


Differentiation between HIV-2 single-infection and HIV-1/-2 dual-infection by the *Bio-Rad* Geenius™ HIV 1/2 supplemental assay



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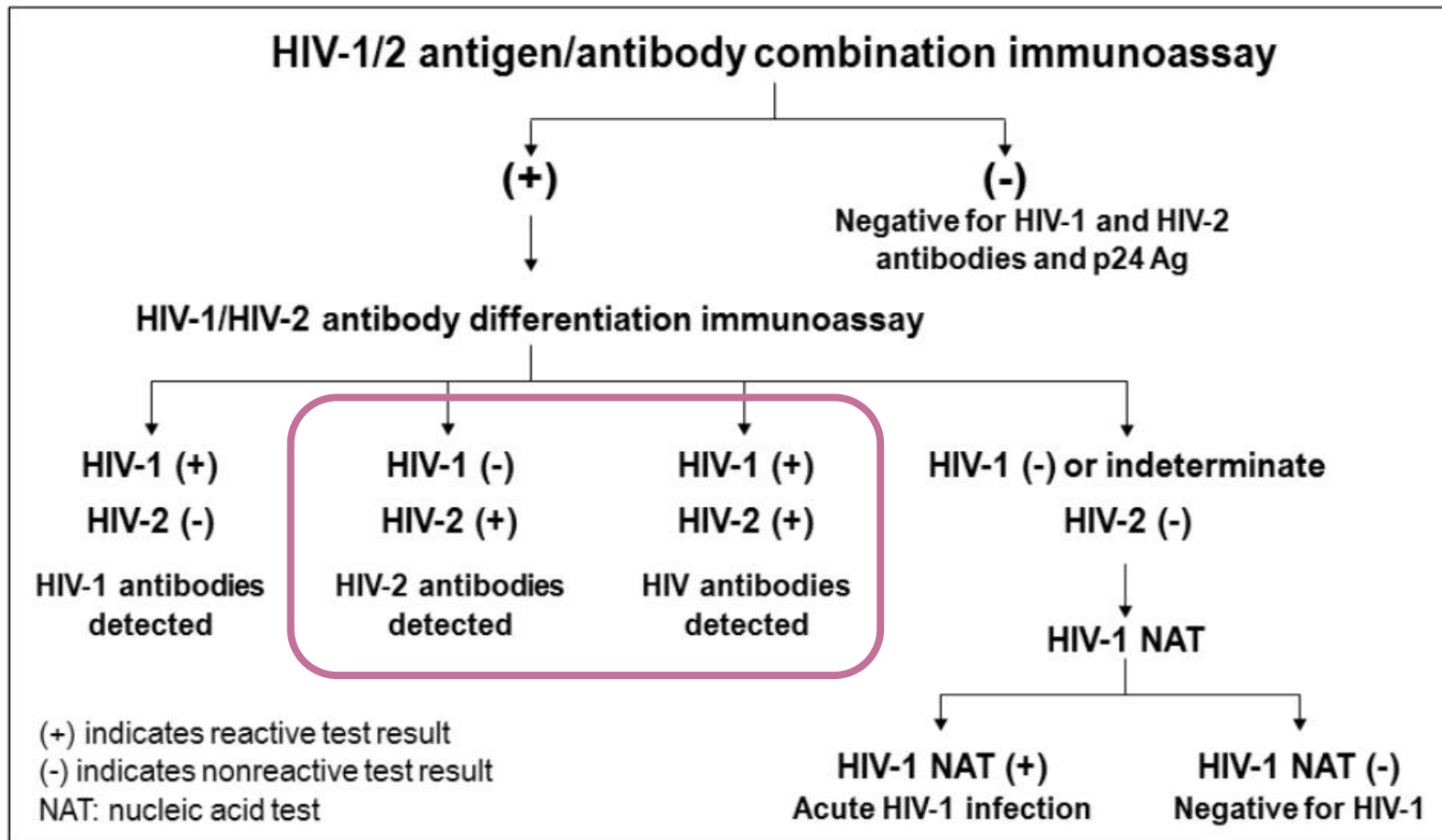


Disclosure

- I have no conflict of interest in regard to this presentation.

HIV Diagnostic Algorithm

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens





Objective

- Evaluate various banding patterns and examine interpretive results generated by the Geenius assay for HIV-2 positive, HIV-2 positive with HIV-1 cross-reactivity, and HIV positive–untypable samples.



Sources of Patients Plasma Samples

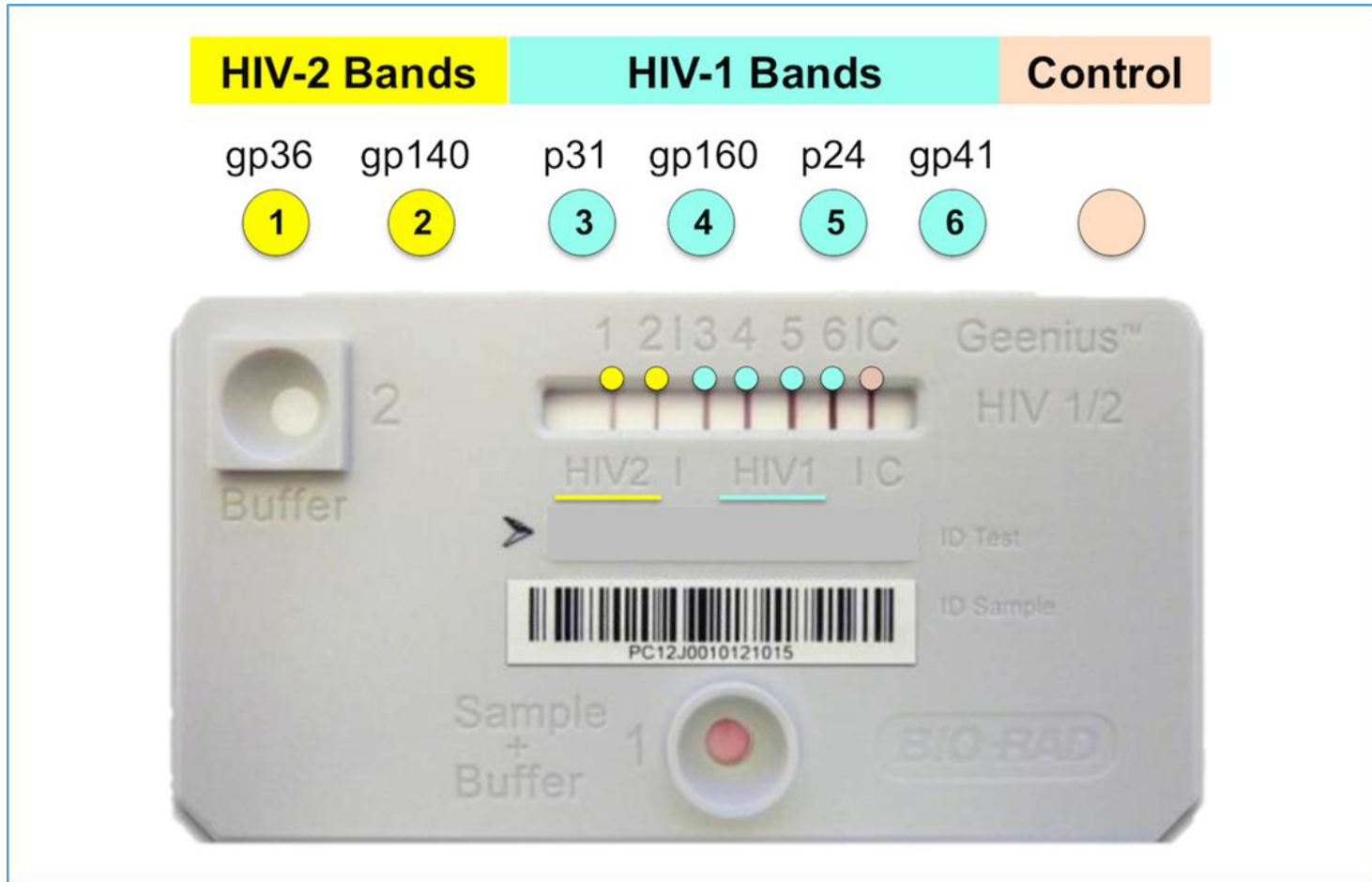
- Senegal
 - From donors with known HIV-2 mono-infection or HIV-1/-2 dual-infection
 - UW-Dakar HIV-2 study group
- US/Canada
 - Referred to the UWMC Retrovirology Lab for HIV-2 quantitative RNA viral load testing
 - From clinics or laboratories in AL, AZ, CA, CO, ID, KS, MA, MI, MN, NC, NJ, OH, PA, RI, UT (ARUP), VA (Quest), WA, Quebec and Ontario, Canada collected from 2011-18
 - Remaining samples were tested retrospectively



Assays

- *Bio-Rad* GS HIV-1/HIV-2 Plus O EIA
- *Bio-Rad* Geenius HIV 1/2 Supplemental Assay
 - A single-use immunochromatographic assay
 - A qualitative assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2
 - Results were interpreted by the Geenius Reader software version 1.1 US or 1.3 US.
 - Band analysis and interpretation for each sample were recorded for this study

Geenius Cassette and HIV Bands



An Excerpted Report

Image



Interpretation

Interpretation type: Automatic

Band analysis:

#	Name	Result
1	gp36	Present
2	gp140	Present
3	p31	Absent
4	gp160	Absent
5	p24	Present
6	gp41	Present
7	CTRL	Present

Conclusion: HIV-2 POSITIVE with HIV-1 cross-reactivity (HIV-1 Ab reactive (cross-reactivity)/HIV-2 Ab reactive)



Interpretation Criteria

Result

Banding pattern

(listed in CE-Marked manual)

HIV-1 POS

Any 2 bands of 4 (p31, pg160, p24, gp41) HIV-1 bands with at least 1 ENV band (gp160 or gp41)

HIV-2 POS

2 HIV-2 bands must be present (gp36 and gp140)

Geenius' Results and Interpretation

Interpretation	Results	
	HIV-1 Ab	HIV-2 Ab
HIV-2 indeterminate	Nonreactive	Reactive to gp36 only
HIV-2 positive	Nonreactive or indeterminate	Reactive
HIV-2 positive with HIV-1 cross-reactivity	Reactive	Reactive
HIV positive- untypable	Reactive	Reactive

Geenius Interpretation of 28 Senegalese Patient Plasma Samples

HIV sero-status	# of patients	Interpretation
HIV-2 mono-infection	11 of 20	HIV-2 positive
	9 of 20	HIV-2 positive with HIV-1 cross-reactivity
HIV-1/-2 dual-infection	8 of 8	HIV positive- untypable



Patient Samples from US/Canada

Number of patients (%)	HIV-2 plasma RNA (DET, NDT)	Geenius' Interpretation
1 (1.5%)	1 NDT	HIV-2 indeterminate; reactive to gp36 only
27 (41.5%)	13 DET; 14 NDT	HIV-2 positive
31 (48%)	14 DET; 17 NDT	HIV-2 positive with HIV-1 cross-reactivity
6 (9%)	3 DET; 3 NDT	HIV positive- untypable

HIV-2 Positive with HIV-1 Cross-Reactivity or HIV-1/-2 Dual Infection?

# of patients	Interpretation	HIV-2 gp36 & gp140	HIV-1 p31, gp160, p24 & gp41
31	HIV-2 positive with HIV-1 cross-reactivity	Reactive to both bands	23 reactive to 2 or 3 bands 8 reactive to all 4 bands
6	HIV positive- untypable	Reactive to both bands	4 reactive to 2 or 3 bands; 2 reactive to all 4 bands



Reproducibility

- Interpretations for 4 HIV positive-untypable, 6 HIV-2 with HIV-1 cross-reactivity, and 1 HIV-2 indeterminate sample (reactive to gp36 only) were confirmed by additional plasma samples collected from different visiting dates



Challenges for Diagnosis

- For patients identified as HIV-1/-2 Abs positive, untypable, additional HIV-1 and HIV-2 DNA or DNA/RNA testing for PBMC or whole blood samples may be useful for further clarification
- Repeat testing for additional samples from different visits



Conclusions

- This study identified 58 patients from US/Canada positive for HIV-2 Abs, 6 positive for HIV-1/-2 Abs and 1 had Ab for HIV-2 gp36 only.
- This study demonstrated various HIV-1 reactivity patterns for samples reported for HIV-2 with HIV-1 cross-reactivity and HIV positive-untypable.
 - Notably, 8 samples concluded to be HIV-2 positive with HIV-1 cross-reactivity had Abs against all 4 HIV-1 Ags.



Limitations

- Only plasma samples available
- Unknown ART status of each patient



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