CHEMBIO
DIAGNOSTICS, INC.

RAPID TESTS FOR EARLIER TREATMENT

Multiplex Screening Assays - Advancing targeted screening of co-morbidity via DPP® HIV-Syphilis Multiplex Rapid Test

Tom Ippolito
March 2016

NASDAQ: CEMI

Brothers Health Collective Collaboration

DPP HIV-Syphilis Assay Features

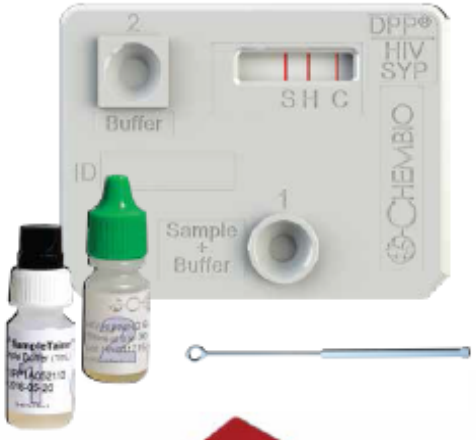
Prospective Pre-clinical Development Study at Brothers Health Collective

- Algorithms used in Study
- Population enrolled in Study
- Performance

Newly identified Infections

DPP HIV-Syphilis Assay
Final Design

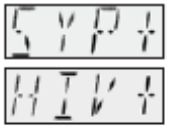
Benefits of DPP® HIV-Syphilis Assay



- High sensitivity to antibodies to HIV 1/2 and *T. pallidum*
- Results in 15 minutes
- Requires no refrigeration, electricity or lab equipment
  - Store at 2° – 30° c
- Testing can be done by midwives and nurses, where women live, reducing travel, expense and time away from family and work
- Easy to use, requiring no specialized medical training
- Test on whole blood, serum or plasma
  - Only 10µL needed
- Reduction in costs due to:
  - Buying, storing, training on one test versus two
  - Expenditure on medicines, transport and other health services
  - Lost productivity or opportunity costs due to time spent seeking care

Chembio DPP® Micro Reader

- CE Marked
- Easy-to-read Digital Display for Objective Results
- Automatic Data Capture
- DPP® Micro Reader minimizes interpretation error



Dimensions:	41 L x 41 W x 40 H mm (1.6 x 1.6 x 1.6 in.)
Weight:	40 g (1.4 oz)
Storage capacity:	100 test results
Time to result:	Approx. 3 sec.
Power supply:	3 batteries CR2032 (3 V/230 mAh) or Micro Reader-specific power cord (optional article)
Interface:	Micro Reader-specific power cord usable for data transfer to PC/laptop *Wireless available soon*

DPP® HIV-Syphilis Assay
High Sensitivity at the Point of Care
Results in 15 Minutes

Minimize Time, Effort and Resource to Identify Those Most at Risk of Dual HIV and Syphilis Infection

- More sensitive than competitors' products to antibodies to HIV 1/2 and *T. pallidum*, the causative agent of syphilis
- Suitable for programs to prevent MTCT (mother-to-child transmission) of HIV and syphilis
- Appropriate to help reduce dual HIV-syphilis infection among men who have sex with men (MSM)

Ordering Information

Catalog Number	65-9525-0
Specimen	10µL Fingerstick/Whole Blood, Serum, Plasma
Type	Device
Pack Size	20 Tests/Kit
Kit Dimensions	241 x 159 x 70mm
Kit Weight	567g
Contents	Device, SampleTainer® Specimen Bottle, Running Buffer Bottle, 10µL Loop
Carton Dimensions	508 x 406 x 406mm
Carton Weight	19kg
Carton Quantity	30 Kits/Carton

REF	18-1001-0	Chembio DPP® Micro Reader

Available in Select Countries

3661 Horseblock Road
Medford, NY 11763 USA
Tel: 1.631.924.1135 / Fax: 1.631.924.2065
customerservice@chembio.com
www.chembio.com

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.
Rapid Tests for Earlier Treatment™

MS-15-012 REV 1

Pre-Clinical Development Study
(Study duration: Feb – Mar 2015)

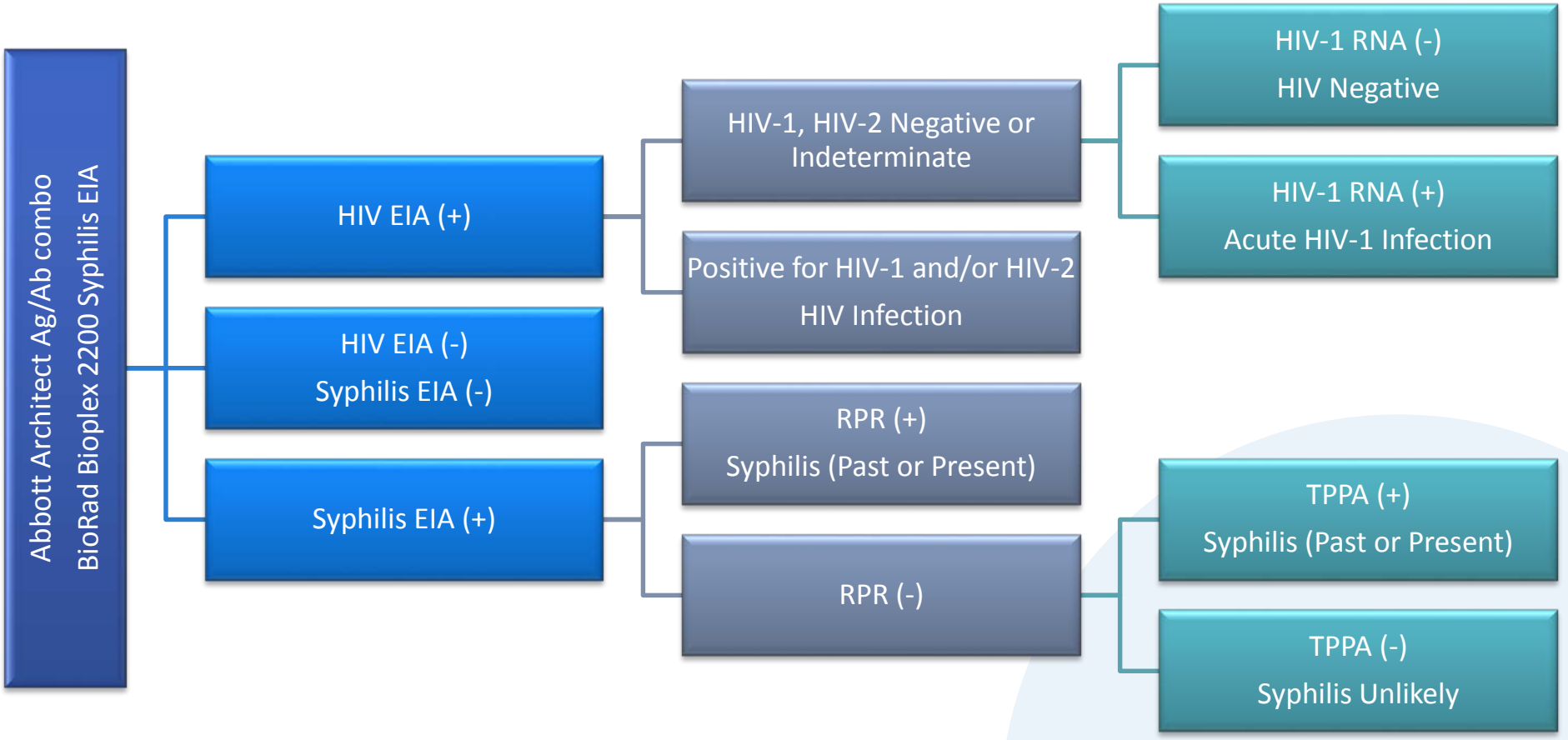
IRB approved Study. Targeted enrollment (n=199) focusing primarily on previously diagnosed persons for HIV and/or Syphilis.

- 96 individuals suspect for Syphilis and previously diagnosed with HIV
- 40 individuals previously diagnosed with HIV and Syphilis
- 13 individuals previously diagnosed with Syphilis
- 50 individuals at risk for HIV infection and suspect for Syphilis

Demographics

- Median age of 43 (18-78)
- Race: 88% Black
- Gender: 74% Male
- Self Identified: 49% MSM

Diagnostic Algorithms



HIV Algorithm: CDC Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations, 2014
Syphilis Alternate Algorithm: Centers for Disease Control and Prevention, MMWR February 11, 2011/60(05); 133-137

DPP HIV-Syphilis Assay Performance
Patient Infected Status (PIS) defined by Algorithms

HIV Performance		Syphilis Performance	
Sensitivity	Specificity	Sensitivity	Specificity
100% (101/101)	100% (55/55)	100% (63/63)	97.1% (132/136)
95% CI: 96.3%-100%	95% CI: 93.5%-100%	95% CI: 94.3%-100%	95% CI: 92.3%-99.5%

Performance Summary
By Population Enrolled

Performance Comparison by Population

	HIV Unknown Syphilis Unknown	HIV Positive Syphilis Unknown	HIV Unknown Syphilis Positive	HIV Positive Syphilis Positive
Reference Laboratory Summary				
HIV Positive	6% (3/48)	98.6% (70/71)	10% (1/10)	100% (27/27)
Syphilis Positive	6% (3/50)	17.8% (17/96)	38.5% (5/13)	95% (38/40)
DPP HIV-Syphilis Assay				
HIV Reactive	6% (3/48)	98.6% (70/71)	10% (1/10)	100% (27/27)
Syphilis Reactive	6% (3/50)	17.8% (17/96)	38.5% (5/13)	95% (38/40)

PIS via Syphilis Alternate Algorithm

BioPlex 2200 Syphilis EIA	BD Macro-Vue RPR	Serodia TP-PA	PIS	DPP HIV-Syphilis Agreement
Positive	Positive	N/A	Positive	100% (40/40)
Positive	Negative	Positive	Positive	100% (23/23)

Overall Data

	HIV Status Unknown Syphilis Unknown	HIV Positive Syphilis Unknown	HIV Status Unknown Syphilis Positive	HIV Positive Syphilis Positive
	n = 50	n = 96	n = 13	n = 40
Median Age (Range)	42.5 (18-66)	47.5 (19-78)	48 (22-57)	41.5 (21-67)
Male	66% (33/50)	77.1% (74/96)	69.2% (9/13)	80% (32/40)
Female	30% (15/50)	20.8% (20/96)	30.8% (4/13)	15% (6/40)
Transgender	4% (2/50)	2.1% (2/96)	0% (0/13)	5% (2/40)
Race				
White	6% (3/50)	10.4% (10/96)	0% (0/13)	5% (2/40)
Black	92% (46/50)	83.3% (80/96)	92.3% (12/13)	95% (38/40)
Other	2% (1/50)	6.3% (6/96)	7.7% (1/13)	0% (0/40)
Risk Factors				
MSM	25% (13/50)	55.2% (53/96)	15.4% (2/13)	75% (30/40)
Multiple Sex Partners	32% (16/50)	15.6% (15/96)	38.5% (5/13)	7.5% (3/40)
Other	42% (21/50)	29.2% (28/96)	46.2% (6/13)	17.5% (7/40)
Reference Laboratory Summary				
HIV Positive: (4^{th} Generation Algorithm)	6% (3/48)	98.6% (70/71)	10% (1/10)	100% (27/27)
Syphilis Positive: (EIA +/ RPR +)	2% (1/50)	13.5% (13/96)	7.7% (1/13)	**62.5% (25/40)**
Syphilis Positive: (EIA +/ RPR -/ TPPA+)	4% (2/50)	4.2% (4/96)	30.8% (4/13)	32.5% (13/40)
DPP HIV-Syphilis Assay				
HIV Reactive	**6% (3/48)**	98.6% (70/71)	**10% (1/10)**	100% (27/27)
Syphilis Reactive	**6% (3/50)**	**17.8% (17/96)**	38.5% (5/13)	95% (38/40)

HIV Known Positive Population

Demographics	Syphilis Unknown (n=17)	Syphilis Positive (n=38)
RPR (Titer) >1:8[1]		
Median Age (Range)	**30 (19-51)**	**31 (22-52)**
Percent Positive (#/Total)	**59% (10/17)**	**32% (12/38)[2]**
Male	70% (7/10)	92% (11/12)
Race (Black)	90% (9/10)	92% (11/12)
MSM	90% (9/10)	92% (11/12)
RPR (Titer) 1:1 - 1:4		
Median Age	**41 (30-49)**	**43 (21-67)**
Percent Positive (#/Total)	**18% (3/17)**	**34% (13/38)**
Male	67% (2/3)	92% (12/13)
Race (Black)	33% (1/3)	92% (12/13)
MSM	67% (2/3)	77% (10/13)
RPR (Titer) Negative		
Median Age	**56 (53-64)**	**49 (23-63)**
Percent Positive (#/Total)	**24% (4/17)**	**34% (13/38)**
Male	50% (2/4)	62% (8/13)
Race (Black)	100% (4/4)	100% (13/13)
MSM	25% (1/4)	62% (8/13)

[1]Newly identified syphilis infections highest titer observed was 1:512
[2]One subject; RPR titer 1:8192 with skin rash (consistent with secondary syphilis)

HIV Status Unknown Population

Syphilis Previously diagnosed, HIV Unknown Population

- 1/10 (10%): newly identified HIV Infection (Co-infected with Syphilis) a 51 y/o black male who had multiple sex partners.

Unknown Status for HIV and Syphilis

- 3/48 (6%) newly identified as HIV Positive. Ages 19, 21 and 41, all subjects were black males and self identified as MSM.
- 3/50 (6%) newly identified with syphilis.
  - 53 and 54 y/o black males, one who had multiple sex partners and one self identified as MSM. RPR was negative, most likely past infections.
  - 48 y/o black female who had multiple sex partners. RPR titer of 1:1, probable past infection.

Summary

This study demonstrates that the multiplex DPP HIV-Syphilis Assay performs equivalently to lab based assays. The DPP test is easy to use and the DPP Micro Reader mitigates risks associated with the subjectivity of visual interpretation.

DPP HIV-Syphilis Assay System

- 100% sensitivity as per HIV and Syphilis Algorithms

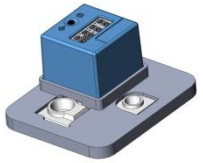
24/159 (15.1%) Newly Identified Infections at Brothers Health Collective

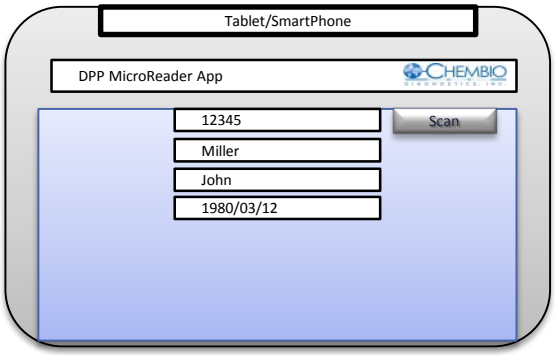
- 4 HIV and 20 Syphilis

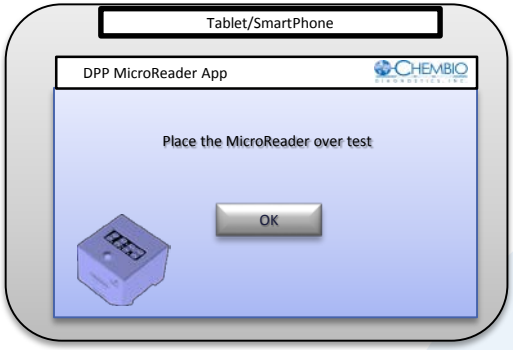
Chembio to initiate clinical studies to support FDA approval and CLIA waiver for the DPP HIV-Syphilis Assay 1Q16.

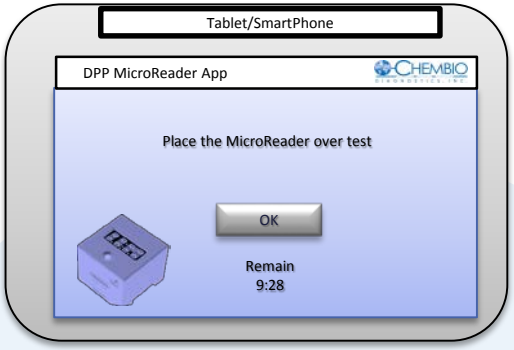
What's next

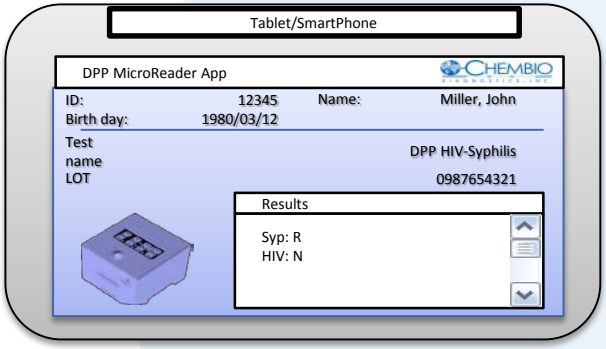
DPP Micro Reader Bluetooth











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