A CARTRIDGE-BASED RAPID IMMUNOASSAY FOR THE DETECTION OF HIV AND SYPHILIS

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BACKGROUND

Point of Care (POC) devices have rapidly reshaped the STI diagnostic landscape. No longer tethered to high complexity laboratory overhead, the ease-of-use and expedited time-to-result of these devices have given patients access to highly sensitive and specific results in a multitude of settings at a lower cost. In this study, we enrolled patients from the Baltimore City Health department's STI clinic (BCHD) and tested them using the Chembio DPP® HIV-Syphilis Assay System, a cartridge-based rapid immunoassay with a digital reader (DPP® Micro Reader).

METHODS

Fingerstick whole blood and venous whole blood specimens were collected from individuals with a known Syphilis infection, a known HIV infection, and a known HIV and Syphilis co-infection, as well as those at high risk for HIV/suspected Syphilis, and those at low risk for HIV/Syphilis infection. Plasma was obtained at BCHD by centrifuging a portion of the venous whole blood. The 3 sample types were aliquoted and transported to the lab for testing. Paired serum/plasma aliquots were shipped within 36 hours of collection to a reference laboratory and 3 comparator tests for both HIV and syphilis were performed.

DPP® MICRO READER

CARTRIDGE HOLDER

MICRO READER WITH HOLDER AND TEST DEVICE

Patient Infected Status Determination Based on Reverse Syphilis Testing Algorithm

EIA/ antibody test	RPR	TP-PA	Patient Infected Status (PIS)	Interpretation
-	N/A	N/A	-	The presence of syphilis unlikely, however, recent infection cannot be ruled out.
+	+	N/A	+	Syphilis present. Past or present infection.
+	-	+	+	Syphilis present. Past or present infection.
+	-	-	-	Unlikely Syphilis. Most likely false positive, which may occur in healthy patients in low prevalence populations or due to cross-reactivity

Patient Infected Status Determination Based on 4th Generation HIV Testing Algorithm

HIV-1/2 Ag/Ab Assay	HIV-1/HIV-2 Differentiation Assay	HIV-1 NAT	PIS / Interpretation
Nonreactive	N/A	N/A	Negative
Reactive	HIV-1 Reactive HIV-2 Nonreactive	N/A	Positive for HIV-1
	HIV-1 Nonreactive HIV-2 Reactive	N/A	Positive for HIV-2
	HIV-1 & HIV-2 Reactive	N/A	Positive for HIV-1/2
	HIV-1 Nonreactive or HIV-2 Indeterminate	HIV-1 NAT Reactive	Positive for HIV-1, Acute Infection
		HIV-1 NAT Negative	Negative for HIV-1

Subjects Enrolled at JHU by Risk Group, used in HIV and Syphilis data calculations

Study Population	Number of Subjects Enrolled (HIV)	Number of Subject Enrolled (Syphilis)
HIV and Syphilis Known Positive ("co-infected")	10	10
HIV Known Positive, Only	6	7
Syphilis Known Positive, Only	23	23
High Risk/Suspected Syphilis	127	143
Low Risk	153	158
TOTAL	319	341

Summary of Overall HIV Sensitivity and Specificity (n=319)

Sample Matrix	HIV Sensitivity (95% CI)	HIV Specificity (95% CI)
Fingerstick Blood	20/20= 100% (83.9% -100%)	298/299= 99.7% (98.1% - 99.9%)
Venous Whole Blood	20/20= 100% (83.9% -100%)	298/299= 99.7% (98.1% - 99.9%)
Plasma	20/20= 100% (83.9% -100%)	298/299= 99.7% (98.1% - 99.9%)

Summary of Overall Syphilis Sensitivity and Specificity (n=341)

Sample Matrix	Syphilis Sensitivity (95% CI)	Syphilis Specificity (95% CI)
Fingerstick Blood	33/33= 100% (89.6% - 100%)	297/308= 96.4% (93.7% - 98.0%)
Venous Whole Blood	33/33= 100% (89.6% - 100%)	295/308= 95.8% (92.9% - 97.5%)
Plasma	33/33= 100% (89.6% - 100%)	294/308= 95.5% (92.5% - 97.3%)

RESULTS

HIV fingerstick blood sensitivity and specificity was 100% (20/20) and 99.7% (298/299), respectively. HIV venous whole blood sensitivity and specificity was 100% (20/20) and 99.7% (298/299), respectively. HIV plasma sensitivity and specificity was 100% (20/20) and 99.7% (298/299), respectively. Syphilis fingerstick blood sensitivity and specificity was 100% (33/33) and 96.4% (297/308), respectively. Syphilis venous whole blood sensitivity and specificity was 100% (33/33) and 95.8% (295/308), respectively. Syphilis plasma sensitivity and specificity was 100% (33/33) and 95.5% (294/308), respectively.

CONCLUSION

With its ease-of-use, 10 minute read time, and high degree of sensitivity and specificity for detecting HIV and Syphilis in fingerstick whole blood, venous whole blood, and plasma, the DPP® HIV-Syphilis Assay System could be readily implemented in a multitude of settings, increasing patient access to affordable, reliable healthcare.

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