

Point-of-Care and Rapid Antibody Testing

Evaluation of pre-market rapid hepatitis C virus (HCV) antibody tests in the laboratory and field (NHBS) study sites

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Overview

- ❑ **Role of Rapid Tests**
- ❑ **Background**
- ❑ **Methods**
- ❑ **Results**
- ❑ **Discussion**
- ❑ **Future research**

Role of HCV Rapid Tests

- ❑ Increase receipt of test results**
- ❑ Increase identification of infected patients for entrance into medical care and treatment**
- ❑ Increase identification of persons to receive prevention messages**
- ❑ Increase feasibility of testing in acute-care (ERs) and outreach (SSPs) settings with point-of-care results**

Background

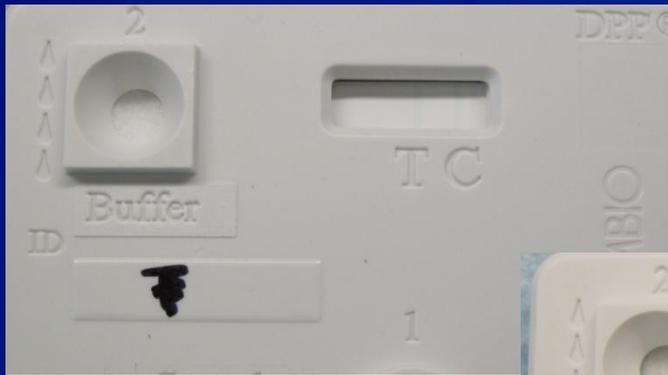
❑ **Published Federal Register Notice in Spring, 2009**

- *“Opportunity to Collaborate in the Evaluation of Rapid Diagnostic Tests for HIV and HCV”*

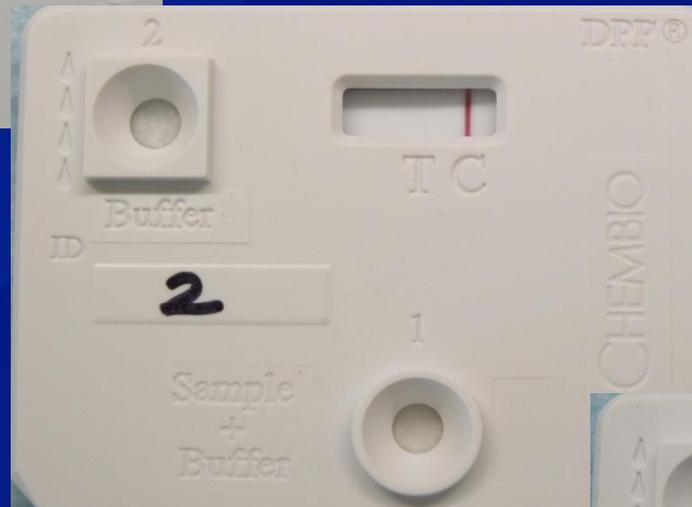
❑ **Three manufacturers had HCV rapid tests**

- Chembio DPP™ HCV test
(Chembio Diagnostic Systems, Inc., Medford, NY)
- Multiplo™ Rapid HIV/HCV Antibody Test
(MedMira Laboratories, Inc., Halifax, Nova Scotia, Canada)
- OraQuick® Rapid HCV Antibody Test
(OraSure Technologies, Inc., Bethlehem, PA)

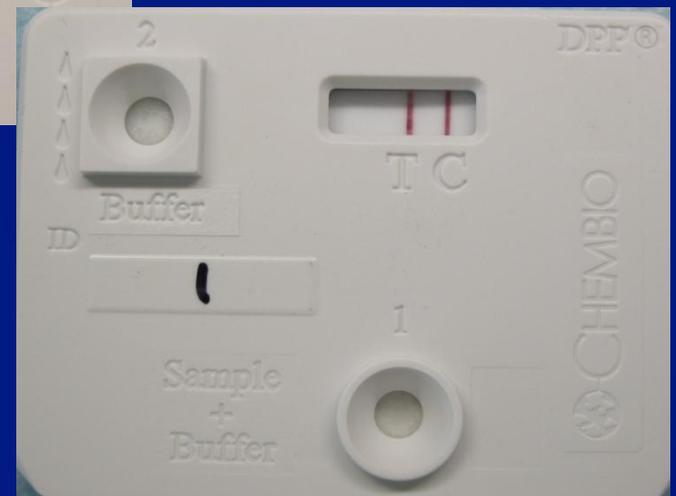
Chembio HCV Rapid Assay



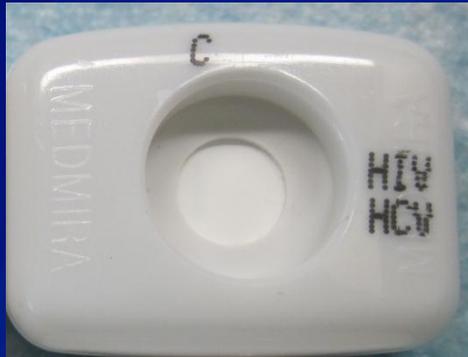
Non-reactive



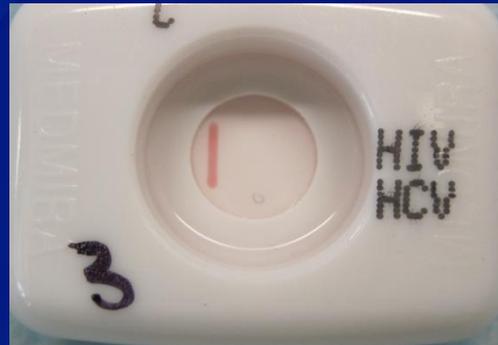
Reactive



MedMira HCV Rapid Assay



Non-reactive



Reactive



OraSure HCV Rapid Assay



Non-reactive



Reactive

HCV Rapid Assays

LABORATORY EVALUATION

Smith, B.D., et al., *Evaluation of Three Rapid Screening Assays for Detection of Antibodies to Hepatitis C Virus*. *Journal of Infectious Disease*, 2011. **204**: p. 825-831.

FIELD EVALUATION AT NHBS SITES

Smith B.D., et al. *Performance of Premarket Rapid Hepatitis C Virus Antibody Assays in 4 National HIV Behavioral Surveillance System Sites*. *Clinical Infectious Diseases*, 2011. **53**(8): p. 780-6.

Reference Methods

❑ Screening anti-HCV Assay Method (SA)

- anti-HCV Enzyme Immunoassay
 - $S/CO \geq 1.0$ (Anti-HCV positive)
 - $S/CO < 1.0$ (Anti-HCV negative)

❑ CDC Recommended HCV Testing Algorithm

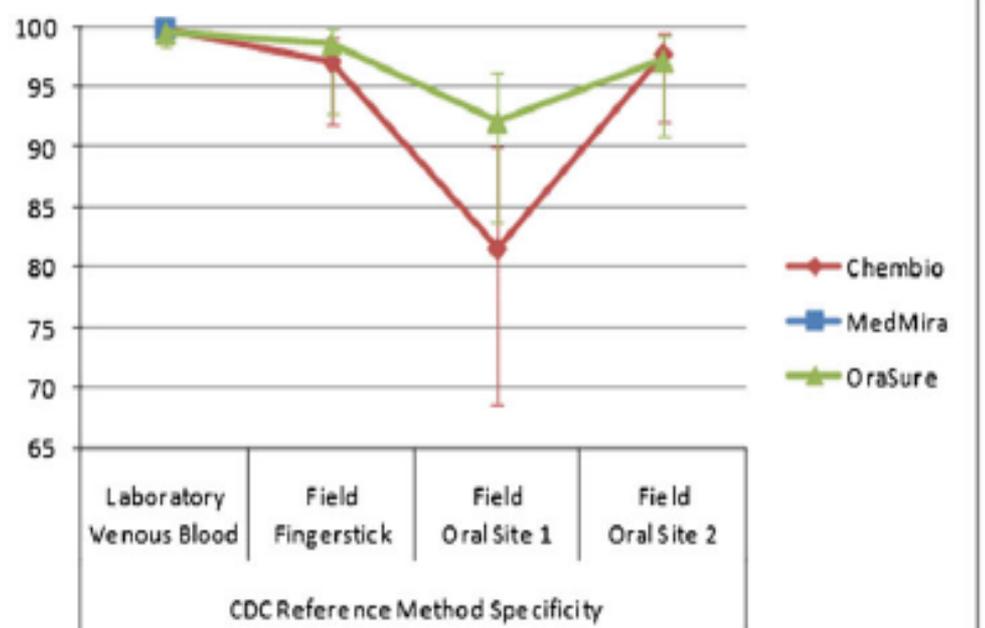
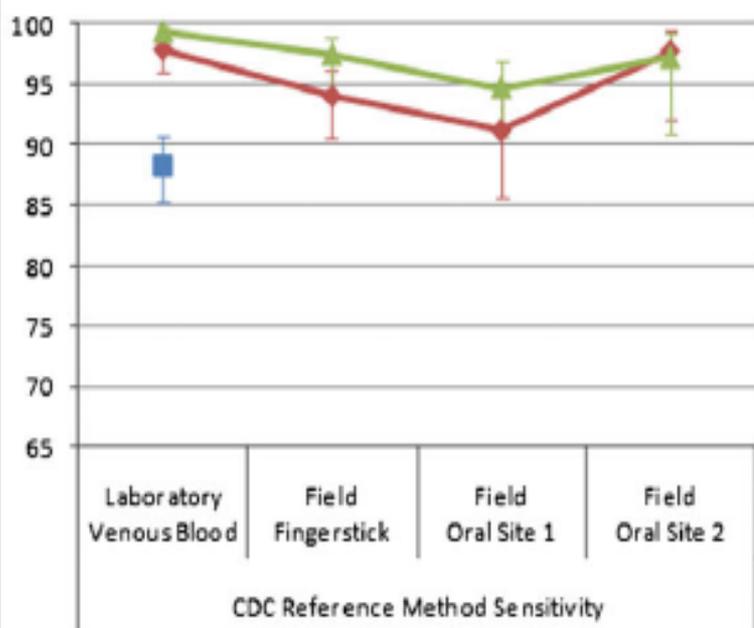
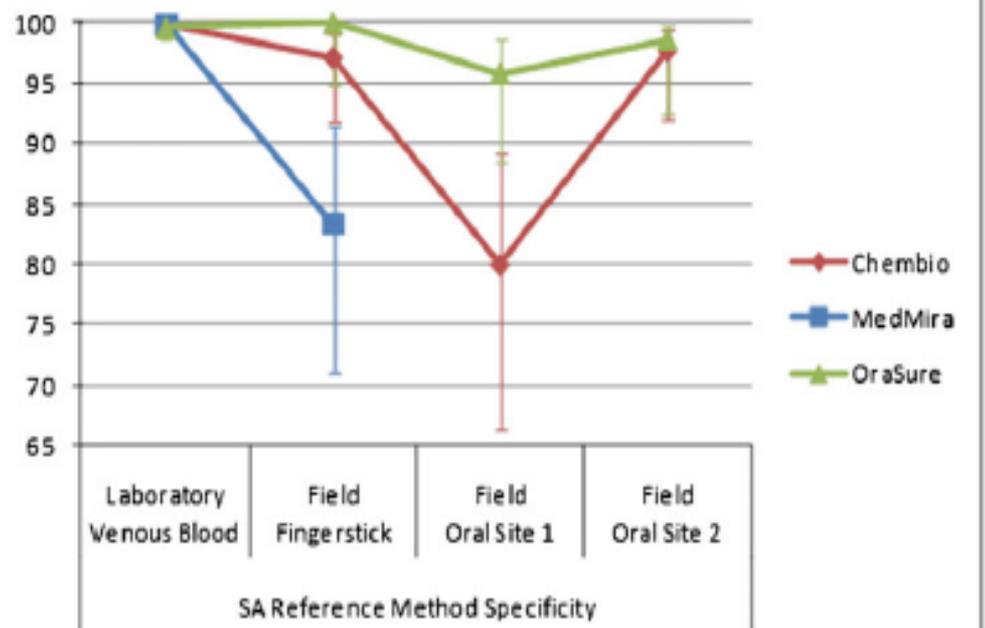
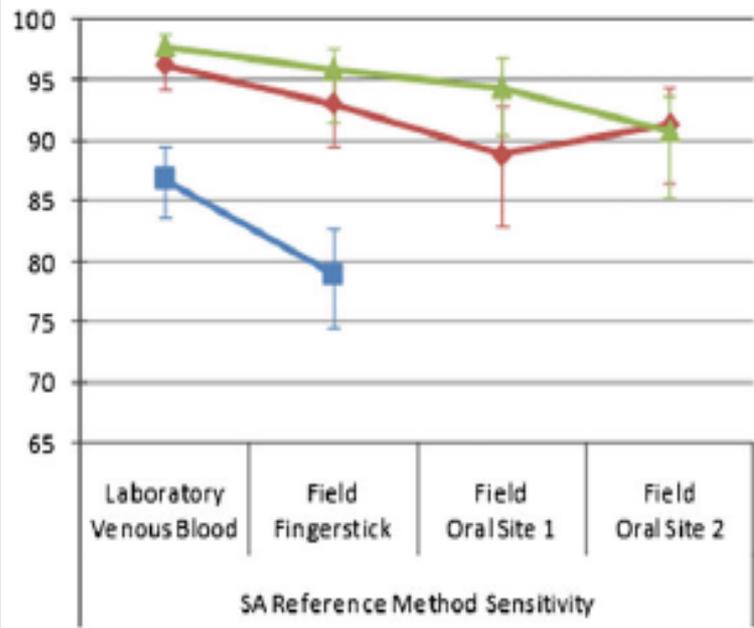
- Screening anti-HCV non-reactive with $S/CO < 1.0$
- Anti-HCV negative
- Screening anti-HCV reactive with $S/CO \geq 8.0$
 - Anti-HCV positive
- Supplemental confirmation of screening reactive samples with a S/CO ratio ≥ 1.0 and < 8.0 by RIBA
 - RIBA positive Anti-HCV positive
 - RIBA negative Anti-HCV negative

Laboratory Evaluation Study Design

- ❑ **Collaborative Injection Drug User Study (CIDUS II)**
 - 1100 serum specimens
 - All participants were 18-30 years old and reported injection drug use in the previous 12 months from 1997-1999

Field Evaluation Study Design

- ❑ **National HIV Behavioral Surveillance Survey (NHBS-IDU2)**
 - New York City (n=490), Denver (n=389), Seattle (n=265), Dallas (n=448)
 - All participants were ≥ 18 years old and reported injection drug use in the previous 12 months in 2009



Laboratory and Field Evaluation Results

False Negative Results Associated with HIV positivity

Site	Manufacturer	Method	aOR (CI95)*	
Laboratory	Chembio Blood	SA	8.2 (2.2-30.9)	
		CDC	11.0 (2.5-48.2)	
	MedMira Blood	SA	3.7 (1.4-9.5)	
		CDC	4.0 (1.5-10.2)	
Field	New York City	Chembio Oral	SA	8.4 (2.2-31.5)
		CDC	9.1 (2.1-39.3)	

*p-value <0.05

Discussion and Implications for Use

- ❑ **Considerable variation in performance characteristics**
 - Sensitivity (78.9 – 99.3)
 - Specificity (80.0 – 100.0)
 - Across sites and rapid tests
- ❑ **RIBA – inefficient**
 - Laboratory (2 out of 10) 20.0% RIBA indeterminate
 - Field (11 out of 51) 21.6% RIBA indeterminate
- ❑ **Sensitive HCV rapid tests are appropriate for:**
 - High-risk populations such as PWIDs
 - Syringe services programs
 - HIV testing venues
- ❑ **Other settings that may benefit:**
 - Health fairs, Laboratories, Outbreaks, Military field operations

Limitations

❑ **Laboratory**

- Experienced lab technicians, not generalizable

❑ **Field**

- Results from different cities cannot be compared
 - Different EIAs, testers, participants, commercial labs
- Lack of antibody confirmatory data in Dallas
- Lack of HCV RNA data to evaluate for chronic infection
 - Algorithm

Future Directions

- ❑ **Demonstration studies**
 - Integrating rapid HCV testing into HIV testing settings
 - Prevention messages

- ❑ **Evaluation of HIV-positive specimen panel**

- ❑ **2nd gen tests that will increase sensitivity**

Thank you!

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Division of Viral Hepatitis

