2010 Conference: Outcomes



Goals for 2010 Conference

- Review the available evidence
- Identify the needs of different stakeholders
- Develop a menu for specific applications
- Begin consensus process for updating testing recommendations



Goals for 2010 Conference

- Review the available evidence
- Identify the needs of different stakeholders
- Develop a menu for specific applications
- Begin consensus process for updating testing recommendations

2010 Conference: Under the Gun







1. Review of the Evidence

- 4th gen assays improve sensitivity
 - □ Conventional = similar to RNA
 - \square Rapid = equivalent (at least) to 3rd gen EIA
- Algorithms: still focus on specificity
- Effect of POC on entry into care: uncertain



2. Needs of Different Stakeholders

■ POC:

- □ Testimony from providers; none from consumers
- □ What's worse: false-negative or false-positive?

Clinicians:

□ "Presumptive" diagnosis is useful

Surveillance:

- □ Change in algorithms has workload implications
- □ "Good old days" of lab reporting may end





Support GROUP



3. Menu for different applications

■ POC:

- □ Rapid positive: → refer for testing and care
- □ Rapid-rapid positive: → refer to care
- □ Rapid positive/negative: → refer for testing and care

Oral fluid:

- □ Conventional oral fluid EIA
- □ Conventional oral fluid Western blot



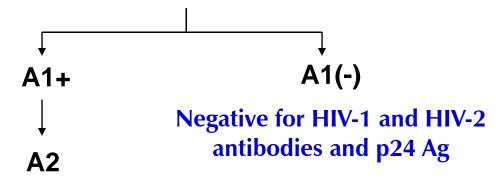
4. Begin consensus process for updating testing recommendations

Proposal:

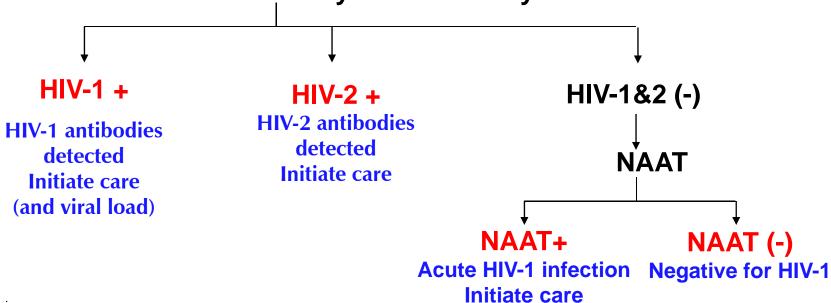
Unified Laboratory Algorithm

(no asterisks)

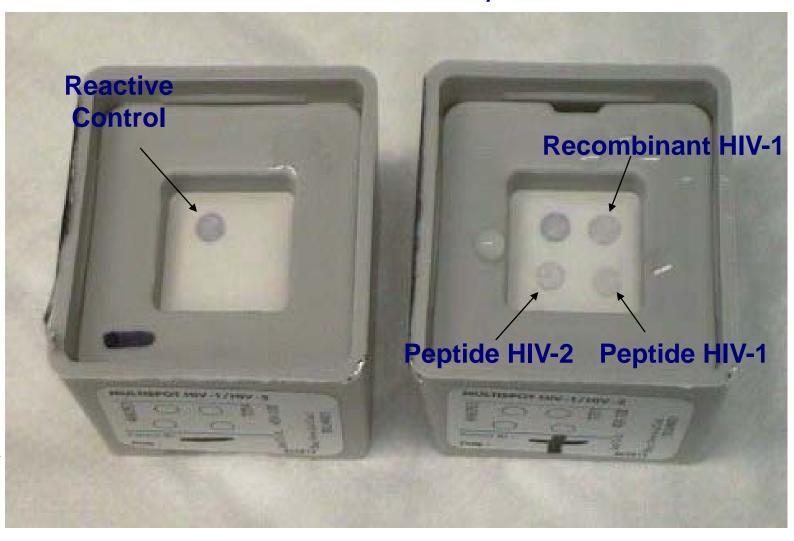
A1: 4th generation HIV-1/2 immunoassay



HIV-1/HIV-2 discriminatory immunoassay



FDA-approved HIV-1/HIV-2 Discriminatory Test



Multi-site Evaluation of Multispot HIV-1/HIV-2 Rapid Test to Detect and Differentiate HIV-1 from HIV-2 andto be a Stand-alone Multi-Test Algorithm Based on Separate Recombinant and Peptide Antigen Spots

N=871 HIV-1 Western blot positive

Multispot pattern	# of patients	Percentage
Both HIV-1 spots 3+ to 4+	832	96%
One or both HIV-1 spots 1+ to 2+	39	4%
Total	871	100%

2006 HIV Diagnostics Conference www.hivtestingcoference.org

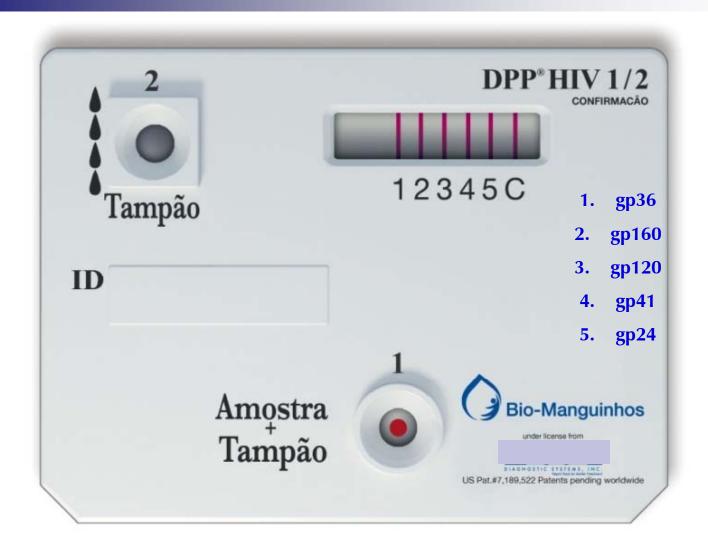
Multi-site Evaluation of Multispot HIV-1/HIV-2 Rapid Test to Detect and Differentiate HIV-1 from HIV-2 andto be a Stand-alone Multi-Test Algorithm Based on Separate Recombinant and Peptide Antigen Spots

N=3146 uninfected patients

Specificity 99.92%

		Spot Reaction Pattern					
Patient	Sample Type	Procedural Control Spot	HIV-2 Peptide	HIV-1 Recombinant	HIV-1 Peptide		
1	Plasma	4	0	0	1		
2	Plasma	4	0	1	0		
3	Plasma	4	0	1	1		
	Serum	4	0	1	0		

2006 HIV Diagnostics Conference www.hivtestingcoference.org



This product is developed for Brazil ONLY and product under registration and recommended for National Algorithm instead of Western Blot

Test result can be read visually or using digital reader (with mobile printer or connectivity to laboratory information system)







Discussion