



# Field Evaluation of a Dual Rapid Diagnostic Test for HIV and Syphilis in Port-au-Prince, Haiti



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## BACKGROUND

- Screening for HIV and syphilis in high-risk groups is highly recommended by the World Health Organization
- Rapid point-of-care tests that can detect multiple infections from a finger stick whole blood specimen using a single device are gaining popularity
- The aim of this study was to evaluate the clinical performance of the BIOLINE HIV/Syphilis Duo test in persons at high risk of HIV and syphilis infections in field settings

## METHODS

- Participants included men and women, at least 18 years of age from GHESKIO clinics in Port-au-Prince, Haiti enrolled from March through July 2014
- Reference standard testing for detection of HIV and syphilis infections, conducted using blood samples collected by venipuncture, included:
  - Treponema Pallidum Hemagglutination Assay (TPHA)* (Human Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany)
  - For TPHA indeterminate results, *Treponema pallidum enzyme-linked immunosorbent assay test (ELISA)* (Architect Syphilis TP; Abbott, Wiesbaden, Germany)
  - Murex HIV-1.2.0 (DiaSorin S.p.A., Saluggia, Italy) or Alere Determine HIV (Alere Inc., Waltham, MA) rapid tests
  - Positive results were confirmed with the KHB rapid test (Shanghai Kehua Bio-Engineering Co., LTD, China)
- The SD BIOLINE HIV/Syphilis Duo test (Standard Diagnostics, Korea) detects IgG, IgM and IgA antibodies to HIV-specific antigens (HIV-1 gp41, sub O, HIV-2 gp36) and specific IgM and IgG antibodies to recombinant *Treponema pallidum* antigens (17KDa) in human blood
- For the Duo test, a fingerprick blood specimen was used
- Sensitivity and specificity were calculated and the exact binomial method was used to determine 95% confidence intervals (CI)



## RESULTS

- Of 298 study participants, 61 (20.5%) were male
- Of 237 females, 49 (20.7%) were pregnant
- Of the 298 participants, 21 had inconclusive TPHA results
- Of those 21 inconclusive results, all (100%) were *Treponema pallidum* ELISA positive

Table 1. Field performance in Haiti for detection of *HIV antibodies* using a dual HIV/syphilis test.

		HIV reference test		Total	Sensitivity (95% CI)	Specificity (95% CI)	Kappa Coefficient (95% CI)
		Pos	Neg				
SD BIOLINE HIV/Syphilis Duo test	Pos	128	5	133	99.2%	97.0%	.96
	Neg	1	164	165	(95.8%, 100%)	(93.2%, 99.0%)	(.93, .99)
Total		129	169	298			

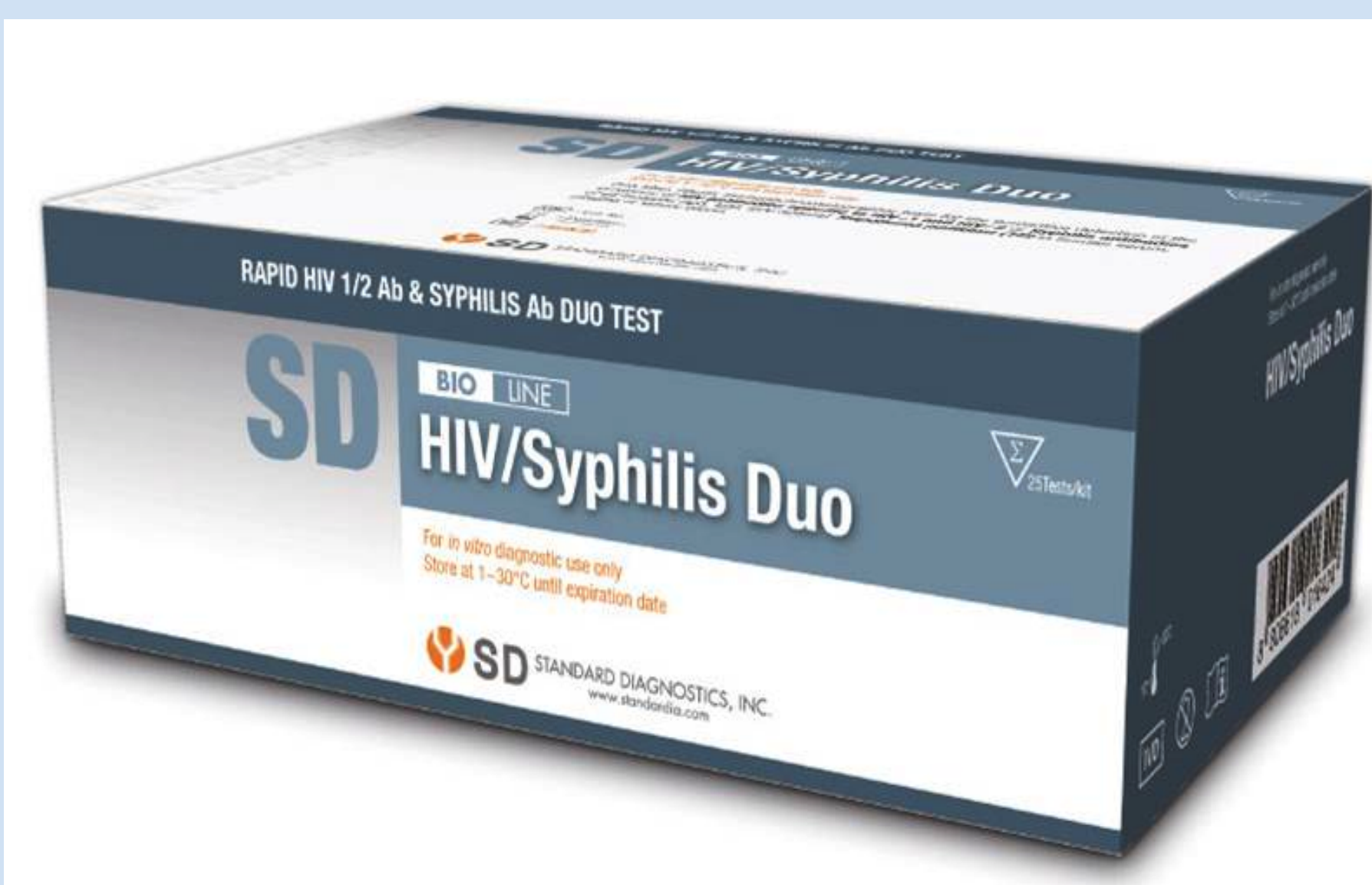
Table 2. Field performance in Haiti for detection of *Treponema pallidum* antibodies using a dual HIV/syphilis test.

		<i>T. pallidum</i> reference test		Total	Sensitivity (95% CI)	Specificity (95% CI)	Kappa Coefficient (95% CI)
		Pos	Neg				
SD BIOLINE HIV/Syphilis Duo test	Pos	109	17	126	96.5%	90.8%	.85
	Neg	4	168	172	(91.2%, 99.0%)	(85.7%, 94.6%)	(.79, .91)
Total		113	185	298			

- Among HIV positive specimens the performance for the *Treponema pallidum* component of the Duo test had a sensitivity of 94.4% (72.7%, 99.9%) and a specificity of 92.8% (86.3%, 96.8%)
- Among HIV negatives the sensitivity was 96.8% (91.1%, 99.3%) and the specificity was 87.8% (78.2%, 94.3%)
- In pregnant women the HIV component sensitivity and specificity of the HIV component were 93.3% (95% CI: 68.0%, 99.8%) and 94.1% (95% CI: 80.3%, 99.3%), respectively
- In pregnant women For the *Treponema pallidum* component the sensitivity and specificity were 100% (95% CI: 81.5%, 100%) and 96.8% (83.3%, 99.9%), respectively

## DISCUSSION

- We evaluated a dual rapid point-of-care test for detection of HIV and syphilis infection
- That high performance of the HIV antibody component of the test suggests the dual test could be used at the point-of-care with whole blood fingerprick specimens for screening
- The *Treponema pallidum* antibody component was highly sensitive however the specificity somewhat lower at just over 90% which is lower than in other field evaluations
- Among pregnant women, we found that the *Treponema pallidum* component of the dual test actually had higher sensitivity and specificity compared with the total study population
- The risks of untreated syphilis infection in pregnancy are very high and an accurate screening test to detect syphilis is paramount to reduce adverse pregnancy outcomes
- This test should be considered for the use in clinical settings to increase uptake of simultaneous testing of HIV and syphilis and accelerate time to treatment for those who need it



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