Field Evaluation of a Dual HIV/Syphilis Test in a Community-Based Clinic, Los Angeles, CA

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INTRODUCTION

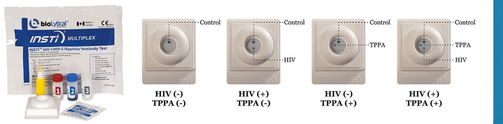
In Los Angeles, 60% of new syphilis cases are co-infected with HIV. Dual rapid assays that screen simultaneously for HIV and syphilis could assist in early detection and treatment of both infections. However, **there is currently no FDA-approved dual HIV/syphilis rapid assay**.

INSTI Multiplex HIV-1/HIV-2/Syphilis Antibody Test (BioLytical, Richmond, BC) is a single-use, flow-through *in vitro* qualitative assay that yields results in 60 seconds. Tests include:

- IgG to HIV-1(gp41)
- IgG to HIV-2 (gp36)
- Treponema pallidum (p17, p47)

Objective: Evaluate the field performance of the INSTI Multiplex in a community-based clinic in Los Angeles.

Figure 1: INSTI Multiplex test kit and results



METHODS

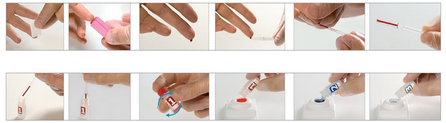
Population (N = 156): Adult clients who sought free STI/HIV testing at AIDS Healthcare Foundation Wellness Centers in Los Angeles.

Sample Collection: Participants provided fingerstick whole blood for INSTI Multiplex during clinic visit. The standard of care comparison included the **Abbott Architect HIV Ag/Ab Combo** (Abbott, IL) and **Serodia-TPPA** (Fujirebio, Japan) with reflex to RPR and titer.

- **n = 55** reactive for HIV antibodies.
- **n = 51*** TPPA reactive.

**39 of those participants were RPR-reactive.*

Figure 2: INSTI Multiplex testing process



RESULTS

Table 1: INSTI Multiplex detection of HIV antibodies.

INSTI Multiplex		Standard of Care: HIV (+)	Standard of Care: HIV (-)	TOTAL
	HIV (+)	54	0	54
	HIV (-)	1	101	102
	TOTAL	55	101	156

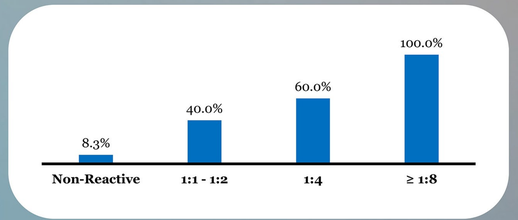
Sensitivity (95% CI): 98.2% (90.3%, 99.9%)
Specificity (95% CI): 100% (96.4%, 100.0%)
Kappa Coefficient (95% CI): 0.98 (0.96, 1.00)

Table 2: INSTI Multiplex detection of syphilis antibodies.

INSTI Multiplex		Standard of Care: TPPA (+)	Standard of Care: TPPA (-)	TOTAL
	TPPA (+)	23	3	26
	TPPA (-)	28	102	130
	TOTAL	51	105	156

Sensitivity (95% CI): 45.1% (31.1%, 59.7%)
Specificity (95% CI): 97.1% (92.0%, 99.4%)
Kappa Coefficient (95% CI): 0.48 (0.34, 0.63)

Figure 3: Improved sensitivity of the INSTI Multiplex dual assay for detection of syphilis antibodies by increased RPR titer among TPPA reactive specimens.



CONCLUSION

INSTI Multiplex showed excellent performance for HIV antibody detection (**Table 1**). Sensitivity for syphilis antibody detection increased in higher RPR titers (**Figure 3**).

Semi-qualitative differentiation between active/recent syphilis infections and past infections could be an important feature for screening programs.

Further research should evaluate the role of the INSTI Multiplex for rapid screening.

Limitations: Small sample size reduces the precision of our results.

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