*gag*)								
G				No viral Ag								
H				HIV-2 gp36 (peptide)								

NEW YORK STATE | Department of Health
Wadsworth Center

Step 3: HIV RNA Diagnostic Tests

HIV

Test (Manufacturer)	Type	Target(s)
Aptima HIV-1 RNA Quant Dx (Hologic)	Qualitative & Quantitative (Viral Load)	HIV-1 RNA
Alinity m HIV-1 (Abbott)	Qualitative & Quantitative (Viral Load)	HIV-1 RNA
Cobas HIV-1/HIV-2 Qualitative (Roche)	Qualitative	HIV-1 RNA & HIV-2 RNA

- New assays (since 2020): Automated, faster, less prone to error
- Dual claim tests (Aptima and Alinity) – Intended Use = 'Confirm HIV-1 infection' and 'Monitor Disease Prognosis'
- Cobas HIV-1/HIV-2 qualitative is only FDA approved assay for HIV-2 RNA diagnostic testing

Point-of-Care (POC) & Self-Tests

HIV

Test (Manufacturer)	Targets	Ab Detected	Specimens	FDA Status
Determine HIV-1/2 Ag/Ab Combo (Abbott)	HIV-1 Ab, HIV-2 Ab, **HIV-1 p24 Ag**	IgM & IgG	FS blood	Waived
DPP HIV-Syphilis System (Chembio)	HIV-1 Ab, HIV-2 Ab, ***T. pallidum Ab***	IgM & IgG	FS blood	Waived
DPP HIV-1/2 Assay (Chembio)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	FS blood, V blood, oral fluid	Waived
HIV-1/2 STAT-PAK Assay (Chembio)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	FS blood, V blood	Waived
SURE CHECK HIV-1/2 Assay (Chembio)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	FS blood, V blood	Waived
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test (OraSure Technologies)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	FS blood, V blood, oral fluid	Waived
INSTI HIV-1/HIV-2 Antibody Test (bioLytical)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	FS blood	Waived
OraQuick In-Home HIV Test (OraSure Technologies)	HIV-1 Ab, HIV-2 Ab	IgM & IgG	**Oral Fluid**	**Self Test**

All reactive results require confirmatory testing

Testing in the Context of PrEP

HIV

Pre-exposure Prophylaxis (PrEP)

- Daily/bi-monthly/bi-yearly treatment to reduce risk of acquiring HIV
- Recommended for HIV-negative people at high risk
- Oral and injectable forms

HIV infection while on PrEP can delay appearance of HIV infection markers

  – Viral RNA near limit of detection, leading to false negative result or fluctuating low positive/negative results

  – Delayed antibody development, leading to false negative, low or borderline results that may waffle between positive and negative

Individuals may not disclose their PrEP usage

Sources: Manak et al 2019 https://pubmed.ncbi.nlm.nih.gov/31217270/
Branson 2019 https://pubmed.ncbi.nlm.nih.gov/31239094/

Testing Associated with PrEP

HIV

1) Ensure individuals are HIV negative prior to PrEP (test<1 wk prior to starting)
   - High-risk: HIV Ag/Ab and HIV-1 RNA using serum/plasma
   - Low-risk: HIV Ag/Ab using serum/plasma – if needed, POC ok with blood

2) Ensure person has not become infected while taking PrEP (test every 2-3 mo)
   - HIV Ag/Ab and HIV-1 RNA using serum/plasma

Oral fluid testing is NOT recommended for PrEP initiation or monitoring

Source: https://www.cdc.gov/hivnexus/hcp/prep/?CDC_AAref_Val=https://www.cdc.gov/hiv/clinicians/prevention/prescribe-prep.html

HIV Summary

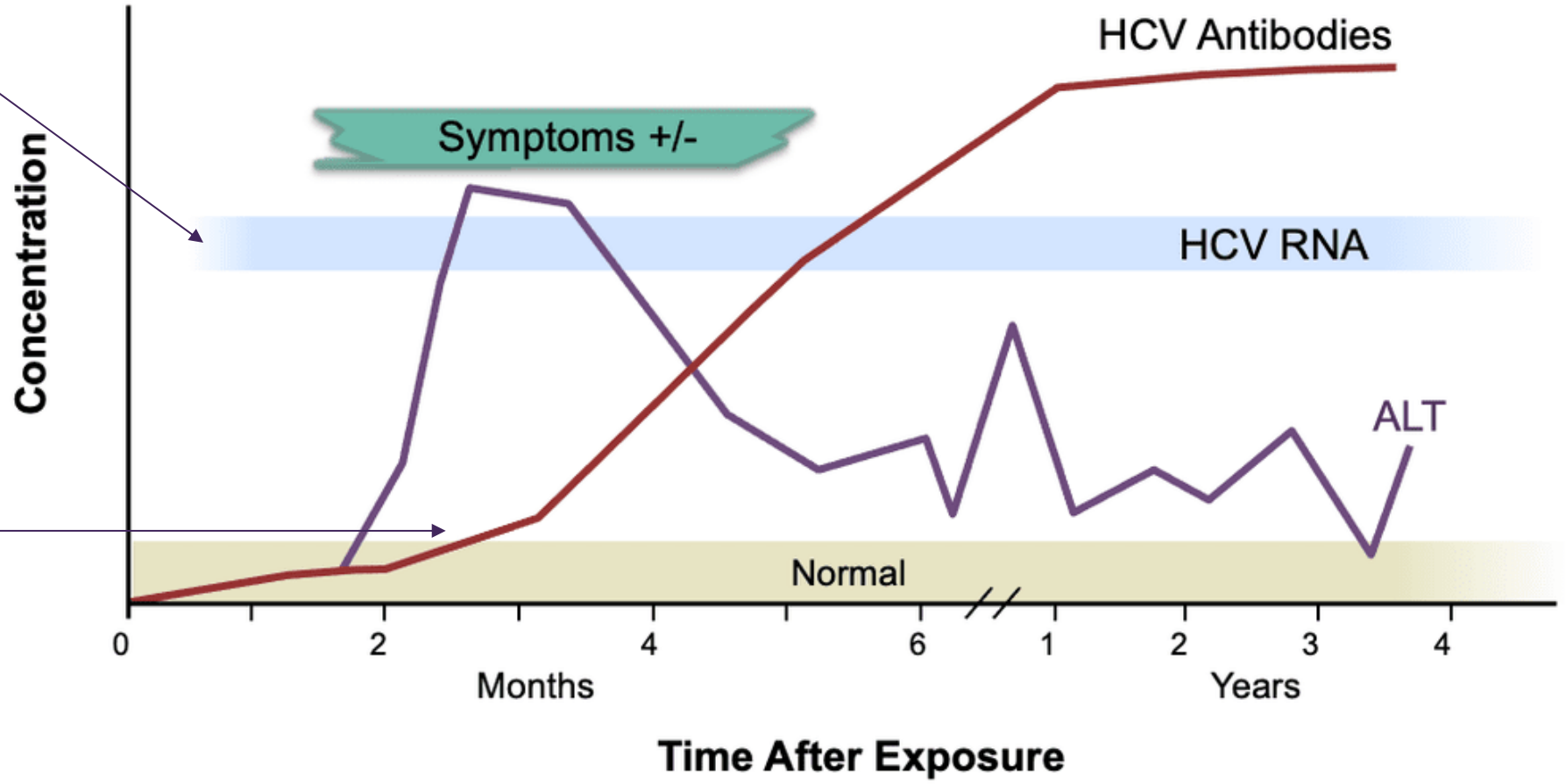
- No HIV cure, so can use Ab or RNA to confirm HIV infection
- Window periods (shortest to longest):
  - RNA → Ag → IgM Ab → IgG Ab
  - Lab → POC
  - Plasma/serum → FS Blood → Oral fluid
- Multiple options for all steps of HIV algorithm for laboratories
- Many POC HIV tests with varying window periods
- PrEP requires additional testing and complicates test interpretation

Markers of Infection & Window Periods

HCV

HCV RNA:1-2 weeks until reactive

HCV Ab: 2-3 months until reactive



NEW YORK STATE | Department of Health
Wadsworth Center

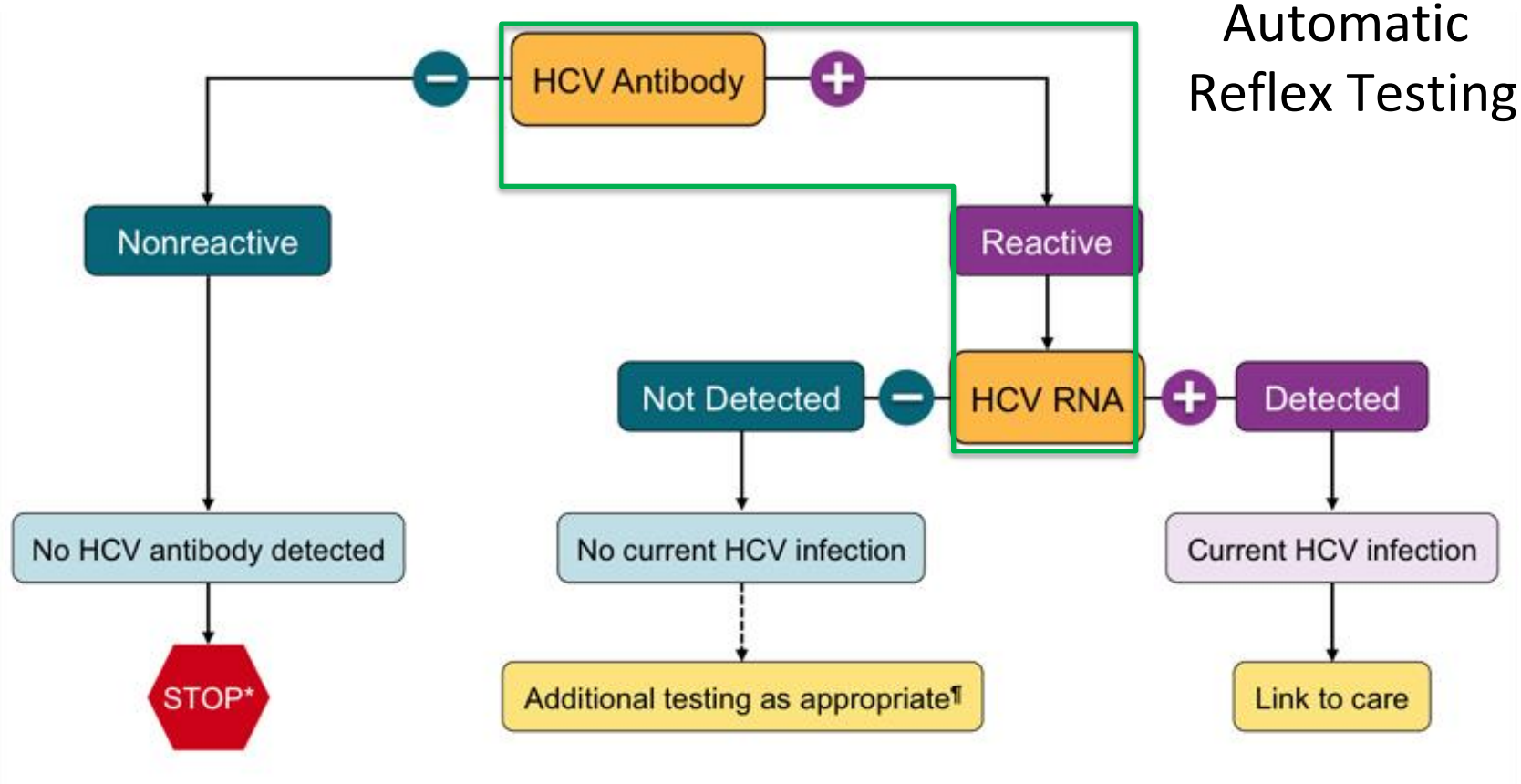
https://www.hepatitisc.uw.edu/go/screening-diagnosis/acute-diagnosis/core-concept/all

Testing Algorithm

HCV

Step 1

Step 2



NEW YORK STATE | Department of Health
Wadsworth Center

https://www.hepatitisc.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all

Step 1: HCV Antibody Testing

HCV

Laboratory Tests

Test	Platform(s)	Manufacturer
Anti-HCV	Architect, Alinity	Abbott
ORTHO HCV v3.0 ELISA	Manual	Bio-Rad
MUREX HCV Ab	LIAISON XL	Diasorin
Anti-HCV	VITROS ECi/ECiQ, 3600, 5600, XT 7600	Ortho-Clinical Diagnostics
Elecsys Anti-HCV II	Cobas e 411, e 601, e 602, e 402, e 801	Roche
HCV Assay	ADVIA Centaur XPT/XP, ADVIA Centaur CP, Atellica IM	Siemens

Point of Care Tests

Test	Sample	Manufacturer
OraQuick HCV Rapid Antibody Test	FS Whole blood	OraSure Technologies

https://www.hepatitisc.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all

Step 2: HCV RNA Diagnostic Tests

Laboratory Tests

Test	Platform(s)	Manufacturer	Type	LOD
cobas HCV	cobas 5800/6800/8800, cobas 4800	Roche	Qualitative & Quantitative (Viral Load)	12-14 IU/mL
Aptima HCV Quant Dx	Panther	Hologic		3-4 IU/mL
Alinity m HCV	Alinity m	Abbott		8-9 IU/mL

Point of Care Test

Test	Sample	Manufacturer	Type	LOD
Xpert HCV (June 2024)	FS Whole blood	Cepheid	Qualitative	32-136 IU/mL

LOD: Limit of Detection

NEW! Xpert HCV Point of Care RNA test

HCV

- Waived, 60-minute test
- Use in adults at risk of HCV and/or those with signs and symptoms of HCV, with or without antibody evidence of HCV
- Performance characteristics not established in pregnant people or people less than 22 years old
- Controls
  - Cartridge has Sample Processing Control, Internal Control High, Probe Check Control, Sample Volume Adequacy Control
  - External controls should be run with new lot, new shipment, new operator, if problems

NEW! Xpert HCV Point of Care RNA test

HCV

Collect >250ul fingerstick blood in microtainer and mix by inverting

Use transfer pipette to transfer 100ul to cartridge

Remaining sample can be stored for 4 hrs at 2-30°C

Run on GeneXpert Xpress instrument:

- HCV Detected
- HCV Not Detected
- NO RESULT – REPEAT TEST
- INSTRUMENT ERROR

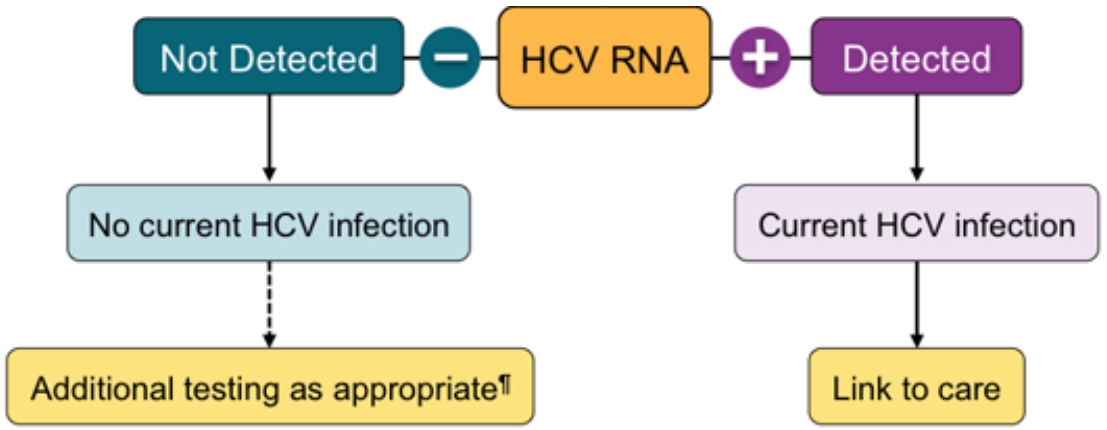
NEW YORK STATE | Department of Health
Wadsworth Center

https://www.cepheid.com/en-US/systems/genexpert-family-of-systems/genexpert-system.html

Alternative Algorithm

HCV

HCV RNA Only
(No Ab testing)



- Enable detection of acute HCV infections
- Reduce turn-around-time
- Lower costs in high-risk populations, higher costs in low-risk populations

POC HCV RNA test can be used on individuals 'with or without HCV antibodies'

Laboratory based HCV RNA tests are to be used on 'HCV antibody positive' individuals – validation or package insert changes needed before 'RNA-first' strategy could be used

HCV Summary

- HCV can be cured, so test for RNA to confirm current HCV infection
- Window periods (shortest to longest):
  - RNA → Ab
  - Lab → POC
- Multiple options for steps of HCV algorithm for laboratories
- One POC HCV Ab & HCV RNA test – can diagnose HCV without the lab
- An alternative ‘viral-first’ algorithm is beneficial, but not currently allowed for lab-based RNA tests

Alternative Specimens – HIV/HCV

Use safety lancet for fingerstick

Wadsworth Center has approved* DBS assays for Geenius HIV-1/2 supplemental, Hologic HIV-1 & HCV Quant Dx RNA assays

Microtainer

Dried blood spots (DBS)

- Collected by minimally trained individuals
- Good for POC testing sites, certain at-risk populations
- Minimal shipping costs (esp. DBS)
- Extended stability (DBS)
- Lower sample volume – higher limit of detection (esp. RNA tests)
- Require lab to perform validation for alternative sample type

NEW YORK STATE | Department of Health
Wadsworth Center

* Approved by NYSDOH Clinical Laboratory Evaluation Program

Other Considerations for HIV/HCV Testing

- Which tests should **programs** choose? Lab vs. POC (blood) vs. self testing (oral)
  - Population: Prevalence, Optimal testing location
  - Organization: Cost, Capacity, Workflows, Resources (venipuncture?)
  - Client: Preferences, Time, Cost, Other priorities/needs
  - Sensitivity: lab > POC (blood) > self testing (oral)
  - Receipt of results by participant: self testing (oral) > POC (blood) > lab
- Which tests should **laboratories** perform?
  - Costs, Volume of testing, Feasibility, Platforms
  - Strict sample stability req: RNA viral load > RNA qualitative >Ag> Ab
  - Need for molecular clean to dirty workflow: RNA (NAT) testing only

FDA approved tests by platform

Table: FDA-Approved HIV, HAV, HBV, HCV, and STD Diagnostic or Monitoring Assays by Manufacturer and Platform[a]

	Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, *Mycoplasma genitalium*
Serologic Assays	Abbott	ARCHITECT System	HIV Ag/Ab Combo	Anti-HAV IgG, Anti-HAV IgM	Anti-HBs, HBsAg (Qual), HBsAg (Qual Conf.), Anti-HBc, Anti-HBc IgM,	Anti-HCV	Syphilis TP (Treponemal)
		Alinity *i*	HIV Ag/Ab Combo	HAVAB IgG, HAVAB IgM	Anti-Hbc, Anti-HBc IgM, Anti-HBs, HbsAg, HBsAg Confirmatory	Anti-HCV	Syphilis TP (Treponemal)
	Avioq	Manual	Avioq HIV-1 Microelisa System, VioOne HIV Profile Supplemental Assay				
	Bio-Rad	EVOLIS	GS HIV Combo Ag/Ab EIA, GS HIV-1/HIV-2 *Plus O* EIA, HIV-2 EIA		MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc EIA, MONOLISA Anti-HBc IgM EIA		Syphilis IgG (Treponemal)
		BioPlex 2200	BioPlex 2200 HIV Ag-Ab				Syphilis Total & RPR assay (Treponemal and Nontreponemal)
		Geenius	Geenius HIV 1/2 Supplemental Assay				
		Manual	GS HIV Combo Ag/Ab EIA, GS HIV-1/HIV-2 Plus O EIA, HIV-1 Western Blot, HIV-2 EIA	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc EIA, GS HBs Ag EIA, GS HBs Ag Confirmatory	ORTHO HCV v3.0 ELISA	
	Diasorin	LIAISON XL	MUREX HIV Ab/Ag HT (Ag/Ab)	Anti-HAV, HAV IgM	MUREX Anti-Hbe, MUREX HBsAg Qual, MUREX Anti HBc , MUREX Anti-HBs	MUREX HCV Ab	Treponema Assay Kit (IgG and IgM)
	Ortho-Clinical Diagnostics	VITROS ECi/ECiQ, 3600, 5600 and XT 7600	Anti-HIV1+2, VITROS HIV Combo (Ag/Ab)	Anti-HAV IgM, Anti-HAV Total	Anti-HBc, Anti-HBc IgM, Anti-HBe, Anti-HBs	Anti-HCV	
	Roche	Cobas e 411 or Cobas e 601		Elecsys Anti-HAV IgM, Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II,HBc Ag, Anti-HBe, HBsAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
		Cobas e 602	Elecsys HIV Combi PT (Ag/Ab)	Elecsys Anti-HAV IgM and Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-HBe, HBeAg, HBsAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
		Cobas e 402 or e 801	Elecsys HIV Duo (Ag/Ab)	Elecsys Anti-HAV IgM and Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-HBe, HBeAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
	Siemens	ADVIA Centaur XPT/XP	HIV Ag/Ab Combo, HIV 1/O/2 Enhanced	HAV IgM, HAV Total	Anti-HBs2, HBc IgM, HBc Total, HBe Ag, HBs Ag Confirmatory, HBs AgII	HCV Assay	Syphilis (Treponemal)
		ADVIA Centaur CP	HIV 1/O/2 Enhanced	HAV IgM, HAV Total	Anti-HBs2, HBc IgM, HBc Total, HBs Ag, HBs Ag Confirmatory	HCV Assay	Syphilis (Treponemal)
		Atellica IM	HIV Ag/Ab Combo, HIV 1/O/2 Enhanced	HAV IgM, HAV Total	HBsAg II, Anti-HBs2, HBc IgM, HBc Total, HBsAg Confirmatory	HCV Assay	Syphilis (Treponemal)

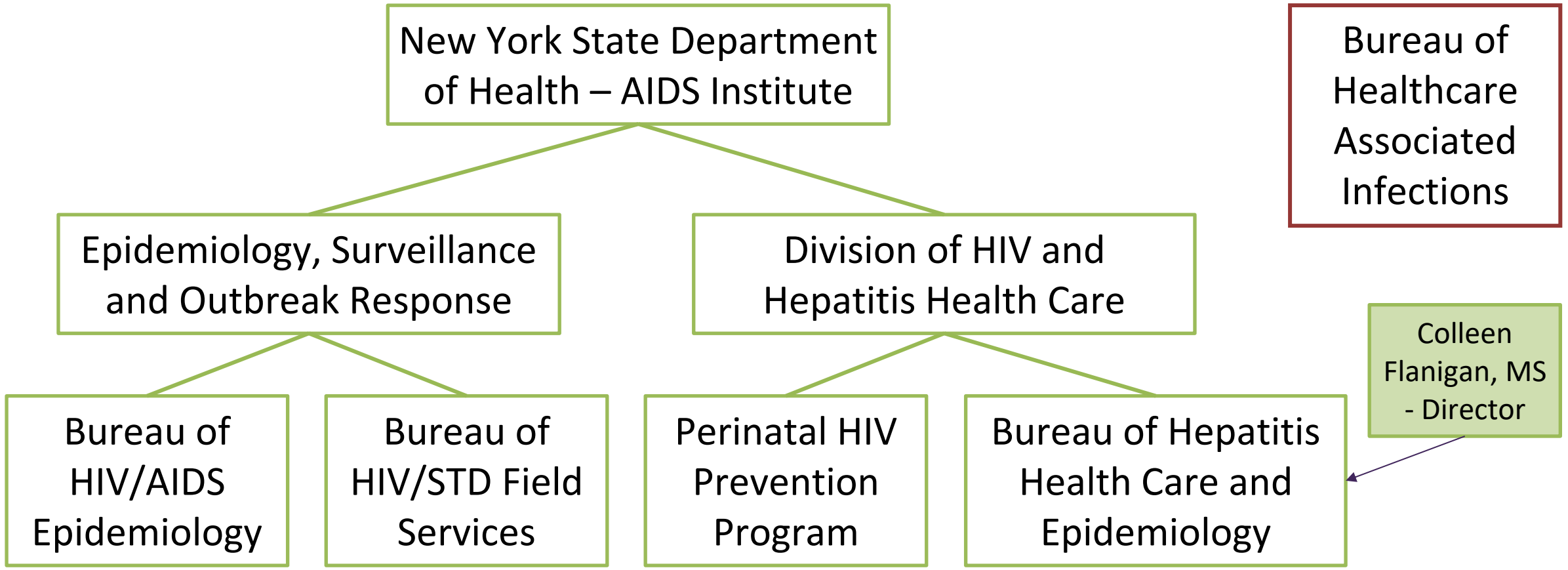
NEW YORK STATE | Department of Health
Wadsworth Center

https://www.aphl.org/programs/infectious_disease/Documents/HIV-VH-STD-Assays_byManufacturer_Platform.pdf

Conclusions

- HIV and HCV are bloodborne viruses that cause chronic infections
- Diverse viruses with effective treatments
- Variety of tests available to use in lab algorithms and POC settings
- Many considerations for selecting the most appropriate tests
- Good communication between the lab and programs is essential!

New York State Department of Health HIV/HCV Programs



NEW YORK STATE | Department of Health
Wadsworth Center

Department of Health
Wadsworth Center

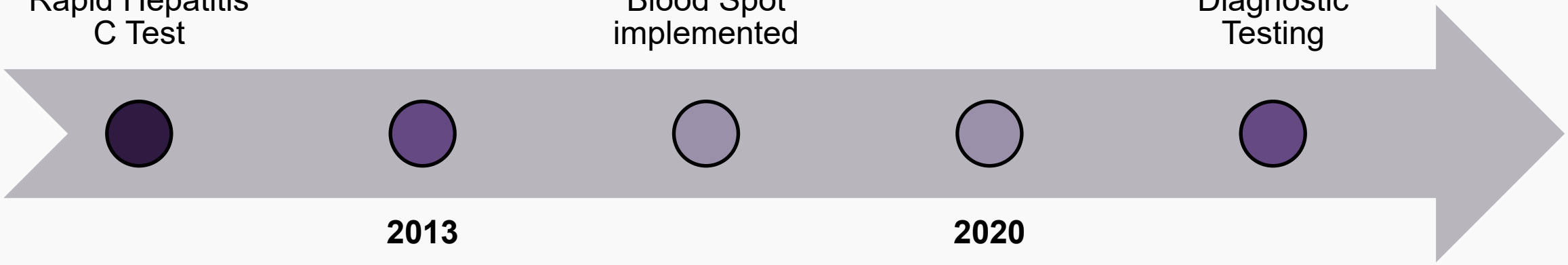
NEW YORK STATE | Department of Health

Evolution of Hepatitis C Testing in New York State

Colleen Flanigan, RN,MS
Director, Bureau of Hepatitis Health Care and Epidemiology

JULY 8, 2025/NASTAD – APHL WEBINAR

TIMELINE



NEW YORK STATE | Department of Health

*Onsite RNA testing = blood sample collected onsite, sent to lab for processing

FACTORS IMPACTING TESTING PROGRAM CHANG

Data

- Low antibody reactivity rates
- Low rates of clients receiving Hepatitis C RNA test result
- Low probability of linkage to care

Budget

- Limited funding available

Setting

- Limited or no availability of phlebotomy
- Client population – people who inject drugs

NEW YORK STATE | Department of Health

NYS HEPATITIS C RAPID TESTING PROGRAM

Launched in April 2012

Modeled off HIV Testing Program

Free Hepatitis C rapid test kits/controls available to programs statewide

Programs must have an agreement with a hepatitis C provider

Onsite Hepatitis C RNA* testing

- Initially contract with Quest then dried blood spot (DBS) by public health lab

NEW YORK STATE | Department of Health

*RNA: Ribonucleic acid

THEN AND NOW

2012

All types of programs

All hepatitis C risks
-From injection drug use to tattoos
50+ agencies enrolled
-Local health departments, syringe service programs, community-based organizations, community health centers

5,000-6,000 tests /year

11% reactivity rate

2024

Programs serving people who inject drugs

25 agencies enrolled

15 syringe service programs

Jails

2,000+ tests/year

32.5% reactivity

NEW YORK STATE | Department of Health

TRANSITION TO HIGH IMPACT TESTING, 2020

Data	• High numbers of tests being performed • Low reactivity rates
Budget	• Limited amount of funding
Setting	• Prioritize settings serving people who inject drugs

NEW YORK STATE | Department of Health

TRANSITION TO HIGH IMPACT TESTING, 2020

Participating programs required to maintain 10% reactivity rate.

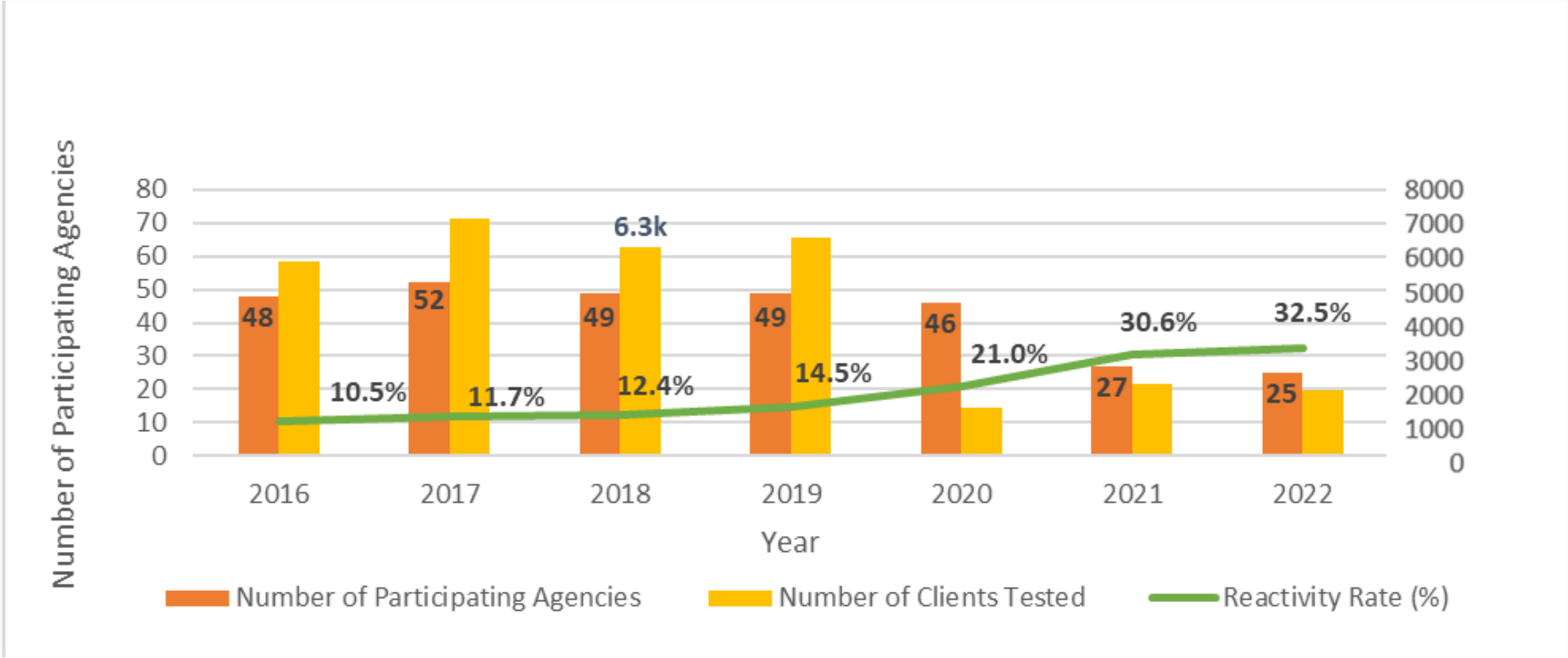
Reviewed data with programs with low reactivity rates.

Provided technical assistance to help better target people who inject drugs.

If unable to reach 10%, disenrolled from the program.

NEW YORK STATE | Department of Health

HEPATITIS C TESTING AND REACTIVITY RATE BY



NEW YORK STATE | Department of Health

HEPATITIS C RNA TESTING – REFERRAL TO ONSI

By referral off site (2012)

Onsite (2013)

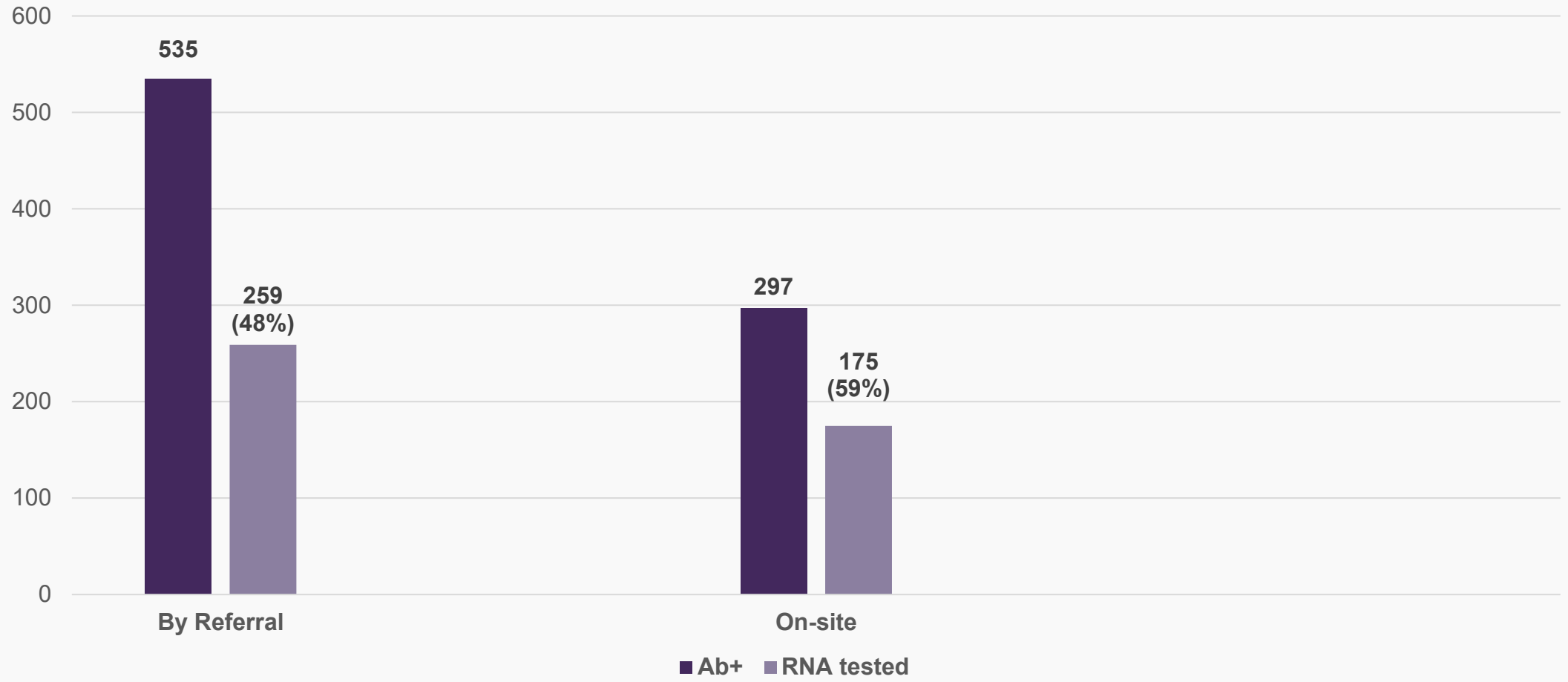
- Contract with Quest Diagnostics
- Limited to agencies with phlebotomy
  - (50% of the programs)

Dried Blood Spot - DBS (2019)

- Public Health Lab
- 84% of programs perform dried blood spot testing

NEW YORK STATE | Department of Health

HEPATITIS C RNA TESTING BY REFERRAL VS. ON



NEW YORK STATE | Department of Health

HEPATITIS C RNA TESTING
WHY THE CHANGES?

Data

- Few receiving the Hepatitis C RNA test by referral

Budget

- Dried blood spot testing provided at no cost to the testing agency
- State funds available and provided to public health lab for DBS testing

Setting

- Staff at most testing programs not trained in phlebotomy
- Client preference (fingerstick vs blood draw)

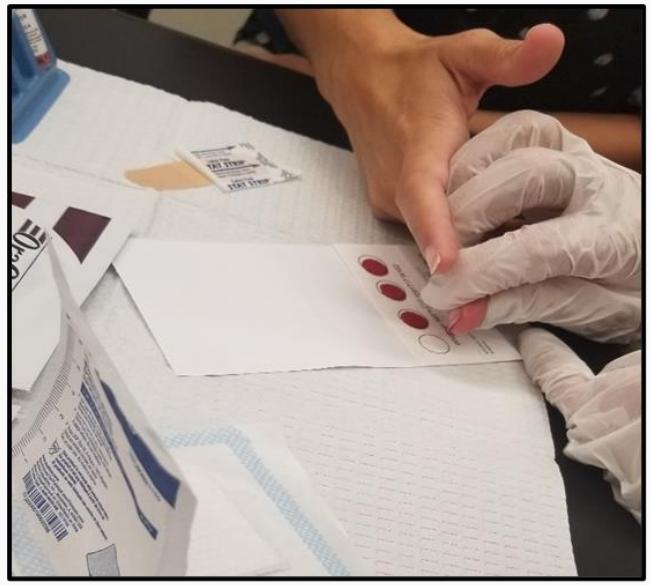
NEW YORK STATE | Department of Health

DRIED BLOOD SPOT TESTING

Limitations

Time from test to result

Getting clients to return for results



NEW YORK STATE | Department of Health

Benefits

Stable to temperature changes

Extends allowable shipping time from 3-15 days

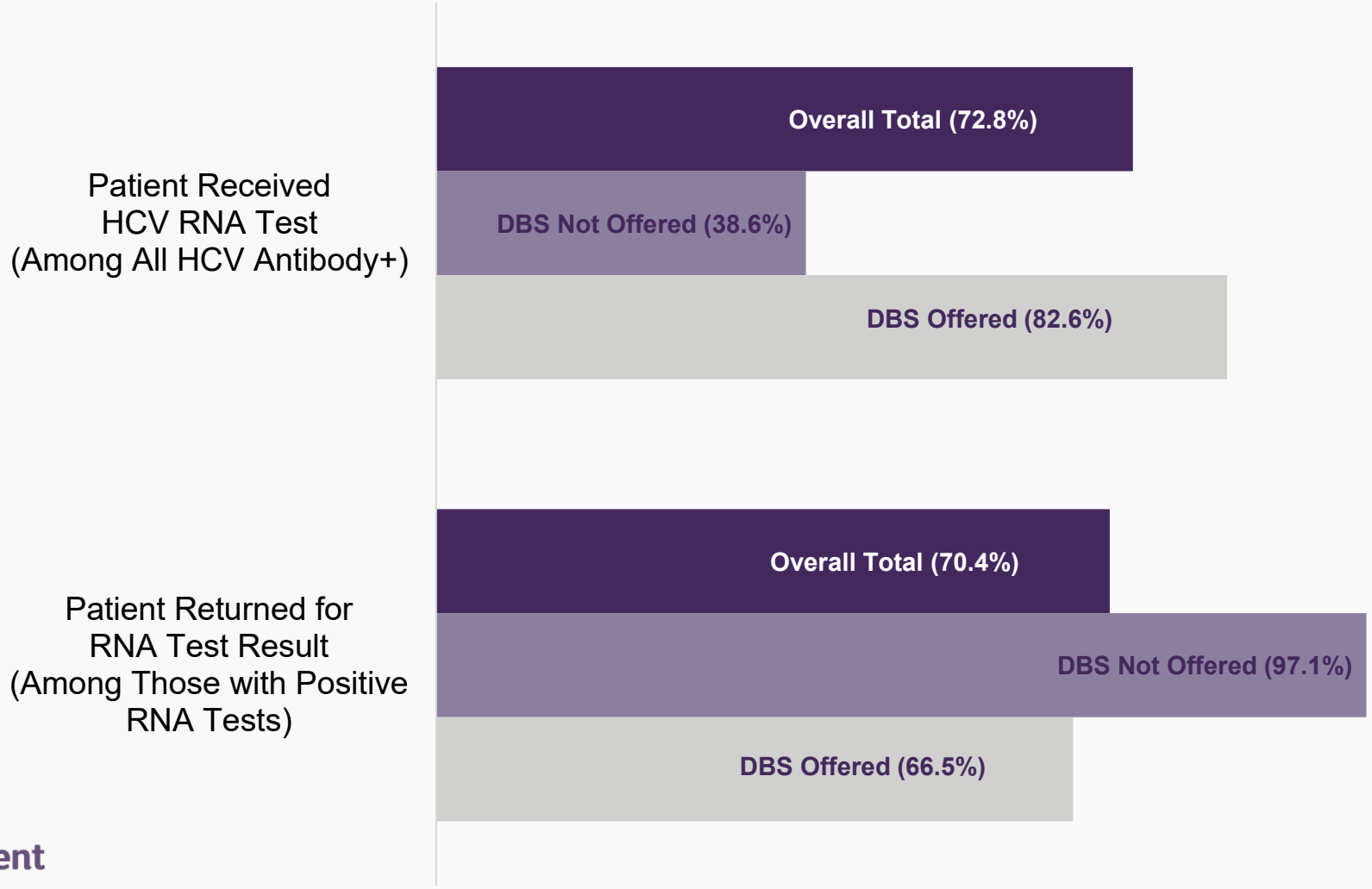
More staff able to do fingerstick vs venipuncture

No special equipment necessary

Allows for testing in outreach/community settings alongside rapid antibody testing

More acceptable, less invasive = more clients getting the hepatitis C RNA test

IMPACT OF DRIED BLOOD SPOT TESTING



Source: NYS Hepatitis C Testing Program, 2019

NEW YORK STATE | Department of Health

INVESTING IN POINT OF CARE HCV RNA TESTING

12 Drug User Health Hubs

- Few provide onsite HCV treatment

Nine hepatitis C primary care sites

Three opioid treatment programs

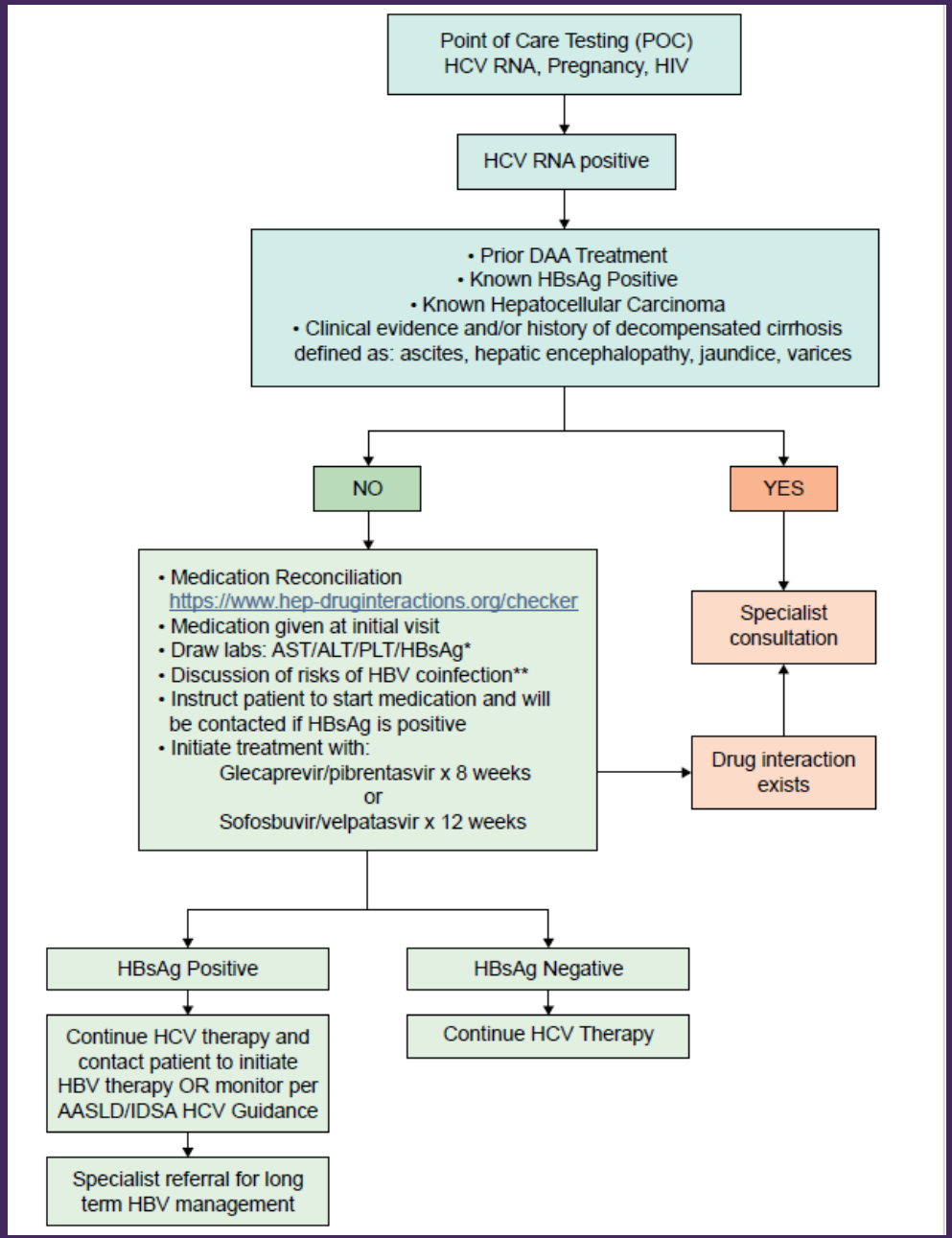
Five Syringe Service Programs

One-time only state funding to purchase instrument

Programs to fund purchase of cartridges, annual maintenance and ancillary supplies

NEW YORK STATE | Department of Health

Hepatitis C Test and Treat Initial Visit



NEW YORK STATE | Department of Health

JAIL TESTING

Identified one medical contractor covering 22/57 local jails in New York State

Confirmed interest in conducting universal hepatitis C screening

- At “processing or booking” along side fingerstick glucose check

Jail Pilot

Large and small jails

  - Large Jail (1) - ~5 months of testing; 985 tests; 4% reactivity (35% refusal rate)
  - Small Jails (7)- ~10 months of testing; 794 tests; 10% reactivity (20% refusal)

NEW YORK STATE | Department of Health

JAIL TESTING

Prioritized the jails using

- Community hepatitis C case rates
- High rates were prioritized

6-month universal hepatitis C screening to establish prevalence

Less than 10%reactivity

- Pay for testing on their own or
- Focus only on individuals receiving medication for opioid use disorder

Discussions with Public Health Lab

- Dried blood spot for both antibody and RNA tests
- Resources needed by lab (staff, reagents, etc.) = funding

Discussion with medical contractor

- Risk based screening only
- Clients on medication for opioid use disorder only
- Prioritize jails for testing
- Dried blood spot for both tests
  - Push back from staff
  - Difficulty getting enough sample

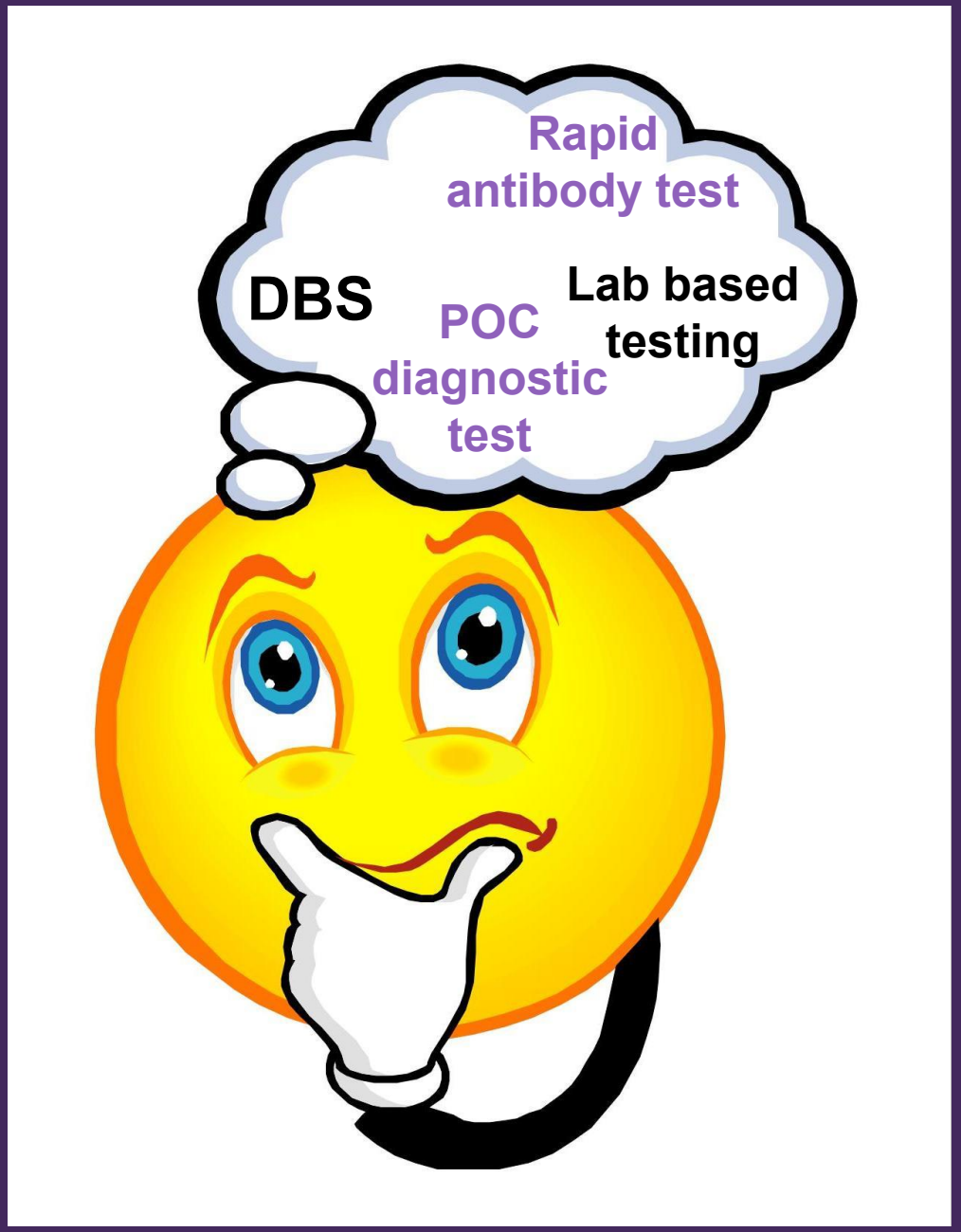
NEW YORK STATE | Department of Health

NAVIGATION SERVICES ARE CRITICAL

Hepatitis C Testing

Hepatitis C Treatment

NEW YORK STATE | Department of Health



- ✓ Setting type
- ✓ HCV prevalence
- ✓ Client volume
- ✓ Level of client engagement
- ✓ Cost
- ✓ Phlebotomy access
- ✓ Staff and patient preferences
- ✓ Treatment access

Thank you

Colleen Flanigan
Bureau Director
Colleen.Flanigan@health.ny.gov

Martha Gohlke
Initiative Director, Hepatitis C Testing and Navigation
Martha.Gohlke@health.ny.gov

Jeff Hotaling
Hepatitis C Screening Program Coordinator
Jeff.Hotaling@health.ny.gov

NEW YORK STATE | Department of Health

RESOURCES

NYS HCV Rapid Testing Implementation Guide: https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/implementation_guide/index.htm

NYS HCV Point of Care Testing Resource Page: https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/point_of_care.htm

NEW YORK STATE | Department of Health

Considerations for Selecting Testing Strategies

Population-Level Factors	Client-Level Factors	Program-Level Factors

• Prevalence
• Incidence
• HIV-2 incidence
• Co-morbidity (HIV and HCV, and/or other infections including STIs, HBV
	• Likelihood of acute HIV infection
	• Likelihood of current HCV infection
	• Likelihood of return for results/linkage
	• Understanding of accuracy of test results
	• Acceptability of testing strategy
	• Appropriateness and relevant to client needs
	• Cost to client for testing, treatment
	• Readiness to engage in treatment
	• Access to treatment
		• Goals and objectives
		• Policy, resources
		• Organizational capacity
		• Staff perceptions, attitudes, preferences
		  • Testing strategy
		  • Client population
		  • Treatment
		• Feasibility of introducing testing strategy into workflow (incld. LTC)
		  • Setting
		  • Staff capabilities
		• Laboratory capacity to implement tests, and/or support strategy
		• Access to, acceptability of treatment, other prevention services (e.g. PreP, DoxyPEP)

SAVE THE DATE!

APHL in Collaboration with CDC will host a virtual consultation: Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the U.S

September 16th – 2:00-5:30 pm ET
September 17th – 1:00-4:45 pm ET

APHL Resources

HIV Homepage

Viral Hepatitis Homepage

- Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm
- Use and Interpretation of Quantitative HIV-1 RNA Test Results: Guidance for Laboratories
- Optimizing HCV Testing: Key Considerations for Reflexing HCV Antibody Reactive Specimens to Confirmatory HCV RNA Testing
- Interpretation of Hepatitis C Virus Test Results: Guidance for Laboratories