David Geffen School of Medicine

Team Klausner
Saving Lives

AHF PUBLIC HEALTH DIVISION

Performance evaluation of a *dual* HIV/Syphilis rapid test in a community-based clinic, Los Angeles

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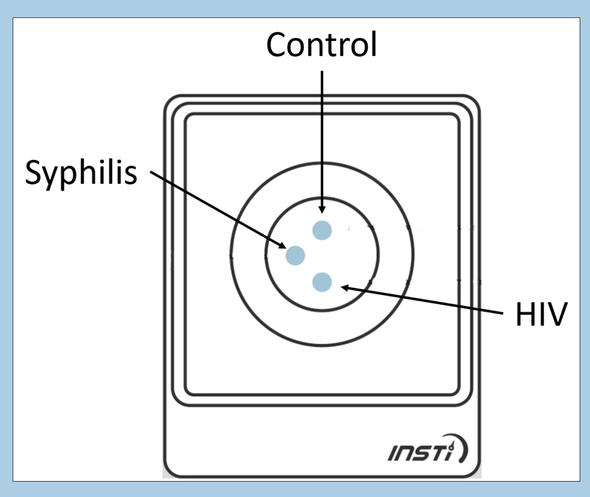
Overview

- Dual rapid assays detect antibodies for both HIV and Syphilis.
- Performance of the Multiplex for detecting antibodies**:**
  - **HIV:** *Sensitivity*=98.2%(90.3%,99.9%); *specificity*=100%(96.4%,100%).
  - **Syphilis:** *Sensitivity*= 45.1%(31.1,59.7); *Specificity*=97.1%(91.8% - 99.4%)
    - Sensitivity increases with RPR titer; ranging from 8.3%(0.2%,38.5%) when RPR is Non-Reactive (↓antibodies) to 100%(66.4%,100%), when RPR≥1:8 (↑antibodies).
- The differentiation between active/recent syphilis infection (↑antibodies) and past infection(↓antibodies) could be an important tool when screening populations with high prevalence of syphilis.

Background

- Currently, there is **no dual HIV/Syphilis FDA-approved device**.
- The **INSTI Multiplex HIV-1/HIV-2/Syphilis Antibody Test** (BioLytical, Richmond, BC, Canada) is a rapid in vitro qualitative immunoassay detecting IgG antibodies to HIV-1(gp41), HIV-2(gp36) and *Treponema pallidum*(p17, p47) in whole/fingerstick blood, serum or plasma.
- Test yields results in **60 seconds**



- **Goal:** Evaluate the performance of the Multiplex in a community setting.

Methods

Population: adult patients of *Hollywood Healthcare Center* and *Hollywood Wellness clinic* of the AIDS Healthcare Foundation between 8/2016 – 9/2017.

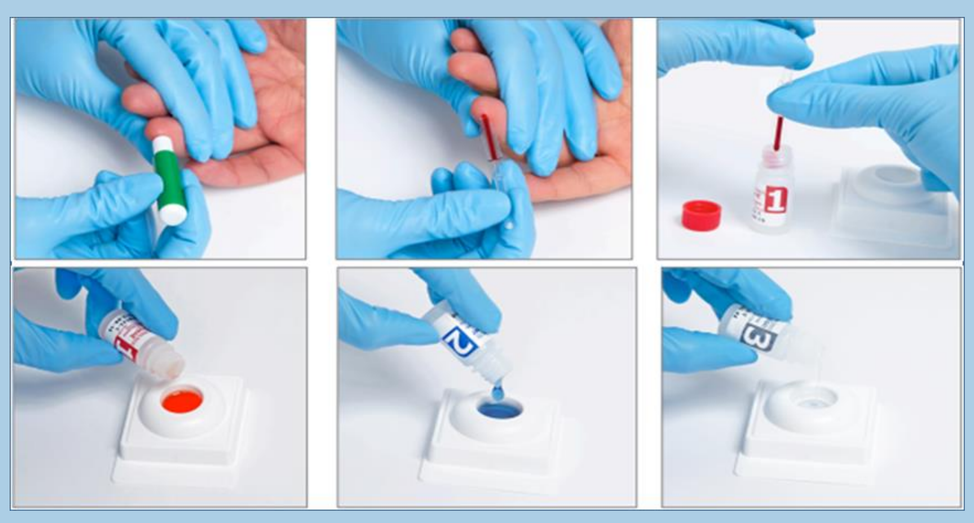


Figure 1: Sample collection and testing

Reference assays:
Fingerstick whole blood compared to serum tested in the laboratory for HIV and TP antibodies.

- **HIV:** Abbott Architect HIV Ag/Ab Combo
- **Syphilis:** Serodia TP-Particle Agglutination with reflex to RPR/titer

Data Analysis: We calculated sensitivity and specificity with respective 95% confidence intervals (CI).

Results

In total, 156 patients participated in the evaluation

- 55 had detectable HIV antibodies,
- 51 had antibodies for TP and 39 had reactive RPR.

No invalid results

Table 1: Performance of the Multiplex for detection of HIV antibodies.

Multiplex HIV	HIV reference		Total	Sensitivity (95%CI)	Specificity (95%CI)
	+	-			
+	54 (TP)	0 (FP)	54	98.2% (90.3,99.9)	100% (96.4, 100)
-	1 (FN)	101 (TN)	102		
Total	55	101	156		

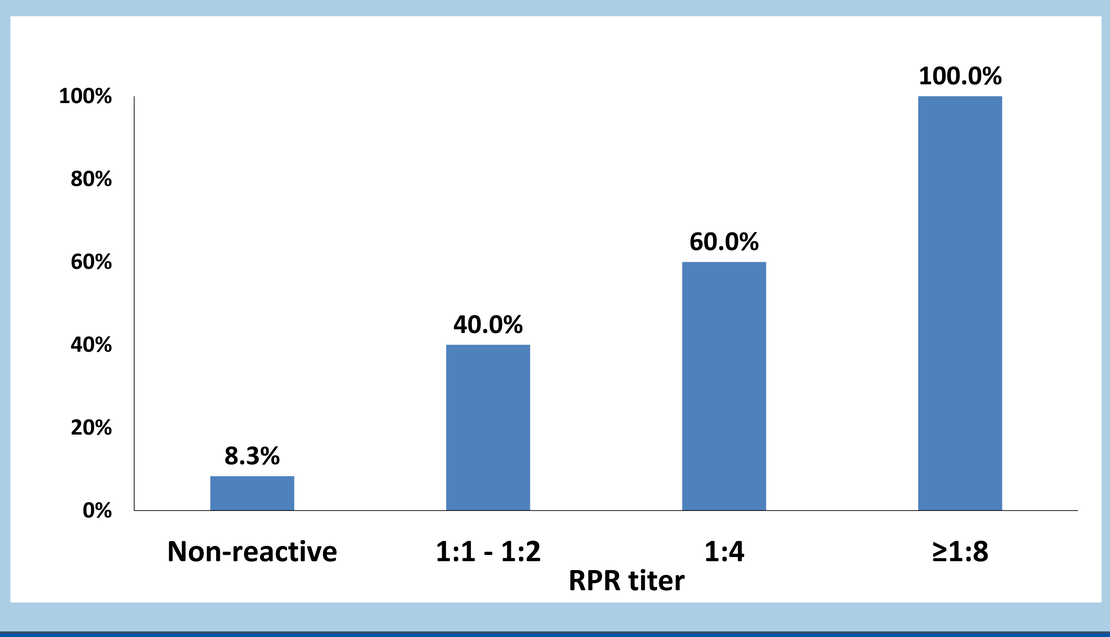
Legend: TP=True Positive/ FP=False Positive/ TN= True Negative/ FN=False Negative

$$\textbf{Sensitivity} = \frac{TP}{TP+FN} \qquad \textbf{Specificity} = \frac{TN}{FP+TN}$$

Table 2: Performance of the Multiplex for detection of antibodies for syphilis.

Multiplex TP	TPPA		Total	Sensitivity (95%CI)	Specificity (95%CI)
	+	-			
+	23	3	26	45.1% (31.1,59.7)	97.1% (92,99.4)
-	28	102	130		
Total	51	105	156		

Figure 2: Sensitivity of the Multiplex for detection of TP antibodies, stratified by RPR titer.



Conclusions

- The Multiplex showed excellent performance for detection of HIV antibodies
- Sensitivity for syphilis detection increased in higher RPR titers.
- Further research should evaluate its role for screening.
- Limitations: small sample size reduces the accuracy of our results

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