Field Evaluation Of A Dual Antibody Rapid Test For Human Immunodeficiency Virus And Syphilis Infection, Vietnam

Team Klausner
Saving Lives

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BACKGROUND

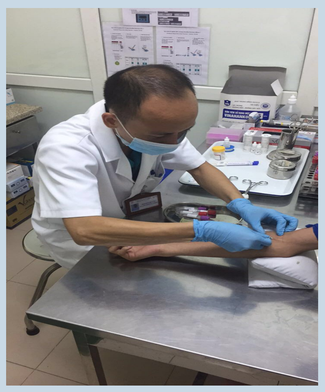
- The **SD BIOLINE HIV/Syphilis DUO** rapid test (SD BIOLINE) is a qualitative, point-of-care, rapid immunoassay.
- Detects:
  - IgG, IgM, IgA antibodies to HIV-1 gp41, sub O, HIV-2 gp36
  - IgG, IgM, IgA antibodies to recombinant *Treponema pallidum* antigen (17 kDa)
  - Fingerprick/whole blood, or serum



- The SD BIOLINE has shown high performance in a wide number of laboratory and field settings around the world
- **Objective:** Evaluate the field performance of SD BIOLINE DUO in Vietnam

METHODS

- **Study sites:** Sexual Health Promotions MSM Clinic, Ha Dong Antenatal Clinic
- **Eligibility: i) ≥**18 years **ii)** willing to return for counseling, testing, and treatment (if necessary)
- Cases with known syphilis and/or HIV infection were intentionally recruited
- **Reference Tests: SD BIOLINE HIV ½ 3.0** (Standard Diagnostics Inc.) and **Treponema pallidum particle agglutination (**SERODIA-TPPA, Fujirebio Diagnostics**)**
- **Fingerstick blood compared to venous blood**
- Sensitivity and Specificity with respective 95%CI were calculated





RESULTS

Participant Demographic Characteristics

Sample size = 280 patients
Median age: 26 years (range: 18-49 years)
Infection status:
- HIV+=17 patients
- TP+=49 patients

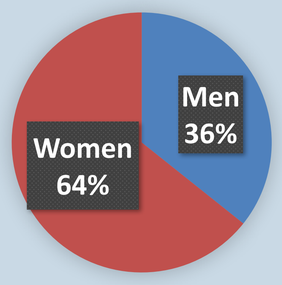


Figure 1. Gender and education level of participants

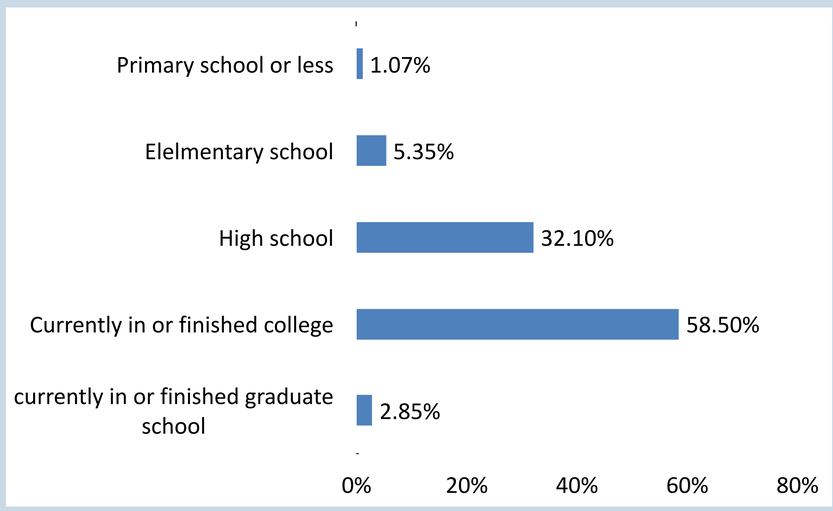


Table 1: Field performance in Vietnam for detection of HIV antibodies using a dual HIV/syphilis test

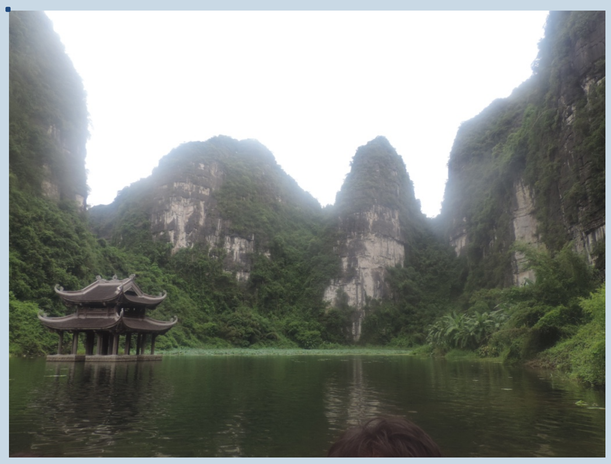
SD BIOLINE HIV	HIV Reference test +	HIV Reference test -	Total	Sensitivity (95%CI)	Specificity (95%CI)	Kappa Coefficient (95% CI)
+	17	0	17	100.0% (80.5, 100.0)	100% (98.6, 100.0)	1.00 (1.00, 1.00)
-	0	263	263			
Total	17	263	280			

Table 2: Field performance in Vietnam for detection of syphilis antibodies using a dual HIV/syphilis test

SD BIOLINE Syphilis	TPPA +	TPPA -	Total	Sensitivity (95%CI)	Specificity (95%CI)	Kappa Coefficient (95% CI)
+	49	0	49	83.1% (71.0, 91.6)	100% (98.3, 100.0)	0.89 (0.82, 0.95)
-	10	221	231			
Total	59	221	280			

CONCLUSIONS

- Our results show good clinical performance of a dual point-of-care test for HIV and syphilis among key populations in a resource-limited setting, such as Vietnam
- Incorporating dual point-of-care assays in screening programs for high-prevalence populations and antenatal screening programs could be an efficient way to screen and treat both infections.
- Future studies should evaluate the rollout of dual rapid point of care test time to treatment and clinical outcomes among high risk populations in resource-limited settings
- Limitation: Precision of the performance estimate due to the small number of positive cases



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