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Evaluation of the BioPlex[®] 2200 HIV Ag-Ab assay: A Fully Automated Screening Method Providing Discrete Detection of HIV-1 p24, HIV-1 Antibody, and HIV-2 Antibody

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Poster 58: BioPlex 2200 HIV Ag-Ab Assay

“5th Generation” HIV Ag-Ab assay design

- Fully automated test simultaneously detects and reports three individual HIV results:
 - HIV Ag-Ab overall result (non-reactive or reactive)
with
 - HIV-1 p24 Ag
 - HIV-1 Ab (groups M & O)
 - HIV-2 Ab
 - Separate reporting of HIV-1 p24 to help identify acute infections
 - Includes HIV-1 and HIV-2 Ab Differentiation in first-round test
 - Can be used to screen organ donors

US version is pending FDA Approval

The Bio-Rad logo is a green rounded rectangle with the text "BIO-RAD" in white, bold, uppercase letters. It is positioned in the bottom right corner of the slide.

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Data from US Clinical Trial and In-House Validation Testing

- Specificity: 99.86% based on 6395 low risk specimens

Sample Status	HIV Ag-Ab (composite result)	HIV-1 Ab	HIV-1 p24	HIV-2 Ab
True Negatives	6367			
False Positives*	9	5	6	2
Confirmed Positives	19			
% Specificity	99.86 (95% CI 99.73-99.93)			

*Some of the 9 false positives were reactive for more than 1 HIV analyte



- Differentiation capability of HIV-1 and HIV-2

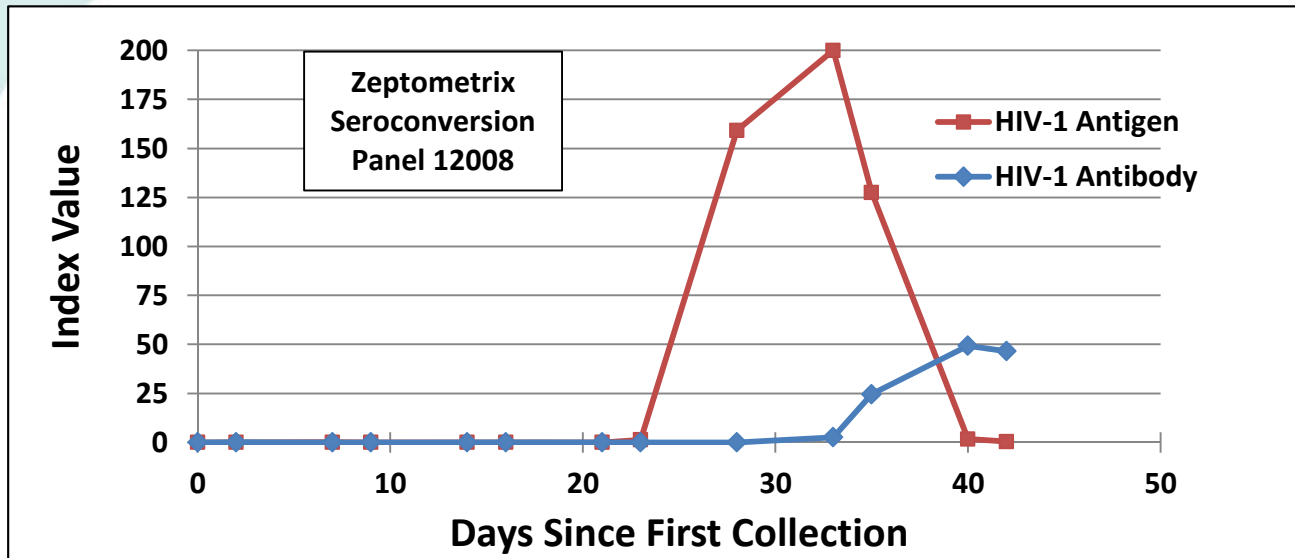
Population	HIV-1 Ab Reactive	HIV-2 Ab Reactive	HIV Ab Reactive Undifferentiated	% Differentiated
Known HIV-1	1483	0	0	100%
Known HIV-2	0	187	13	93.5%

- Seroconversion: Earlier detection in 7 of 42 panels, later in 1

Seroconversion Panels	BioPlex 2200			FDA-approved HIV Ag/Ab assay
	HIV Ag-Ab	HIV-1 Ab	HIV-1 p24	
Total reactive Bleeds	214	140	133	205
Total Reactive Panels	42	39	39	42
# Panels more sensitive	7 (16.7%)			1 (2.4%)

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Data from US Clinical Trial and In-House Validation Testing



- HIV-1 p24 LOD using CLSI 17-A: 5.2 pg/mL, 0.33 IU/mL
- Assay reproducibility: 4.5-11.7% total CV over 3 sites, each testing with 3 reagent lots
- Assay detects all subtypes tested
 - HIV-1 p24 detected in 54 cell culture supernatants representing group O, group N, and 10 group M subtypes
 - Antibody detected in sera from 216 patients representing 10 HIV-1 group M subtypes, 63 HIV-1 group O and 200 HIV-2 sera

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