

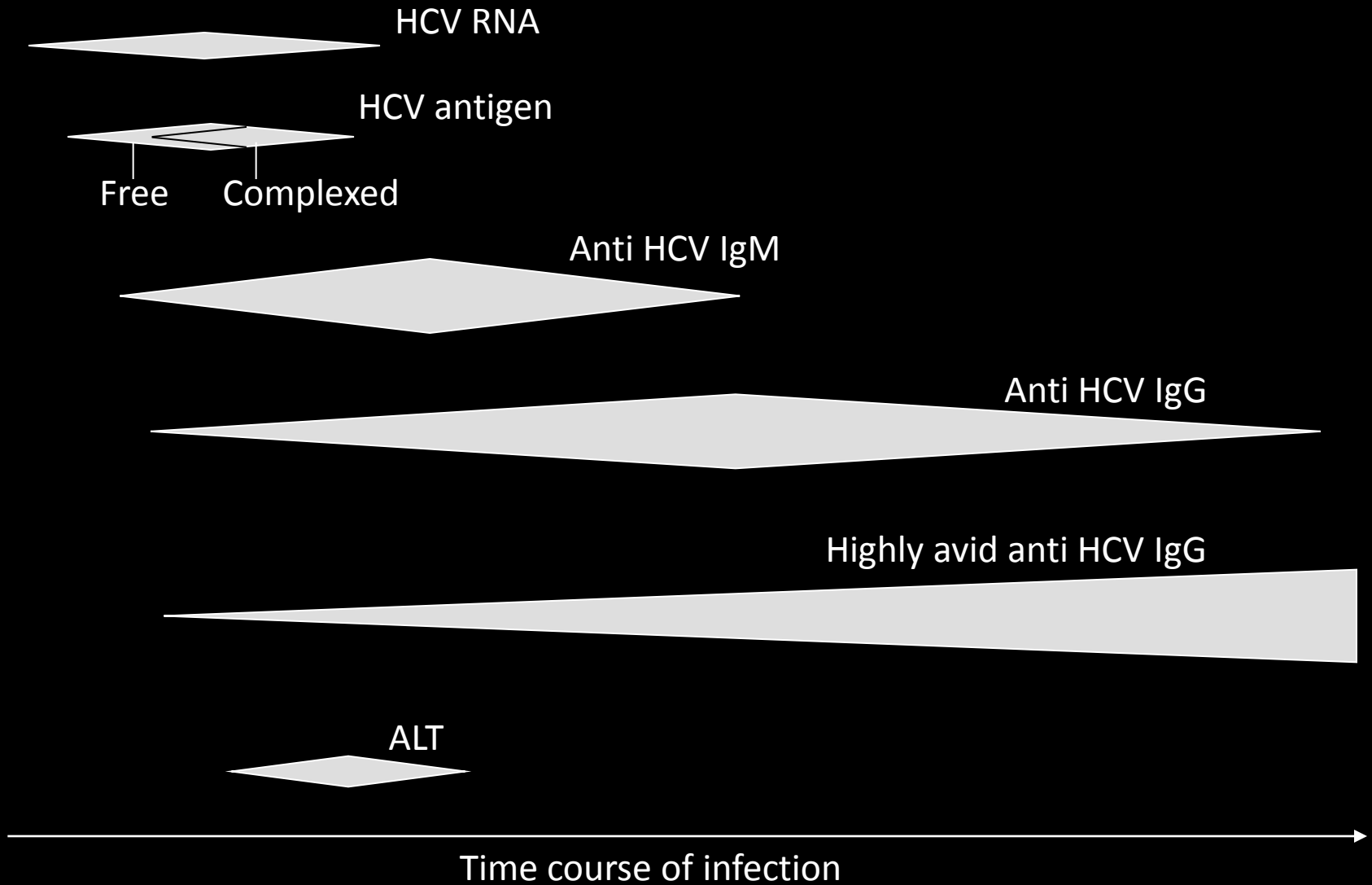
# HCV Diagnostics and Testing Update

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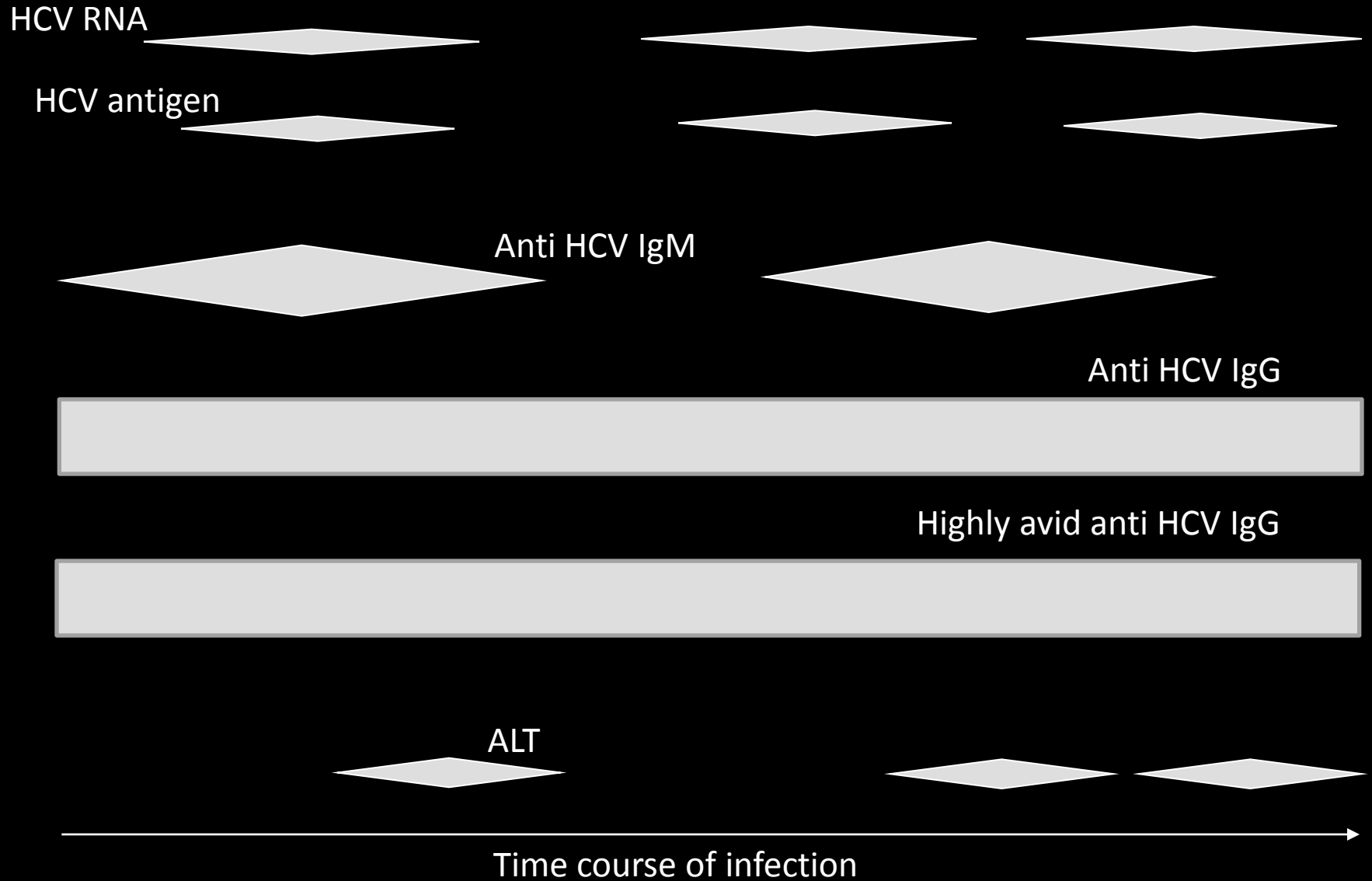
Division of Viral Hepatitis

CDC

# Idealized kinetics of some biomarkers appearing in blood: primary HCV infection (with resolution)



# Idealized kinetics of some biomarkers appearing in blood: chronic HCV infection



## Diagnostic markers of HCV infection\*

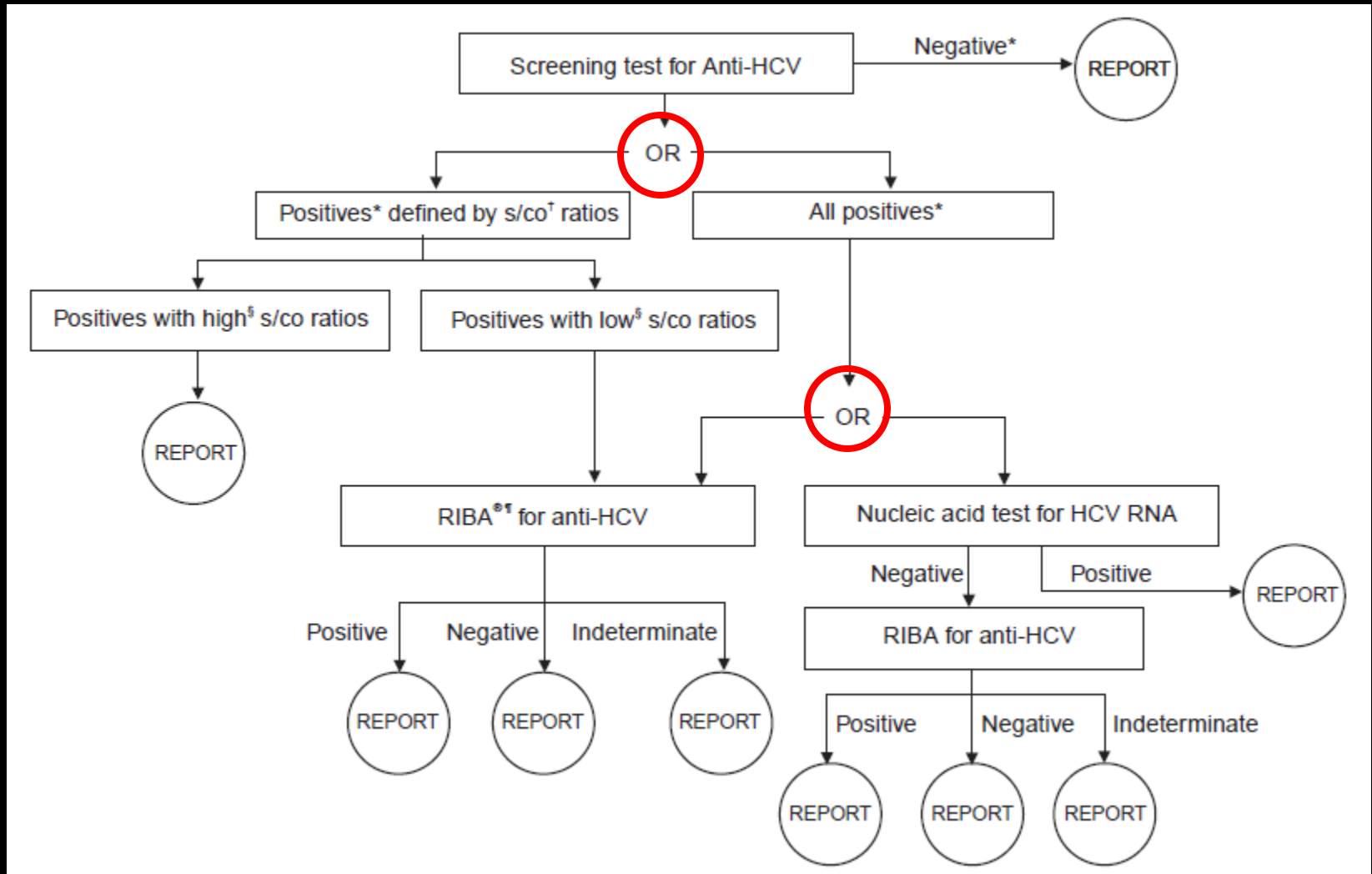
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Marker	Indicator of	Appropriate for 1 <sup>st</sup> -line testing?
RNA	current infection	Possibly
Ag	current infection	Possibly
IgG Ab	past or current infection	Yes
IgM Ab	early infection	Unlikely

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\*via single-specimen testing

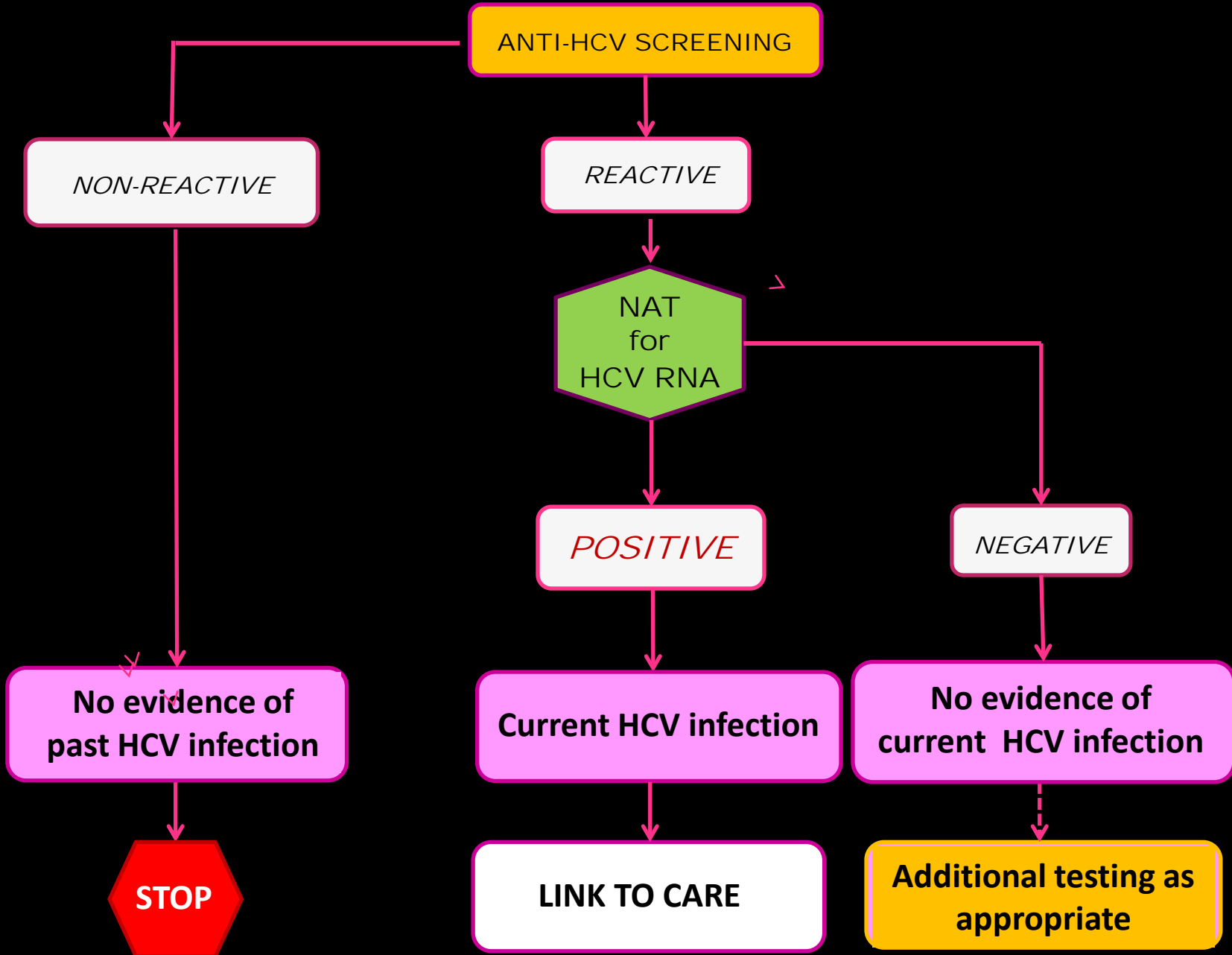
# Current CDC algorithm for testing for HCV infection



## Significant changes since publication of CDC's 2003 HCV testing guidelines

- Rapid tests of IgG HCVAb are now available and receiving FDA approval and CLIA waiver
- Manufacture of RIBA may be discontinued
- Quantitative HCV NATs are as or more sensitive than qualitative NATs
- HCV Ag tests are also available and their performance characteristics have been actively validated in Europe
- **Orally delivered anti-HCV pharmaceuticals are being developed and approved for treatment of chronic hepatitis C**
- Persons with early HCV infection respond to antiviral treatment better than those with longstanding infection

# Proposed Algorithm for Testing for Active HCV Infection



# Contemporary issues in HCV testing

Benefits and feasibility of rapid testing for HCV IgG Ab

Expanding HCV NAT

HCV Ag testing as alternative to HCV NAT

Identifying early HCV infection



# Rapid testing for HCV IgG Ab

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Setting	Beneficial?	Feasible?
Outreach center	Yes	Yes
Community		
• health fair		
• pharmacy		
Needle exchange		
Health-care provider office	Yes	Possibly

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# Expanding HCV NAT

- Reduce cost of testing
  - Bulk purchase of test equipment and reagents by public health agencies
  - Pooling
  - Early lifting of HCV patent
- (To what extent is “cost” the issue in the era of The Affordable Care Act?)
- Testing by public health laboratories following the model of the national influenza surveillance system

## HCV Ag testing as alternative to HCV NAT

- Suitable for reflex testing of samples screened to be Ab-positive
- Sensitivity of viremia detection approaches but not equivalent to NAT
  - unlikely to be acceptable as 1<sup>st</sup>-line test for current HCV infection

# Identifying early HCV infection

IgM HCVAb unreliable as marker of early infection

Other serologic markers being considered

- Low-avidity IgG HCVAb
- Ag-specific IgG HCVAb
- IgG HCV Ab subclasses
- Signature HCV genomic changes
- Specific interleukins, cytokines or miRNAs

Demonstration of seroconversion remains critical

## Conclusions

- Rapid tests for IgG HCVAbs open new vistas for identifying HCV-infected persons
- HCV NAT remains mainstay to identifying current HCV infection
- HCV Ag testing likely to be acceptable as reflex testing for HCV viremia
- Diagnosis of early HCV infection by single-specimen testing remains elusive